

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re: GUIDANT CORP. IMPLANTABLE
DEFIBRILLATORS PRODUCTS
LIABILITY LITIGATION

MDL No. 05-1708 (DWF/AJB)

This Document Relates to:

Leopoldo Duron, Jr.,

Plaintiff,

v. Civil No. 06-25 (DWF/AJB)

Guidant Corporation, Guidant Sales
Corporation, Boston Scientific Corp., and
Cardiac Pacemakers, Inc.,

Defendants.

**MEMORANDUM OPINION
AND ORDER**

This matter came before the Court on May 18, 2007, pursuant to eight summary judgment motions brought by Guidant Corporation, Guidant Sales Corporation, Boston Scientific Corp., and Cardiac Pacemakers, Inc. (collectively, "Guidant"). For the reasons set forth below, the Court grants in part and denies in part Guidant's motions.

BACKGROUND

Plaintiff Duron

Plaintiff Leopoldo Duron, Jr. is a 73-year old father of three daughters who lives in California with his wife of 35 years. In 2000, Duron developed some serious heart problems, which eventually led to Dr. Steven Higgins surgically implanting an implantable cardioverter defibrillator ("ICD"), the VENTAK PRIZM 2 DR, Model 1861

(the “Prizm 2”), in Duron in March 2002. Prior to his surgery, Duron watched a video that explained the risks associated with the implantation and use of an ICD. Guidant manufactured the Prizm 2. Guidant included a warranty with the Prizm 2 that purported to limit certain remedies and stated that it would either pay for full replacement of the ICD if it was replaced within 1-36 months and one-half the cost of the ICD if it was replaced within 36-72 months.

Prizm 2

An ICD is a device that is implanted in a patient with certain ventricular arrhythmias or with a risk of having such arrhythmias. It monitors a patient’s heart rhythm and, if needed, acts to correct or restore that rhythm by delivering a shock to the patient. If the shock is not delivered when needed, a patient can suffer serious injury or death. An ICD can function both as a pacemaker and a defibrillator. In general, an ICD needs to be replaced every four to six years. As with other medical devices, ICDs are not foolproof devices; rather, there are some physical risks associated with their use, including some life-threatening risks. In addition to physical risks associated with ICDs, a patient implanted with an ICD may also experience emotional reactions based on the presence of an ICD in their bodies. The Prizm 2 had one of the lowest risks of failures in the market.

In the Prizm 2, the shock is generated by an electrical pulse generator within the device that is carried by a charged wire, known as the feedthru or DF- wire, to the DF-lead, which is then carried to the heart. The feedthru wire travels through a

non-hermitically sealed portion of the device known as the header, where it is positioned near a titanium cylinder known as the backfill tube.

Before an ICD may be marketed or sold, it must be approved by the Food and Drug Administration (“FDA”) through a process known as a Premarket Approval (“PMA”). *See* generally Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301, *et seq.*, as amended by the Medical Device Amendments of 1978 (“MDA”). The PMA process requires a safety risk analysis of each component used in an ICD and full disclosure of information published or known concerning whether a device is safe and effective. *See* 21 U.S.C. § 360(e)(c). If a manufacturer is seeking approval of a device that is related to an already-approved device, the manufacturer can pursue an expedited approval through a PMA-Supplement process. The FDA classifies ICDs as Class III devices. Under the MDA to the FDCA, Class III medical devices are used for “supporting or sustaining human life” or are of “substantial importance in preventing impairment of human health.” 21 U.S.C. § 360c(a)(1)(C)(ii)(I).

In August 2000, the FDA approved the use of the Prizm 2 through a Guidant-submitted PMA-Supplement Application. There are factual disputes concerning whether Guidant properly disclosed the use of polyimide to insulate the feedthru wire and the precise manufacturing specifications for the placement of the feedthru wire with respect to the backfill tube.

Guidant Learns of Possible Defects in the Prizm 2

In February 2002, Guidant received a field report of an “arcing” or short-circuiting failure in Prizm 2 devices. That device had improperly delivered three shocks to a patient

while she was dancing. Thereafter, the patient had the device explanted and sent to Guidant for testing. Eventually, two problems were identified for causing the arcing. First, Guidant used an insulating material known as polyimide on the portion of the feedthru wire that passes through the header of the device. Polyimide can degrade and lose its insulation properties under certain conditions or when it is improperly bent. When polyimide degrades, the charge carried by the feedthru wire will arc, causing the feedthru wire to short against any nearby surface. Second, in some devices, the negatively charged feedthru wire was not placed a sufficient distance apart from the positively charged backfill tube in the header. During manufacturing, Guidant employees, known as operators, placed the wire in that location by hand. The operators were required to place the wire at least 13.5 mils¹ from the backfill tube.

In April 2002, Guidant instituted a design and manufacturing change plan for its Prizm 2 and, in November 2002, Guidant instituted another design and manufacturing plan. Both were directed at solving the arcing problem. The parties dispute whether Guidant properly informed the FDA of these changes. Based on the reports of failures in the devices manufactured after the changes were implemented, Guidant asserts that “the overall effectiveness of the April and November changes were remarkable.” (Guidant Summ. J. Reply at 14.) Yet, Guidant continued to sell its pre-April 2002 Prizm 2 devices

¹ A mil is equivalent to 0.001 inches.

after these change plans were implemented. Duron's Prizm 2 was manufactured and implanted prior to April 2002.

By May 2002, Guidant learned of at least three Prizm 2 device failures due to arcing problems, and Guidant opened an internal tracking system to monitor device malfunctions. Guidant continued to receive failure reports for Prizm 2's manufactured both before and after its change plans. Between April 2002 and May 2005, Guidant received notice of at least twenty-six cases of sudden device failure, including at least one failure resulting in death. During this time, Guidant began receiving reports of failures with another ICD line, the Contak Renewal 1 and 2 devices, and it began testing the polyimide conditions to determine causes of the degradation. By June 2005, Guidant stopped using polyimide as an insulator and replaced it with a different material.

In May 2005, Guidant issued a public notice and confirmed that twenty-six Prizm 2 devices had malfunctioned, resulting in at least one death and two cases of serious bodily injury. In this notice, Guidant characterized these malfunctions as "random component failure" and recommended that doctors continue to monitor their patients with Prizm 2 devices. (Pls. Ex. 59.) Guidant did not discuss the cause of the failure or that the failure could not be predicted or tested. Close to that same time, the *New York Times* published an article detailing the death of a 21-year-old college student in March 2005 due to a Prizm 2 failure.

In May and June 2005, Guidant met with the FDA to discuss the failures in the Prizm 2. Eventually, the FDA determined that the failures were based on polyimide

deterioration in the header and due to inadequate wire spacing. (Pls. Ex. 50.) The parties dispute the percentage of Prizm 2 devices that are affected by these failures.

Guidant Recalls its Prizm 2

On June 17, 2005, Guidant issued a notice to doctors stating that its Prizm 2 devices were subject to a recall because the device could short circuit. In that notice, Guidant conceded that actual rates of failures may be greater than reported, and it explained that there was no way to predict whether a particular device might fail. (Pls. Ex. 52.) Also in that notice, Guidant did not recommend replacement of the devices but instead deferred to the individual doctor's judgment with respect to particular patients. Guidant also agreed to pay for any replacement device if a Prizm 2 needed to be replaced and for other minor incidental costs. It did not agree to pay for the surgical and other costs associated with the explant surgery.

On June 29, 2005, the FDA classified Guidant's recall as a Class I recall, which is the FDA's highest level of recall reserved for devices that create a reasonable probability of serious adverse health consequence or death. Following the recall, thousands of patients had their devices explanted.

Duron Learns of Recall

On June 20, 2005, Duron read an article in the newspaper about Guidant's recall and called Kaiser Permanente ("Kaiser")² to determine whether his ICD had been

² Kaiser is Duron's insurance and healthcare provider.

recalled. In early July 2005, Kaiser eventually confirmed that Duron's Prizm 2 device had indeed been recalled and referred Duron to Dr. Sardul Singh for an evaluation. On July 11, 2005, Kaiser sent Duron a letter explaining that his ICD had been recalled because "it might develop an internal short, causing the device to fail." (Duron Ex. 9.) Kaiser also explained that there were at least two deaths associated with the Prizm 2 and that it could not "recommend any tests that will predict if the device will fail in the future." (*Id.*) At some point after receiving this information, Duron decided that he wanted to have his device explanted. Before he had his explant surgery, however, he was very concerned and nervous that he might die prior to surgery. In fact, he drafted his own obituary during that time.

On August 11, 2005, Duron met with Dr. Singh to discuss whether he should have his ICD explanted and replaced. Dr. Singh recommended an explant surgery, in part, because there was no way to test Duron's Prizm 2 to determine if it might fail and because the information concerning Guidant's failure rates may not have been complete.³ On August 19, 2005, Dr. Singh explanted Duron's Prizm 2 and replaced it with a different Guidant-manufactured ICD. As part of that surgery, Dr. Singh had to induce a ventricular fibrillation, and, as a result, Duron had to sign a consent form concerning the risk of infections and death associated with the explant surgery. A Guidant representative, Kevin Fosdick, was present during the surgery. After the surgery, Duron

³ Dr. Singh performed 10 to 15 explant surgeries based on the Prizm 2 recall.

experienced post-operative pain associated with his surgery. Nonetheless, the parties agree that Duron's case should be classified as an "explant without complications" case.

Duron's Prizm 2 Post-Explant Tests

After Duron's ICD was removed, it was sent to Guidant for testing. There are factual disputes concerning the interpretation of the test results. Guidant asserts that Duron's Prizm 2 passed all of the tests, whereas Duron contends that it failed the battery voltage, shock stress, cumulative charge time, and shipping parameters tests. The post-explant inspection showed that there was no space between the feedthru wire and the backfill tube. There is no dispute, however, that Duron's Prizm 2 never failed to deliver a life-saving shock while it was implanted in Duron.

Duron Commences Suit Against Guidant

Sometime after his explant surgery, Duron filed a complaint against Guidant in the Southern District of California. The Judicial Panel on Multidistrict Litigation subsequently transferred his case to this Court pursuant to 28 U.S.C. § 1407. Through a long selection and strike process, the parties and the Court eventually selected Duron's case to be the first bellwether trial. (*See* May 22, 2007 Memorandum Opinion and Order (discussing the bellwether selection process in this MDL and Duron's specific claims).)

ARGUMENT

Summary judgment is proper if there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The Court must view the evidence and the inferences, which may be reasonably drawn from the evidence, in the light most favorable to the nonmoving party. *Enter. Bank v. Magna*

Bank of Mo., 92 F.3d 743, 747 (8th Cir. 1996). As the United States Supreme Court has stated, “[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed ‘to secure the just, speedy, and inexpensive determination of every action.’” *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (quoting Fed. R. Civ. P. 1).

The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. *Enter. Bank*, 92 F.3d at 747. The nonmoving party must demonstrate the existence of specific facts in the record that create a genuine issue for trial. *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995). A party opposing a properly supported motion for summary judgment may not rest upon mere allegations or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986).

I. Preemption

Guidant’s first motion for summary judgment is based on the doctrine of federal preemption. Specifically, Guidant argues that federal law preempts all fourteen of Duron’s state law claims. A state law that conflicts with a federal law is preempted under the Supremacy Clause of the Constitution. U.S. Const. art. VI, cl. 2. Congressional intent to preempt state law can either be expressed in statutory language or implied in the structure and purpose of federal law. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516

(1992). Here, Guidant asserts that Duron’s claims are both expressly and impliedly preempted.⁴

A. Express Preemption

Express preemption is found when Congress declares a clear intent to preempt state law. *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712-713,

(1985). The MDA to the FDCA provide that:

no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

An MDL transferee court analyzes questions of federal law under the law of the circuit in which the court is located. *See In re Temporomandibular Joint Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996). Thus, in interpreting § 360k, this Court

⁴ Originally, Guidant submitted a global preemption motion, which it later withdrew with permission of the Court after the *In re Medtronic, Inc. Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886 (D. Minn. 2006) decision on global preemption in that MDL was announced, in order to file a case-specific preemption motion in this case.

Guidant contends that both express and implied preemption apply in Duron’s case because, even if true, most of the allegations Duron complains about occurred after Dr. Higgins implanted the Prizm 2 in Duron. The Court acknowledges that the timeline in Duron’s case may raise some issues, but those issues are directed at causation, not preemption.

is guided by the United States Supreme Court's precedent, in particular, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (plurality opinion) ("*Lohr*"), and Eighth Circuit precedent, namely *Brooks v. Howmedica Inc.*, 273 F.3d 785 (2001) (en banc). In addition, three opinions from district courts in the Eighth Circuit are instructive. See *Mattingly v. Medtronic, Inc.*, --- F. Supp. 2d ---, No. 406-cv-789 HEA, 2007 WL 1469447 (E.D. Mo. Mar. 8, 2007); *In re Medtronic, Inc. Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886 (D. Minn. 2006) ("*Medtronic*"); *In re St. Jude Med., Inc. Silzone Heart Valve Prods. Liab. Litig.*, MDL No. 01-1396 (JRT/FLN), 2004 WL 45503 (D. Minn. Jan. 5, 2004) ("*St. Jude*").

The parties agree that a court must engage in a three-step process to determine if express preemption applies under § 360k: (1) determine whether there are any device-specific federal requirements imposed on Guidant for the Prizm 2; (2) determine what the particular state law requirements are with respect to Duron's individual claims; and (3) determine whether a state law claim would impose a requirement "different from, or in addition to" the specific federal requirement. *Lohr*, 518 U.S. at 511; *Brooks*, 273 F.3d at 794; *Medtronic*, 465 F. Supp. 2d at 892 (analyzing in depth the "wondrously complex" *Lohr* and discussing requirements announced in *Lohr* and *Brooks*). (Guidant's Preemption Summ. J. Mem at 13-14); (Duron's Preemption Opp'n at 2.) In practice, however, the parties' three-step process is often collapsed into a two-step process.

The federal and state requirements must be "carefully compared" to ascertain whether a conflict exists. *Lohr*, 518 U.S. at 500; *Brooks*, 273 F.3d at 794. As Justice Breyer said in his concurring opinion in *Lohr*, "if a jury were to find negligence in the use

of a wire longer than one inch in the manufacture of a hearing aid when the FDA had required a two inch wire, there would be federal preemption as surely as if a state regulation were to impose such a limitation.” *Brooks*, 273 F.3d at 796 (quoting *Lohr*, 518 U.S. at 504 (Breyer, J., concurring)).

1. Device-Specific Federal Requirement

Like the device in *Brooks*, the Prizm 2 is a PMA-approved device.⁵ At oral argument, Duron conceded for the purposes of this motion that the PMA-process itself imposed specific federal requirements on the Prizm 2. *Compare Medtronic*, 465 F. Supp. 2d at 893 (discussing caselaw surrounding whether PMA-process creates specific federal requirements and concluding that it does), *with St. Jude*, 2004 WL 45503, at *7 (concluding PMA-process itself does not amount to a requirement). According to Guidant, the specific federal requirements are the “totality of the design, manufacturing processes, and labeling.” (5/18/07 Hearing Tr. at 129.)

As stated previously, the Prizm 2 was approved through a PMA Supplement, not a full PMA. For the purposes of this motion only, the Court accepts Guidant’s definition of the device-specific federal requirements. The Court concurs, however, with Chief Judge Rosenbaum’s observation that the supplemental process makes it difficult to determine

⁵ The *Lohr* device was not PMA-reviewed; instead, its approval was obtained under the § 510k process. *Lohr*, 518 U.S. at 493-94 (O’Connor, concurring in part and dissenting in part); *Medtronic*, 465 F. Supp. 2d at 892 n.4 (discussing approval process at issue in *Lohr*).

what the exact “two-inch wire” is in a specific medical device. *Medtronic*, 465 F. Supp. 2d at 893 n.7.

2. Conflicting State Law Requirements

Next, the Court examines the state law requirements for each of Duron’s claims and compares those requirements with the device-specific federal requirements to determine whether the state law-based claims impose state requirements “different from” or “in addition to” those required by the FDA. *Lohr*, 518 U.S. at 514. To establish preemption, Guidant must show that Duron’s state claims would require it to design, manufacture, or label its devices in a manner inconsistent with its PMA specifications.⁶ *Medtronic*, 465 F. Supp. 2d at 894.

The parties do not specifically address each of Duron’s fourteen claims individually; instead, they loosely group them into categories of claims, which the parties

⁶ While Guidant does touch on groups of Duron’s individual claims, its primary argument is that the PMA-process somehow shields it and other medical device manufacturers from any and all liability based on state law claims. But courts apply preemption sparingly to avoid the “unintended encroachment on the authority of the States” and therefore are “reluctant to find preemption” where the subject is one “traditionally governed by state law.” *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 663-64 (1993). Guidant’s argument ignores the possibility that state law claims can—and often do—impose requirements that are parallel to federal requirements, and it ignores the factual record before the Court that the FDA may not have been presented with sufficient information. If the Court were to adopt Guidant’s view, “once a medical device manufacturer obtains PMA approval, it would be insulated from liability even if it chose to conceal data from the FDA to maintain its approval.” *Medtronic*, 465 F. Supp. 2d at 895. “Neither *Lohr* nor the FDA regulatory scheme can be stretched so far.” *Id.*

appear to agree include all of Duron's claims.⁷ The Court will address each category in turn.

a. Design-Related Claims

Guidant asserts that Duron's product liability design-related claims in both negligence and strict liability are preempted because those claims would impose different and additional requirements than the requirements imposed by the FDA. For example, Guidant notes that under California law,⁸ a plaintiff with a design defect claim must establish that his device did not perform as safely as an ordinary consumer would have expected at the time of use. (Guidant's Summ. J. Mem. at 24 (citing *Campbell v. Gen.*

⁷ As discussed in the Court's May 22, 2007 Memorandum Opinion and Order, the parties agree that the operative complaint in this case is Duron's Amended Complaint-by-Adoption or, as Duron describes it, "the new superceding complaint." (*See, e.g.*, Duron's Choice-of-Law Reply at 4.) Despite this, Guidant references and draws inferences from Duron's original Complaint throughout its various summary judgment memoranda because it assumed that "[Duron's] adoption of the MDL Complaint is meant to supplement, rather than, replace his original Complaint in the Central District of California." (Guidant's Preemption Mem. at 32 n.16.) The Court disagrees with this assumption. The Amended Complaint-by-Adoption is the operative pleading in this case.

The Court notes that both parties' analyses of claims in categories, as opposed to individual claims, and Guidant's reliance on Duron's original Complaint, make it difficult to determine the precise contours of Duron's claims. The Court's analysis is in conformity with the parties' briefing and does not reach the issue of what claims are actually in each type of category. The better practice would have been for the parties to address each of the fourteen claims separately. Even so, the result reached today would not change if that practice had been employed.

⁸ For the reasons stated in the Court's May 22 Memorandum Opinion and Order, California law applies to all but two of Duron's claims, specifically Minnesota law applies to his breach of warranty and negligent infliction of emotional distress claims.

Motors Corp., 32 Cal. 3d 112, 126 n.6 (Cal. 1982); *Brown v. Superior Court*, 44 Cal. 3d 1049, 1059 (Cal. 1988).) Guidant contends that, under California law, Duron's design defect claims would necessarily impose different and additional requirements on Guidant because the FDA already determined that the Prizm 2 necessarily performed safely when it approved the PMA Supplement. According to Guidant, the FDA specifically approved as a federal requirement the use of polyimide in the Prizm 2, and any jury verdict to the contrary would impose different and additional requirements. In this way, Guidant is asserting that the use of polyimide in the header is its "two-inch wire" and that any verdict determining that it should not have been used must be preempted.

Duron does not directly respond to this argument, except to the extent that he has a section of his brief devoted to his assertion that when a manufacturer fails to comply with FDA regulations, claims related to that noncompliance are not preempted. For example, Duron contends that Guidant did not comply with FDA regulations when it placed the feedthru wire in contact with the backfill tube.

As the *St. Jude* court observed, *Brooks* did not address a claim for design defect, but it did conclude that a claim for failure to comply with FDA regulations is not preempted because such a claim imposes no additional or different requirements. *St. Jude*, 2004 WL 45503, at *11 (citing *Brooks*, 273 F.3d at 798-99). To the extent Duron's design-defect claims are based on Guidant's failure to comply with various FDA regulations, those claims would not impose different or additional requirements and are therefore not preempted. *Id.* at *11; *see also Mattingly*, --- F. Supp. 2d ---, 2007 WL 1469447, at *4 (allowing negligence per se claim to go forward because such a state law

claim could impose parallel similar requirements sufficient to withstand federal preemption).

b. Failure-to-Warn Claims

Guidant asserts that each of Duron’s warning-related claims—whether they are framed in terms of an affirmative misrepresentation, material omission, or failure to warn—are preempted because, at their core, all of those claims challenge the sufficiency of the labeling that the FDA approved for the Prizm 2. (Guidant’s Summ. J. Mem. at 29 (citing *Brooks*, 273 F.3d at 796; 21 U.S.C. §§ 360e(c)(1)(B)-(C) (F) and 360e(d)(2)(A)-(D).) For example, Guidant explains that under California law, a claim for negligent failure to warn requires a plaintiff to prove that a manufacturer failed to adequately warn of a danger that the manufacturer knew or reasonably should have known. *See* Judicial Council of California, Civil Jury Instructions § 1222. Guidant asserts that by definition, however, the FDA approved Guidant’s exact labeling as adequate so that any attempt by Duron to allege a claim for negligent failure to warn imposes additional and different requirements than the FDA imposes. As such, Guidant asserts that all of Duron’s warning-related claims are preempted. Guidant also asserts that Duron’s fraud, emotional distress, consumer protection, and unjust enrichment claims are preempted for this same reason because they are based exclusively on FDA-regulated labeling, advertising, or promotional materials. (Guidant’s Summ. J. Mem. at 32-34.)

In response, Duron contends that his claim does survive preemption because the FDA was not aware of the risks the Prizm 2 presented when the FDA approved the

labeling for that device. Duron relies on the reasoning set forth in *Medtronic* and *St. Jude* to support his analysis. (Duron’s Opp’n Mem. at 17-18 (citing *Medtronic*, 465 F. Supp. 2d at 896; *St. Jude*, 2004 WL 45503, at *11-13).)

The Court agrees with Duron. In *Brooks*, the FDA was aware of the risk at issue when it approved the labeling the plaintiff was challenging and, for that reason, the plaintiff’s warning claims were preempted. *Brooks*, 273 F.3d at 797. That reasoning “implies that if the FDA had not been aware of the risk, plaintiff Brooks’ failure to warn claim would not have been preempted.” *St. Jude*, 2004 WL 45503, at *11.

Here, Duron has produced evidence to show that there are triable issues of fact concerning whether Guidant complied with FDA regulations and disclosed the potential for polyimide degradation before the initial PMA supplemental approval and whether Guidant appropriately disclosed information to the public after it received field reports of arcing failures of the Prizm 2 due to polyimide degradation. In this way, Duron’s claims are distinguishable from those in *Mattingly*, where there were no allegations that the FDA did not receive all relevant information and where the device was not subject to a recall. *Mattingly*, --- F. Supp. 2d ---, 2007 WL 1469447, at *3. If the FDA was unaware of a risk, it could not have imposed specific federal requirements about that risk. Given that Duron’s warning-related claims are based on triable issues of fact regarding the FDA’s awareness, those claims are not preempted because, if proven, they do not impose

additional or different requirements than the ones imposed by federal law.⁹ *Medtronic*, 465 F. Supp. 2d at 896-97; *St. Jude*, 2004 WL 45503 at *13.

c. Manufacturing Claims

Guidant concedes that “true” manufacturing defect claims—those premised on the allegations that Guidant did not manufacture the Prizm 2 in conformity with FDA-approved manufacturing regulations—are not preempted under § 360(k). (Guidant’s Summ. J. Mem. at 35.) Guidant argues, however, that Duron’s manufacturing claims are not “true” claims. It asserts that Duron’s manufacturing claims are actually based on the fact that the FDA-approved process itself is flawed, and, for that reason, Guidant asserts that the claims are preempted. Guidant contends that Duron is improperly attempting to shield himself from preemption by claiming that the majority of his claims are manufacturing-related.

Duron responds that his manufacturing claims are indeed based on Guidant’s failure to manufacture his Prizm 2 in accordance with the FDA-approved manufacturing process, for example, with respect to the spacing between the feedthru wire and the backfill tube. Therefore, Duron asserts that his manufacturing claims are “true” manufacturing claims.

⁹ Duron’s consumer protection claims are also not preempted because the FDA implementing regulations specifically exclude state unfair trade practices claims from preemption. 21 C.F.R. § 801.1(d); *Medtronic*, 465 F. Supp. 2d at 898 (analyzing whether consumer protection statutes are preempted); *St. Jude*, 2004 WL 45503, at *11 (same).

The parties agree that true manufacturing claims are not preempted. *See Lohr*, 518 U.S. at 487. Duron specifically limits his manufacturing claims to the issue of whether Guidant manufactured his Prizm 2 in accordance with FDA requirements. If a jury finds Duron’s manufacturing allegations to be true, such a verdict would not impose any additional or different requirements on Guidant. For this reason, Duron’s manufacturing claims are not preempted.

d. Implied Warranty Claims

Duron asserts that Guidant breached its implied warranties of merchantability and fitness for a particular purpose because it sold Duron a Prizm 2 that was not merchantable, fit, or safe for ordinary use. (Master Compl. ¶ 299.) Under Minnesota law, to establish a claim for breach of the implied warranty of merchantability, a plaintiff must demonstrate that a product is not suitable “for the ordinary purposes for which such goods are used.” Minn. Stat. § 336.2-314(2)(c). To establish a claim for breach of the implied warranty of fitness, a plaintiff must show that the purchaser of the product, when selecting that product, relied on the judgment of the seller. Minn. Stat. § 336.2-315.

Because the FDA approved the design and manufacturing criteria of the Prizm 2 when it approved Guidant’s PMA Supplement, Guidant asserts that Duron’s implied warranty claims are preempted because they are based on different design and manufacturing criteria than specified by the FDA. Guidant contends that Duron’s warranty claims are just failure-to-warn/design-claims in disguise. Duron responds that his claims are based on Guidant’s failure to manufacture his Prizm 2 in accordance with

the requirements the FDA set when it approved the Prizm 2's PMA Supplement, not on additional or different state requirements.

Both the *Medtronic* and *St. Jude* courts addressed arguments essentially identical to Guidant's here. The Court finds their reasoning persuasive and adopts both as its own. *Medtronic*, 465 F. Supp. 2d at 897; *St. Jude*, 2004 WL 45503, at *11-12. First, it is possible that "[a] state judgment for breach of implied warranty that rested on allegations about standards other than those permitted by the FDA would necessarily interfere with the PMA process and, indeed, supplant it." *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997). Such is not the case here, however, because Duron alleges that Guidant deviated from its PMA manufacturing standards and thus manufactured and sold a defective device. If these facts are proven at trial, a jury verdict would not impose any different or additional requirements on Guidant. *See Brooks*, 273 F.3d at 798-99. Therefore, to the extent Duron alleges Guidant breached its implied warranties due to the fact that his Prizm 2 was manufactured in a manner inconsistent with its PMA-approved standards, the claims survive summary judgment.

Second, even if Guidant did not violate its PMA requirements, the FDA's own implementing regulations provide that such a claim is not preempted. The applicable regulation states: "[t]he following are examples of State or local requirements that are not regarded as preempted . . . requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as . . . the Uniform Commercial Code ["UCC"] (warranty of fitness))." 21 C.F.R. § 801.1(d). Because Minnesota, along with most other states, has adopted the UCC

implied warranty provision, Duron’s implied warranty claims are not preempted.

Medtronic, 465 F. Supp. 2d at 897; *St. Jude*, 2004 WL 45503 at *11.

B. Implied Preemption

In addition to express preemption, a state law may be impliedly preempted. As the *St. Jude* court explained:

Implied preemption has two types—field preemption and conflict preemption. Field preemption occurs when Congress legislates so pervasively in a particular field that no room remains for concurrent state legislation. Conflict preemption occurs even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when compliance with both federal and state regulations is a physical impossibility, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

St. Jude, 2004 WL 45503, at *5 (internal citations and quotations omitted). When analyzing implied preemption, a court should presume “that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) (internal quotation omitted).

Relying on *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001), Guidant asserts that Duron’s fraud and negligence-based claims are impliedly preempted because they are incorrectly premised on the idea that Guidant withheld certain information from the FDA. Guidant asserts that the FDA, not Duron, is the only one that can regulate whether Guidant correctly supplied it with information and that Duron’s allegations conflict with the FDA’s responsibility to police itself. Guidant contends that

Duron's fraud and negligence-based claims are merely "fraud-on-the-FDA" claims in disguise.¹⁰

Guidant's reliance on *Buckman* is misplaced. The claims at issue in *Buckman* were actual "fraud-on-the-FDA" claims and involved claims against an FDA consultant, not a medical manufacturer. *Buckman*, 531 U.S. at 348; *see also St. Jude*, 2004 WL 45503, at *10 (discussing *Buckman* in detail); Daniel W. Sigelman, *Is Fraud on the FDA a Dead Letter After Buckman v. Plaintiffs' Legal Committee?*, 2 ATLA-CLE 2483 (2001) (discussing procedural posture in *Buckman*). The sole claim in that case involved allegations that the FDA was defrauded by a consultant, and absent that fraud, the products at issue would not have been on the market. *Buckman*, 531 U.S. at 347. There were no allegations that the products themselves were defective. *Id.* Reviewing the plaintiff's claim, the United States Supreme Court concluded that true fraud-of-the-FDA claims are preempted because the FDA is responsible for policing its own fraud and because such claims could cause applications to the FDA to be later used against manufacturers in state court. *Buckman*, 531 U.S. at 351.

Here, Duron does not complain of fraud-on-the-FDA. He "does not seek to usurp the policing authority of the FDA. Rather, his claim is that Guidant's failure to comply with various FDA regulations *also* violates state statutory and common law duties."

(Duron's Preemption Opp'n at 25 (emphasis in original).) As Duron explains, he "seeks

¹⁰ Interestingly, in later briefing, Guidant asserts that "a fraud on the FDA claim does not appear in Mr. Duron's Complaint or in the Master Complaint." (Guidant's Mem. in Supp. of its Mot. to Exclude Selected Test. of Pl.'s Experts at 12, n.7.)

recovery because he was deceived and injured by Guidant's conduct in manufacturing defective devices, continuing to sell them after knowing they were defective, and failing to notify him or his physician." (*Id.* at 26.) In this way, these claims are not based on any duty to the FDA but are instead based on alleged duties owed to Duron. Given this, and under *Lohr* and *Buckman*, Duron's claims are not impliedly preempted to the extent they are expressly limited to the manner in which he describes in his preemption opposition memorandum. See *Medtronic*, 465 F. Supp. 2d at 900; *St. Jude*, 2004 WL 45503 at *13. Therefore, the Court denies Guidant's preemption summary judgment motion.¹¹

In reaching this conclusion, the Court is mindful of Guidant's arguments that allowing these claims to go forward will open the floodgates and unfairly stifle medical invention. The Court does not see such a harsh result. The FDA regulatory system and a state tort system can and should work together. Each serve different, yet related, functions. A regulatory system ensures products on the market have a favorable risk-reward profile, and a tort system provides incentives to manufacturers to develop and maintain safe devices. In this way, private tort remedies strengthen federal standards.

¹¹ Consistent with the Court's directive in its March 7, 2007 letter, Guidant must seek permission before filing any additional preemption motions for the remaining bellwether trials. Because the *Clasby* preemption motion was filed prior to this Order, Guidant shall explain how the *Clasby* preemption issues are legally and factually different than those in *Duron* in its *Clasby* preemption reply.

II. Summary Judgment Based on Lack of Injury Caused by Malfunction

Guidant asserts that it is entitled to summary judgment on most of Duron's claims because he cannot establish that he was injured due to a malfunction of his Prizm 2. Specifically, Guidant directs this motion to the following claims: Strict Liability—Failure to Warn (Count I); Strict Liability—Design and/or Manufacturing Defect (Count II); Negligence (Count III); Negligence Per Se (Count IV); Breach of Implied Warranty (Count V); Breach of Negligent Infliction of Emotional Distress (Count X); and Intentional Infliction of Emotional Distress (Count XI).¹² Relying on *Khan v. Shiley, Inc.*, 217 Cal. App. 3d 848 (Cal. Ct. App. 1990), Guidant asserts that in all claims where a plaintiff alleges a defective product, proof that the product malfunctioned is essential to establishing liability for an injury caused by that defect. Here, Guidant contends that the causal link between Duron's alleged injury and the manifest defect is wholly absent because Duron's device never malfunctioned before it was explanted. And Guidant points out that post-explant data shows that Duron's Prizm 2 had no defect and that no expert can opine if and when it would have malfunctioned.

Relying on *Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273 (Haw. 1992), Duron responds that the facts here are distinguishable from those in *Kahn*. Specifically, in this case there was an explant surgery that involved a device that could not be medically

¹² Guidant also directs its motion to claims for negligent misrepresentation and breach of express warranty. These claims were asserted only in Duron's original Complaint, which has been superceded by his Amended Complaint-by-Adoption.

monitored. Duron asserts that cases involving unexplanted, working devices do not control this issue. Duron also argues that, at a minimum, there are genuine issues of material fact with respect to whether his device shows evidence of malfunction post-explant.

There are no cases that directly address the factual situation in this case. Specifically, this case involves an implantable device that cannot be monitored for a defect that worsens over time. However, *Kahn, Larsen*, and another case, *O'Brien v. Medtronic*, 439 N.W.2d 151 (Wis. Ct. App. 1989), establish a persuasive framework in which to consider Guidant's argument. The Court will discuss the cases in chronological order.

In *O'Brien*, the plaintiff had a pacemaker implanted. *O'Brien*, 439 N.W.2d at 152. Two years later, the defendant pacemaker manufacturer notified doctors that the plaintiff's pacemaker was subject to an FDA Class II¹³ recall and then later informed the public that the recall was reclassified as a Class I recall. *Id.* The recall involved a problem with one of the pacemaker's leads. *Id.* The defendant recommended that patients with the recalled devices be monitored monthly to detect any malfunction because such monitoring could disclose whether the pacemaker was functioning properly. *Id.* Based on that information and the fact that the plaintiff was not

¹³ The FDA classifies a recall as a Class II if it involves products that may cause temporary or reversible adverse health consequences or the probability of serious health consequences is considered remote. *O'Brien*, 439 N.W.2d at 152 n.1.

pacemaker-dependent, the plaintiff's doctor recommended that the plaintiff's pacemaker be monitored monthly. *Id.* Despite this advice, the plaintiff was extremely "agitated and concerned" that his pacemaker would malfunction. *Id.*

Eventually, the plaintiff's doctor agreed that surgery was necessary, not because the plaintiff's pacemaker was malfunctioning or that the plaintiff was pacemaker-dependent but "on the fact that surgery was the only way to alleviate the extreme emotional distress suffered by [the plaintiff] once he heard about the advisories and the recall." *Id.* at 153. After recovering from complications related to his surgery, the plaintiff sued the defendant, alleging various products liability claims. *Id.* Reviewing the district court's grant of summary judgment in favor of the defendant, the Wisconsin Court of Appeals affirmed the district court's decision, noting that there was an insufficient causal relationship between the defendant's conduct and the plaintiff's injuries to support a claim of relief. *Id.* The *O'Brien* court noted that there was no evidence that the plaintiff's lead was defective, that the lead malfunctioned, that the doctor recommended surgery, or that there was an objective reasonable belief that the surgery was necessary. *Id.* Had there been any of this evidence, the plaintiff may have had a cause of action. *Id.*

In *Kahn*, the plaintiff, who had an implanted heart valve, admitted that her valve "had done its job" and had not yet malfunctioned. *Kahn*, 217 Cal. App. 3d at 851, 854 n.9. She nonetheless sued the defendant valve manufacturer under different theories based on the emotional distress damages she incurred after she learned that her valve was the subject of an FDA Class I recall due to a propensity to fracture. *Id.* at 851-52. The

propensity of the valve to fracture, however, decreased over time. *Id.* The plaintiff's doctors advised her, based on the information obtained from the defendant, that the risk of a second open-heart surgery was higher than the risk of the possibility of malfunction, and, as a result, the plaintiff did not have the valve replaced. *Id.* at 851.

Reviewing the district court's grant of summary judgment in favor of the defendant, the California Court of Appeals rejected the plaintiff's argument that "the owner of a product, functioning as intended but containing an inherent defect which may cause the product to fail in the future, has an action against the manufacturer." *Id.* at 854. Instead, the *Kahn* court held that no matter what claim is pled, "where a plaintiff alleges a product is defective, proof that the product has malfunctioned is essential to establish liability for an injury caused by the defect." *Id.* at 855. The court explained that the plaintiff's claims were missing causation because the plaintiff's "alleged injury was not caused by any defect in the valve. Rather, it was caused, if at all, by the knowledge the valve may, at some future time, fracture." *Id.*

In *Larsen*, the plaintiff was implanted with a pacemaker that had a potential malfunction at temperatures slightly above normal body temperature. *Larsen*, 837 P.2d at 1278. The defendant manufacturer had previously monitored its pacemakers at normal body temperature but had not tested them at slightly elevated temperatures. *Id.* at 1279. The defendant recalled¹⁴ the pacemakers and informed hospitals and doctors of this

¹⁴ *Larsen* does not mention if the recall was classified, if at all, by the FDA as a Class I or Class II recall.

potential problem and recommended that doctors consider replacing pacemakers for pacemaker-dependent patients. *Id.* As a result, the plaintiff's doctor informed him about his pacemaker's defect and that he was pacemaker-dependent, advised him about the risks associated with replacement surgery, and recommended that his device be replaced. *Id.* The plaintiff had surgery shortly thereafter and later experienced additional complications. *Id.* After the surgery, the plaintiff's device was tested and found not to exhibit a defective temperature sensitivity. *Id.*

The plaintiff sued the defendant under various theories for his injuries related to the recall, and a jury returned a verdict in the plaintiff's favor. *Id.* at 1278. The defendant appealed various issues, and the Hawaii Supreme Court affirmed the district court's denial of the defendant's underlying summary judgment motion. *Id.* at 1283. The *Larsen* court addressed, among other things, the issue of whether the plaintiff's pacemaker was defective. *Id.* at 1285. The court first addressed policy arguments and determined that the pacemaker, unlike a new and experimental drug, was capable of being made safe for its intended use because the defendant had the ability to test it at elevated temperatures; therefore the pacemaker was not an unavoidably unsafe product. *Id.* at 1286. In doing so, the *Larsen* court expressly noted that Hawaii follows and has adopted California's rules concerning strict products liability. *Id.* at 1284, 1286.

Next, the court turned to defendant's argument that the pacemaker was not defective because it did not malfunction. *Id.* at 1286. The *Larsen* court stated "neither the tort nor the warranty formulations of the test for product defectiveness heretofore enacted by the legislature or *adopted* by this court require that a product actually

malfunction.” *Id.* (emphasis added). The court acknowledged that in its case, as in *Kahn* and *O’Brien*, each plaintiff’s alleged injuries were allegedly caused by the propensity of an implantable product to malfunction. *Id.* at 1287. The court distinguished *Kahn* and *O’Brien* from the case before it, however, noting that the plaintiff in *Kahn* suffered no physical injury from a surgery or a product malfunction and noting that the plaintiff in *O’Brien* was not pacemaker-dependent and the doctor had originally recommended against surgery. *Id.* at 1287. Conversely, in *Larsen*, there was legal causation between the plaintiff’s injury and defect because both the defendant and doctor recommended explant surgery and the plaintiff was pacemaker dependent. *Id.*

Duron’s case is factually more similar to *Larsen* than to *Khan* or *O’Brien*. For example, this case, like *Larsen*, involves a doctor-recommended explant surgery. Guidant disagrees, asserting that, like the plaintiff in *O’Brien*, Duron had his device explanted without medical advice.¹⁵ Guidant’s argument is based on the fact that Duron testified at his deposition that he had decided to explant his device after receiving notice of the recall but prior to consulting with his explanting doctor. Any person can believe they want to receive a certain medical procedure prior to consulting with a doctor. That

¹⁵ A true example of acting with medical advice would be the act of refusing treatment when a doctor recommends a specific test or procedure. Indeed, Dr. Singh required his patients who refused explant surgery for defective Guidant devices to sign a consent form that they were acting against medical advice. And, as the Court observed at oral argument, if Duron had not had the explant surgery and his device later malfunctioned, it is quite likely that Guidant’s primary argument against liability would be that Duron either assumed the risk of failure or failed to mitigate his damages.

decision, however, does not mean that if a patient ultimately receives that medical treatment, he or she did so without medical device. Rather, a person generally only receives medical treatment when a doctor deems it medically necessary. Here, Dr. Singh, Duron's explanting doctor, testified that he believed that Duron's explant surgery was medically necessary based on the FDA Class I recall,¹⁶ which is served for devices that create a reasonable probability of serious adverse health consequence or death, and given the fact that there was no way to test for the defect. This is factually distinct from *O'Brien* where the doctor originally advised against the surgery and where the surgery was ultimately performed only to relieve emotional distress.

In addition, while being most like *Larsen*, this case is factually distinguishable from the above-mentioned cases for four reasons. First, unlike valves or pacemakers that function continuously, the defibrillation feature of the Prizm 2 functions only when called upon. While it is true that the Prizm 2 does have pacemaking functions, those functions are not at issue in this case. Second, unlike most defects in pacemakers, the Prizm 2 cannot be monitored to determine if a malfunction has occurred or is likely to occur. Third, a patient with a pacemaker or valve malfunction likely will exhibit symptoms prior to a complete failure, which oftentimes allows a patient to receive medical treatment. Here, if the Prizm 2 fails to defibrillate, a patient likely will be severely injured or die.

¹⁶ Guidant's recall letter did not specifically recommend explant surgery but instead stated that it ultimately deferred to each physician's judgment to make the final determination about whether a device should be explanted.

Fourth, in *Kahn* the potential for the defect in the valve (a valve usually remains implanted for life) decreased over time, whereas here, there are, at a minimum, genuine issues of material fact as to whether the alleged defects in Duron's Prizm 2 would have worsened over the time it was to be in Duron.

At first blush, Guidant's argument that *Kahn* precludes Duron's claims is persuasive, despite the factual similarities and differences between this case and the three above-mentioned cases. The flaw in Guidant's argument, however, is that it is premised on the faulty assumption that the Prizm 2 only malfunctions when it fails to deliver a life-saving shock. The facts presented by Duron, however, create a genuine issue of material fact as to whether the Prizm 2 also malfunctions when the device, with the polyimide lining, is exposed to body fluids.

Kahn instructs that "where a plaintiff alleges a product is defective, proof that the product has malfunctioned is essential to establish liability for an injury caused by the defect." *Kahn*, 217 Cal. App. 3d at 855. Guidant's entire motion rests on the premise that the only malfunction would be the failure of Duron's Prizm 2 to deliver a life-saving shock while implanted in Duron's body. And, because this did not occur, Guidant contends most of Duron's claims fail as a matter of law. The record before the Court does not allow such a limited view of malfunction. Rather, the record before the Court shows, at a minimum, that there are genuine issues of material fact with respect to whether Duron's device malfunctioned in the following manner. Duron's device contained polyimide, which malfunctioned over time by degrading, which in turn necessitated Duron's explant surgery. In this way, Duron's claims survive under *Kahn*

because he has alleged a defect, which malfunctioned and resulted in injury. In other words, the polyimide degradation is the basis for both the defect and the malfunction. Of course, there are factual issues with respect to the extent or speed of the degradation, the impact of the placement of the feedthru wires, and whether a life-saving shock could have been delivered. These factual issues, however, do not negate the fact that there is no dispute that, at this stage, Duron has sufficiently established a causal link to survive summary judgment. Although this does not equate to a win at trial, the Court denies Guidant's motion with respect to lack of injury caused by malfunction.

The result reached today, especially given the unique factual circumstances of this case, comports with the public policy surrounding products liability law, especially given the factually distinct issues noted before in this case. When there is evidence in the record to suggest that this defect could have been tested and/or detected, the law is not furthered by allowing a manufacturer to escape liability for a defective product simply because a plaintiff elected to remove a medical device—one that was subject to an FDA Class I recall, could not be monitored, and worsened over time—from his body before it malfunctioned and possibly killed him. The potential for damages in this case serves to motivate potential tortfeasors to produce safe and effective products.

III. Breach of Implied Warranties (Count V)

In Count V, Duron alleges a claim for breach of implied warranty because the Prizm 2 was not merchantable or fit for a particular purpose.¹⁷ As discussed above in connection with Duron's opposition to the preemption motion, he explained that his implied warranty claims are based of Guidant's alleged failure to follow the PMA-approved standards in the manufacturing of Duron's Prizm 2. Under Minnesota law, to establish a claim for breach of the implied warranty of merchantability, a plaintiff must demonstrate that a product is not suitable "for the ordinary purposes for which such goods are used." Minn. Stat. § 336.2-314(2)(c). To establish a claim for breach of the implied warranty of fitness, a plaintiff must show that the purchaser of the product, when selecting that product, relied on the judgment of the seller. Minn. Stat. § 336.2-315.

¹⁷ As stated above, the operative complaint here is Duron's Amended Complaint-by-Adoption, which asserts only a claim for breach of implied warranty, which references both merchantability and fitness for a particular purpose. In the parties' choice-of-law briefing, both parties described this claim only as a claim for breach of the implied warranty of merchantability. In their briefing in connection with the present motion, Guidant discusses claims for breach of implied warranties of merchantability and fitness for a particular purpose and breach of express warranty, and Duron references claims for breach of implied warranty of merchantability and express warranty. The Court does not reach any claim for express warranties because Duron never pled such a claim in his Amended Complaint-by-Adoption, but it will address both implied warranties, although it is unclear if Duron is asserting both claims. The Court notes that the express warranty related to Duron's device purports to disclaim the implied warranties, but Guidant apparently concedes that this disclaimer does not defeat Duron's claims because it does not address this disclaimer in its implied warranties arguments. (See Guidant's Implied Warranty Summ. J. Mem. at 3-8, Ex. D.)

Guidant moves for summary judgment on Duron's implied warranty claims, asserting that Duron cannot show a manifest defect, which it contends is necessary to support any breach of implied warranty claim based on a product defect.¹⁸ In response, Duron contends that an FDA Class I recall is a per se breach of the implied warranty of merchantability. He also contends proof of a manifest defect is not an element of an implied warranty claim under both California and Minnesota law.

Taking away Guidant's privity argument, this motion presents essentially the same argument as was discussed in Guidant's second summary judgment motion. As discussed above, Duron has presented genuine issues of material dispute with respect to the use of polyimide in the header. Like *Larsen* and unlike some cases involving experimental drugs, at the time Guidant was developing and manufacturing the Prizm 2, it had the scientific capability to monitor, test, or detect the alleged polyimide defects in the Prizm 2. Polyimide was not new. In this way, Duron has alleged facts that indicate that the Prizm 2 was capable of being made safe for its intended use, in particular the part of the device that created the defect could have been tested for that particular defect.

In addition, Duron has established that there are factual disputes with respect to whether Guidant manufactured Duron's Prizm 2 in accordance with the PMA-requirements that required a space between the feedthru wire and the backfill tube.

¹⁸ Guidant also moves for summary judgment based on lack of privity in Duron's implied warranty claims under California law. The Court previously determined that Minnesota law applies to this claim in its May 22, 2007 Order. Minnesota does not require privity. *SCM Corp. v. Deltak Corp.*, 702 F. Supp. 1428, 1432 (D. Minn. 1988).

These alleged defects contributed to the FDA Class I recall which, in turn, resulted in Duron having an explant surgery. Without ruling whether all FDA Class I recalls constitute per se breaches of implied warranties, here, both of these alleged defects create, at a minimum, material factual disputes concerning the elements of Duron's implied warranty claims. Therefore, the Court denies Guidant's motion with respect to Duron's claims for breach of implied warranties.

IV. Unfair and Deceptive Trade Practices Act (VIII)

A. CLRA

In Count VIII, Duron alleges that Guidant violated several sections of the California Consumers Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.* ("CLRA"). The CLRA provides protection for consumers against unfair and deceptive business practices. *See Bescos v. Bank of America*, 105 Cal. App. 4th 378, 387 (Cal. Ct. App. 2003). A requirement for filing a claim under the CLRA is that a plaintiff must meet certain notice standards prescribed in § 1782. This section provides the following:

(a) Thirty days or more prior to the commencement of an action for damages pursuant to this title, the consumer shall do the following:

(1) Notify the person alleged to have employed or committed methods, acts, or practices declared unlawful by Section 1770 of the particular alleged violations of Section 1770.

(2) Demand that the person correct, repair, replace, or otherwise rectify the goods or services alleged to be in violation of Section 1770 The notice shall be in writing and shall be sent certified or registered mail, return receipt requested, to the place where the transaction occurred or to the person's principal place of business within California.

Cal. Civ. Code § 1782.

Guidant asserts that all of Duron's claims under CLRA fail as a matter of law because Duron only gave notice as required by § 1782 after it received Guidant's summary judgment motion in April 2007, despite the fact that he filed his Amended Complaint-by-Adoption in October 2006. Duron responds that his claims survive because Guidant had "adequate notice" of his claims, as evidenced by the letter he sent to Guidant in April 2007, and because Duron purports to seek some kind of injunctive relief. (Duron's Deceptive Trade Practices Opp'n at 11; Duron Ex. 43.)

In Outboard Marine Corp. v. Superior Court, the California Court of Appeals addressed the notice requirements of § 1782. *Outboard Marine*, 52 Cal. App. 3d 30, 40-41 (Cal. Ct. App. 1975). In that case, the plaintiff argued that only substantial compliance is required to satisfy the requirements of § 1782. *See id.* In addressing the plaintiff's claim, the court looked to the intent of the legislature, stating that the purpose of the § 1782 requirement, "is to give the manufacturer or vendor sufficient notice of alleged defects to permit appropriate corrections or replacements" and to "facilitate pre-complaint settlements of consumer actions wherever possible." *Id.* at 40-41. The court found that strict application of the requirement was necessary in order to achieve this goal, although it did determine that the defendant had actually waived such notice because it had told plaintiffs in writing that it was treating one of plaintiff's letters as an official notice under CLRA. *See id.* at 41.

Here, both parties agree that the applicable notice in this case is Duron's April 2007 letter, which was sent months *after* he filed his Amended Complaint-by-Adoption.¹⁹ As discussed above, § 1782 enumerates certain notice requirements that a plaintiff must meet in order to state such a claim. *See* Cal. Civ. Code § 1782. According to the statutory language, the plaintiff must, thirty days prior to commencing a CLRA action for damages, send the defendant, by certified or registered mail, a notice and demand letter. *See id.* The letter must identify the particular § 1770 violations that the plaintiff is alleging and demand that the defendant correct those violations. *See id.*

Here, Duron failed to meet this notice requirement. The other forms of "notice," all part of the post-complaint litigation process, do not satisfy the requirements of § 1782. *Bufano v. State Farm Gen. Ins. Co.*, No. B166899, 2004 WL 2526422, at *7-8 (Cal. Ct. App. Nov. 9, 2004) (concluding plaintiffs could not pursue CLRA claim because they failed to comply with notice requirement, even though the defendant raised for the first time the issue on appeal);²⁰ *Laster v. T-Mobile, USA, Inc.*, 407 F. Supp. 2d 1181, 1195-96 (S.D. Cal. 2005) (dismissing plaintiff's claim with prejudice for failure to comply with

¹⁹ Duron's April 30, 2007 letter specifically lists the four sections of the CLRA under which he alleges claims. (*See* Duron Ex. 43 (listing §§ 1770(a)(1), (5), (7), and (15)).) Interestingly, he sent this letter at the same time he was arguing in connection with his choice-of-law argument and this motion that he was only alleging consumer claims under Minnesota law and that Minnesota provides the most appropriate consumer protection in this case.

²⁰ The Court notes that California Rules of Court 976 and 977 do not allow unpublished cases to be cited to California state courts and for this reason, there is a negative key cite history associated with this case.

notice provisions); *Von Grabe v. Sprint PCS*, 312 F. Supp. 2d 1285, 1304 (S.D. Cal. 2003) (same).²¹ Accordingly, the Court grants Guidant’s summary judgment motion with respect to Duron’s CLRA claims.²²

B. UCL

Duron also asserts a claim under Section 17200, *et seq.*, of the California Business and Professions Code (“UCL”), which provides, in relevant part, that “unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice.” Cal. Bus. & Prof. Code 17200. Guidant asserts that it is entitled to summary judgment on this claim based essentially on Guidant’s position that Duron received a fully-functioning device and that he was not injured. As discussed above, there are genuine issues of material fact with respect to any alleged defects in Duron’s device and any injuries he may have suffered. As a result, the Court denies Guidant’s motion with respect to Duron’s UCL claim.

²¹ Section 1782(d) does allow the filing of an action for injunctive relief without first providing notice to the defendant. Cal. Civ. Code § 1782(d). Duron attempts to save his CRLA claims based on *Deitz v. Comcast Corp.*, No. C 06-06352, 2006 WL 3782902, at *5-6 (N.D. Cal. Dec. 21, 2006). In that case, the court granted the plaintiff leave to amend his punitive class action complaint because it asserted injunctive relief and only alluded to a request for damages. *Deitz*, 2006 WL 3782902, at *5. Duron asserts that his CRLA claims survive because the Master Complaint makes reference to injunctive relief. When pressed by Guidant, however, to address the injunctive relief, Duron failed to do so. (*See* Duron’s Deceptive Trade Practices Opp’n at 12-13, 27-28.) A passing reference to injunctive relief, without more, cannot save a CRLA claim and would not serve the purposes of the act. For this reason, the Court agrees with Guidant that *Deitz* does not alter the result of Guidant’s motion with respect to Duron’s CRLA claims.

²² Since Duron cannot maintain a claim under § 1782, his senior citizen claim (Count IX) must likewise be dismissed. *Von Grabe*, 312 F. Supp. 2d at 1304, n.16.

V. Intentional and Negligent Infliction of Emotional Distress (Counts X & XI)

Guidant moves for summary judgment on Duron's intentional infliction of emotion distress ("IIED") and negligent infliction of emotional distress ("NIED") claims because it asserts that Duron cannot provide sufficient evidence to support the elements of either an IIED or NIED claim.²³ Specifically, Guidant contends that the evidence does not show that Duron suffered serious or severe emotional distress because his alleged distress lasted only a brief six weeks. Guidant also asserts that Duron adequately coped with any such stress because he was able to work after the recall but before his explant surgery, did not seek mental health counseling, and had the wherewithal to consult a doctor about explanting his device. Guidant asserts that Duron's fear for his own safety was "unreasonable" based on the statistical difference between the risk of possible failure and risks incurred with an explant surgery.

Duron responds that, at a minimum, there is a genuine issue of material fact with respect to whether he suffered serious or severe emotional distress resulting from his need to undergo explant surgery to remove a potentially defective device. He points to two experts' opinions that conclude that he has an extreme stress/anxiety disorder. He explains that he was so anxious before his explant surgery that he wrote his own obituary and that he was constantly panicked over the fear of dying. Finally, he points to the

²³ Guidant also asserts that because the IIED and NIED claims are derivative of Duron's other product liability claims, the IIED and NIED claims fail as a matter of law because Duron cannot establish that his Prizm 2 ever malfunctioned. For the reasons set forth above, the Court rejects that argument.

testimony of his family members and co-workers to show that he changed after learning his Prizm 2 was the subject of an FDA Class I recall.

Under California law, there are three elements for an IIED claim: (1) extreme and outrageous conduct by a defendant with the intent of causing, or reckless disregard of the probability of causing, emotional distress; (2) the plaintiff's suffering is severe or extreme; and (3) the defendant's outrageous conduct was the actual and proximate cause of the plaintiff's emotional distress. *KOVR-TV, Inc. v. Superior Court*, 37 Cal. Rptr. 2d 431, 433 (Cal. Ct. App. 1995). To establish a claim for negligent infliction of emotional distress under Minnesota law, a plaintiff must establish that he or she: (1) was within a zone of danger of physical impact; (2) reasonably feared for his or her own safety; and (3) suffered severe emotional distress with attendant physical manifestations. *K.A.C. v. Benson*, 527 N.W.2d 553, 557 (Minn. 1995).

Viewing the evidence in the light most favorable to Duron, the Court agrees with Duron that there are genuine issues of material fact with respect to whether he has established the necessary elements for an IIED claim under California law or an NIED claim under Minnesota law. Guidant's argument that it was "unreasonable" for Duron to fear for his safety is unavailing. At oral argument (although not with respect to this motion), Guidant analogized the Prizm 2's recall to a recall on a car's brakes. Guidant asserted that there would no basis for recovery for the recalled brakes if a person suffered no problems before the recall and was able to get the problem fixed after the recall. This analogy is flawed because immediately upon receipt of a brake recall, a person can either take the car to a repair shop or stop driving it until the brakes are fixed.

Here, Duron had no such choice. The device was implanted in him and until he had surgery, he had to live with a potentially defective device—one that could not be tested while implanted and one that could have killed him if his Prizm 2 failed to defibrillate when needed. While it may be proven that the risk of failure in the Prizm 2 was low, the fact is that, unlike one's brakes, a patient with an implantable device has no immediate recourse within his or her own control. In this way, a patient is not a willing participant in taking on such a risk, especially in this case where, unlike in the case of an experimental drug, the alleged defects could have been discovered and tested prior to implantation.

Therefore, there are genuine issues of material fact concerning whether Guidant's actions, as described above, meet the elements of an IIED or NIED claim and as to the extent of Duron's emotional distress injuries in light of the dispute in their gravity and given the six-week timeframe between the recall and the explant surgery. Given this, the Court denies Guidant's motion with respect to Duron's IIED and NIED claims.

VI. Strict Liability—Design Defect (Count II)

In Count II, Duron alleges a strict liability claim based on a design defect and/or a manufacturing defect. Guidant moves for summary judgment on the design defect portion of Count II because it is precluded under California law. (Guidant's Design Defect Summ. J. Mem. at 4-5 (listing cases).) Duron concedes that this portion of his claim fails under California law. (Duron's Summ. J. Design Defect Opp'n at 6.) The Court agrees with Guidant and Duron that such a strict liability design defect claim is not available under California law because California exempts manufactures of prescription drugs and medical devices from design defect claims. *See, e.g., Brown v. Superior Court*, 751 P.2d 470, 482-83 (Cal. 1988); *Artiglio v. Superior Court*, 22 Cal. App. 4th 1388, 1394-96 (Cal. Ct. App. 1994); *Morton v. Centerpulse Orthopedics, Inc.*, No. Civ. S032601GEBGGH, 2005 WL 1366494, at *3 (E.D. Cal. 2005). Therefore, the Court grants Guidant's motion with respect to Duron's strict liability claim based on a design defect.

VII. Unjust Enrichment (Count XVII)

Guidant asserts that it is entitled to summary judgment on Duron's unjust enrichment claim for four reasons. First, Guidant asserts that California law does not recognize a claim for unjust enrichment. Second, Guidant asserts that Duron's unjust enrichment claim fails because he has adequate remedies at law. Third, it contends that the claim fails because Duron has produced no evidence that the Prizm 2 caused him any harm financially, given that Duron incurred no out-of-pocket expenses related to his

explant. Fourth, Guidant asserts that public policy reasons dictate dismissal of Duron's unjust enrichment claim.

In response, Duron maintains that he is entitled to plead alternative theories of recovery under Federal Rule of Civil Procedure 8(a) and that California law does indeed recognize a claim for unjust enrichment. Duron also asserts that Guidant was unjustly enriched because it retained profits on the sale of Prizm 2. Specifically, Duron asserts that Guidant was unjustly enriched because it did not refund the price of the Prizm 2, despite the fact that it provided Duron with a free replacement IDC.

California law does recognize a claim for unjust enrichment. Under California law, the elements of a claim for unjust enrichment are "receipt of a benefit and unjust retention of the benefit at the expense of another." *Lectrodryer v. SeoulBank*, 91 Cal. Rptr. 2d 881, 883 (Cal. Ct. App. 2000). Duron is correct that, in certain circumstances, a plaintiff is allowed, generally at the motion to dismiss stage, to plead alternative theories of recovery under Federal Rule of Civil Procedure 8, especially if it is not clear if the parties disagree whether a valid contract governs their particular dispute. *See, e.g., Pinnacle Pizza Co. v. Little Caesar Enters., Inc.*, 395 F. Supp. 2d 891, 903 (D.S.D. 2005) (denying defendant's motion for judgment on the pleadings and allowing unjust enrichment claim to proceed because the dispute may not have been governed by the parties' contract).

But here Duron seeks recovery in tort, not contract, and Guidant seeks summary judgment, as opposed to dismissal, of his claim. These facts make this issue distinguishable from most of the legal authority cited by both parties. In general,

California embraces the principle that equitable relief will not be afforded when the plaintiff's remedies at law are adequate to redress his or her injury. *See Ramona Manor Convalescent Hosp. v. Care Enter.*, 177 Cal. App. 3d 1120, 1140 (Cal. Ct. App. 1986); *Taliaferro v. Taliaferro*, 144 Cal. App. 2d 109, 113 (Cal. Ct. App. 1956); 7 Witkin, *Summary of Cal. Law* § 3, at 5230 (8th ed. 1974). As discussed above, the Court has concluded that Duron has available remedies at law for his tort claims. Given this, the Court grants Guidant's motion for summary judgment on Duron's unjust enrichment claim.

VIII. Punitive Damages

In his Amended Complaint-by-Adoption, Duron seeks punitive damages for Guidant's alleged misconduct. Under California law, punitive damages are appropriate where a plaintiff establishes by clear and convincing evidence that the defendant is guilty of (1) fraud, (2) oppression, or (3) malice. Cal. Civ. Code § 3294(a). A plaintiff may not recover punitive damages unless the defendant "engaged in despicable conduct with a conscious disregard of the rights or safety of others." *Kransco v. Am. Empire Surplus Lines Ins. Co.*, 23 Cal. 4th 390, 398-99 (Cal. 2000); *see also* Cal. Civ. Code § 3294(c) (listing definitions for "fraud," "oppression," and "malice").

Guidant asserts that there are no genuine issues of material fact with respect to whether Duron can prove any facts to show clear and convincing evidence that Guidant's conduct amounted to fraud, malice, or oppression with respect to Guidant's actions specifically towards Duron. Guidant focuses on the fact that at the time Duron received his Prizm 2, Guidant had received only one field report of an arcing failure. To support

this argument, it points to Dr. Higgins' statements in his affidavit that he would not have wanted to know about that one field report. Guidant contends that any focus on other acts Guidant allegedly did both pre- and post-explant is not constitutionally permissible because they are not similar bad acts. (Guidant's Reply Mem. at 111-113 (citing cases).)

Duron responds that Guidant is incorrectly focusing the Court's attention on Guidant's conduct with respect to Duron only when it should be focusing attention on whether Guidant acted with a disregard of the probability that Guidant's actions would result in injury. (Duron's Punitive Damages Opp'n at 11 (citing cases).) He also focuses on Guidant's alleged failure to (1) disclose to doctors and patients the use of polyimide to insulate the feedthru wire, despite the information that was publicly available at the time the FDA approved the Prizm 2; (2) adequately inform the public about the safety of its devices to the public; and (3) disclose knowledge of the alleged defects, including the wire placement and polyimide, sooner. Duron contends that these actions caused him and others to be fraudulently induced into purchasing Guidant's Prizm 2.

Viewing the evidence in the light most favorable to Duron, the Court concludes that a reasonable fact-finder could determine that there is clear and convincing evidence to show that Guidant acted with fraud, malice, or oppression with respect to Guidant's actions concerning the manufacturing and disclosures about Duron's Prizm 2. Given this, the Court denies Guidant's motion with respect to punitive damages. A denial of summary judgment, however, does *not* equate to a victory at trial or rule out the possibility of a directed verdict. Instead, here, given the procedural posture of this

motion, a denial simply means that there are genuine factual disputes concerning the issue of whether Duron can establish entitlement to punitive damages.

CONCLUSION

This case should not undermine the fact that Guidant, its employees, and other medical device manufacturers make life-saving and valuable devices for persons with very serious medical conditions. Advances in medical technology undoubtedly help patients. With those advances, however, the public's expectations can become inflated, especially when directed at complex organs such as the heart. The way to deflate those expectations is with the disclosure of information. This case concerns the issues of whether, how, and to whom information was shared (and to whom it should have been shared) about a device with an alleged defect and the cause of that alleged defect.

Based on the foregoing, it is **HEREBY ORDERED** that:

1. Guidant's Motion for Summary Judgment on Plaintiff Leopoldo Duron, Jr.'s Claims Based on Federal Preemption (MDL No. 05-1708 (DWF/AJB), Doc. No. 1427; Civ. No. 06-25 (DWF/AJB), Doc. No. 11) is **DENIED**.
2. Guidant's Motion for Summary Judgment Based on Lack of Injury Caused by Malfunction (MDL No. 05-1708 (DWF/AJB), Doc. No. 1443; Civ. No. 06-25 (DWF/AJB), Doc. No. 57) is **DENIED**.
3. Guidant's Motion for Summary Judgment Based on Lack of Breach of Warranties (MDL No. 05-1708 (DWF/AJB), Doc. No. 1506; Civ. No. 06-25 (DWF/AJB), Doc. No. 88) is **DENIED**.

4. Guidant's Motion for Summary Judgment on Plaintiff Leopoldo Duron, Jr.'s Claims Regarding Unfair and Deceptive Trade Practices (MDL No. 05-1708 (DWF/AJB), Doc. No. 1533; Civ. No. 06-25 (DWF/AJB), Doc. No. 115) is **GRANTED IN PART AND DENIED IN PART.**

5. Guidant's Motion for Summary Judgment on Plaintiff Leopoldo Duron, Jr.'s Claims Regarding Intentional and Negligent Infliction of Emotional Distress (MDL No. 05-1708 (DWF/AJB), Doc. No. 1517; Civ. No. 06-25 (DWF/AJB), Doc. No. 99) is **DENIED.**

6. Guidant's Motion for Summary Judgment on Plaintiff Leopoldo Duron, Jr.'s Cause of Action for Strict Product Liability (Design Defect) (MDL No. 05-1708 (DWF/AJB), Doc. No. 1498; Civ. No. 06-25 (DWF/AJB), Doc. No. 80) is **GRANTED.**

7. Guidant's Motion for Summary Judgment on Plaintiff Leopoldo Duron, Jr.'s Unjust Enrichment Claim (MDL No. 05-1708 (DWF/AJB), Doc. No. 1490; Civ. No. 06-25 (DWF/AJB), Doc. No. 72) is **GRANTED.**

8. Guidant's Motion for Summary Judgment on Plaintiff Leopoldo Duron, Jr.'s Punitive Damage Claim (MDL No. 05-1708 (DWF/AJB), Doc. No. 1474; Civ. No. 06-25 (DWF/AJB), Doc. No. 41) is **DENIED.**

9. Count II to the extent it is based on design defect, Count VIII to the extent it is based on the California Consumers Legal Remedies Act, Count IX, and Count XVII expressed in Plaintiff Leopoldo Duron, Jr.'s Amended Complaint-by-Adoption are **DISMISSED WITH PREJUDICE.**

Dated: June 12, 2007

s/Donovan W. Frank
DONOVAN W. FRANK
Judge of United States District Court