

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

MDL No. 01-1396 (JRT/FLN)

IN RE: ST. JUDE MEDICAL, INC.
SILZONE HEART VALVES
PRODUCTS LIABILITY LITIGATION

**MEMORANDUM OPINION
AND ORDER DENYING
DEFENDANT’S MOTION FOR
SUMMARY JUDGMENT**

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On April 18, 2001, the cases making up this multidistrict litigation were transferred to this Court by the Judicial Panel on Multidistrict Litigation for consolidated pretrial proceedings under 28 U.S.C. § 1407. Defendant St. Jude Medical (“St. Jude” or “SJM”) requests summary judgment, arguing that all plaintiffs’ claims are preempted by

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federal law. Plaintiffs argue that key material fact questions prevent summary judgment. The motion was extensively briefed, and the Court heard lengthy argument on the matter. For the reasons discussed below, defendant's motion is denied.

BACKGROUND

I. Factual Background¹

Defendant St. Jude, a company with headquarters and manufacturing facilities in Minnesota, manufactures a variety of medical devices including prosthetic heart valves. Such valves are surgically implanted into patients whose natural valves have been damaged by disease. Among St. Jude's products is the Silzone heart valve, which has a coating of silver on the sewing cuff, the part of the valve that is sewn to the patient's body. Aside from the silver coating, the Silzone valve is essentially the same as other St. Jude heart valves that have been approved by the U.S. Food and Drug Administration ("FDA") since 1995. Silver has been known to have anti-microbial properties, and St. Jude introduced the silver-coated valves to combat endocarditis, a potentially life-threatening infection of the cardiac tissue that is a well-known possible consequence of prosthetic heart valve implantation.

¹In support of their respective positions, both parties submitted multi-volume Appendices. For ease of reference, the Court will cite to these Appendices as, for example, "Pl. App. Vol. X at Tab. Y." In addition, defendant submitted two affidavits not in Appendix form. Those will be referred to by the last name of the affiant, and the Tab (exhibit) number. Finally, the Court also cites to the parties' respective memoranda as "Def. Brief" or "Def. Reply" and "Pl. Brief."

The FDA approved the Silzone valve for commercial distribution on March 24, 1998. As part of this approval, however, the FDA prohibited St. Jude from claiming that the Silzone coating would reduce the risk of endocarditis, as no clinical tests had been performed to study this claim.² After the FDA approved the Silzone valve, St. Jude sponsored the Artificial Valve Endocarditis Reduction Trial (“AVERT”) study, a multi-national clinical trial designed to study whether the Silzone-coated heart valve reduced the incidence of endocarditis in humans. Approximately 36,000 Silzone valves have been implanted in patients worldwide, with approximately 10,535 of these in the United States. AVERT was originally intended to involve 4,400 heart valve patients. However, the study enrolled only 792 patients, with approximately half of those receiving Silzone-coated valves and another half, the control group, receiving conventional (non-Silzone) valves. The results of AVERT are reviewed by an independent monitoring board.

In January 2000, the AVERT monitoring board reported that recipients of the Silzone valve were more likely than recipients of conventional valves to experience a complication called paravalvular leak,³ requiring the prosthetic valve to be removed and replaced with another valve. The data showed that two percent of AVERT participants with Silzone valves required such an “explant,” while only .25 percent of participants

²The FDA also required that all labels bearing the name “Silzone” must carry the following statement: “No clinical studies have been performed to evaluate the effect of the Silzone coating in reducing the incidence of endocarditis.”

³Paravalvular leak involves leakage at the point where a heart valve is sutured to a patient’s tissue. See J.E. Schmidt, *Attorney’s Dictionary of Medicine and Word Finder*, Vol. 4, P-79 (2002).

with conventional valves required the procedure. On January 21, 2000, the monitoring board decided to suspend enrollment in the AVERT trial because of this increase in paravalvular leak.⁴ On the same day, St. Jude voluntarily recalled all un-implanted Silzone products. As part of the recall, St. Jude notified hospitals and physicians, instructing them not to use Silzone products. St. Jude also sent letters regarding the care and management of patients with implanted Silzone valves, and established a reimbursement program to pay for uninsured medical costs associated with the detection, diagnosis and treatment of paravalvular leak.

In response to the voluntary recall, the FDA informed St. Jude that its actions would be considered a “recall.” *See* Plaintiffs’ Appendix Vol. VI, Ex. 100, March 20, 2000, Memorandum from Cardiovascular and Neurological Devices Branch (“We are assigning recall numbers to [Silzone valves] . . . We are classifying the firm’s actions as a voluntary recall.”). *See also* Plaintiffs’ Appendix Vol. V, Ex. 24, March 22, 2000 letter from Edwin Dee to St. Jude (“We agree with your firm’s decision to recall [the Silzone valve] . . . We have reviewed your action and conclude that it meets the formal definition of a ‘Recall’. This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market.”).

⁴Although enrollment in AVERT was suspended, the participants continue to be monitored and data are still collected and studied.

II. Statutory Regulatory Scheme

Regulation of medical devices is governed by the Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended by the Medical Device Amendments of 1976 (MDA), 90 Stat. 539, 21 U.S.C. § 301. *See generally Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). Devices are separated into three Classes (I, II, and III). The Silzone valve is a Class III device. Class III devices are defined as those devices that “presen[t] a potential unreasonable risk of illness or injury.” § 360c(a)(c)(ii)(II). Because of the potential risks, Class III devices are subject to the strictest regulation of the three classes of devices. *Id.*

Typically, Class III devices must undergo an exhaustive review process with the FDA, called premarket approval (PMA) before they may be approved and marketed. The PMA “requires the applicant to demonstrate a ‘reasonable assurance’ that the device is both ‘safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.’” *Buckman*, 531 U.S. at 344 (quoting §§ 360e(d)(2)(A), (B)).

There are also “exemptions” to the PMA process, one such exemption is the 510k exemption. The 510k process allows devices that are “substantially equivalent” to medical devices in existence in 1976 to be marketed and sold without PMA approval, in order not to stifle competition with technology existing at the time of the enactment of the MDA. See 21 U.S.C. § 360j(g)(1). This limited form of review “averages only 20 hours of review as opposed to some 1200 hours in the PMA process.” *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221-22 (6th Cir. 2000) (hereinafter “*Kemp*”) (citing *Martin*

v. Telectronics Pacing Sys., 105 F.3d 1090, 1095 (6th Cir. 1997); *Reeves v. AcroMed Corp.*, 103 F.3d 442, 446 (5th Cir. 1997)).⁵

If the FDA approves a PMA, “it does so subject to conditions described in a document entitled ‘Conditions of Approval.’” *Kemp*, 231 F.3d at 223. The Conditions of Approval form “requires manufacturers to submit the device’s proposed labeling before marketing, limits advertising to the approved labeling, requires the manufacturer to submit a PMA supplement for review and approval before making any change affecting the safety or effectiveness of the device, requires the manufacturer to submit post-approval reports, and requires the manufacturer to report any incidents of adverse reaction to, or known defect of, the approved device.” *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802, 805-06 (W.D. Va. 2002).

FDA regulations provide that:

FDA may impose postapproval requirements in a PMA approval order . . . Postapproval requirements may include as a condition to approval of the device: . . . (2) continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. FDA will state in the PMA approval order the reason or purpose for such requirement and the number of patients to be evaluated and the reports required to be submitted . . . (9) Such other requirements as FDA determines are necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device.

⁵There is also an exemption for experimental or investigational devices (investigational device exemption or “IDE”). The IDE provides an exemption for devices representing innovative technology, and allows for unapproved devices to be utilized in human trials. An IDE permits a manufacturer to market “a device that otherwise would be required to comply with a performance standard or to have premarket approval for the purpose of conducting investigations of that device.” 21 C.F.R. § 812.1.

21 C.F.R. § 814.82(a). “A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.” 21 C.F.R. § 814.80.

The FDA can withdraw approval if the manufacturer has not met all post-approval requirements, if the device is unsafe or ineffective, or if the PMA contained or was accompanied by an untrue statement of material fact. 21 U.S.C. § 360(e)(1) and 21 C.F.R. 814.46. At least one court has held that the failure to comply with PMA conditions invalidates FDA approval. *Woods*, 218 F. Supp. 2d at 808 n.4.

III. Approval of the Silzone Valve

The Silzone valve was a modification to St. Jude’s previously approved heart valve, as such, the Silzone valve itself did not go through the PMA process, but instead was approved via the “PMA Supplement” process.⁶ 21 U.S.C. §360e(d)(6)(A)(i); 21 C.F.R. § 814.39. *See Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221-22 (6th Cir. 2000) (“Should a manufacturer merely propose to modify a Class III device that has already received approval pursuant to the PMA process, the manufacturer may submit a PMA Supplement rather than re-submitting the entire device for review.”) *See generally United States v. Prigmore*, 243 F.3d 1, 5 (1st Cir. 2001) (describing PMA supplement process). The PMA Supplement, like the initial PMA application “must contain scientific information that provides a basis for approval of the modified device.” *Prigmore*, 243

⁶The previously approved valve was the “Masters Series” valve, which itself was approved via a PMA supplement, rather than the full-blown PMA process.

F.3d at 5 (quoting 21 C.F.R. § 814.39(c)). *Id.* “All procedures and actions that apply to [a PMA] application under § 814.20 also apply to PMA supplements.” § 814.39(c).

Defendant argues that approval pursuant to a PMA supplement is “sufficient evidence” that the device is “reasonably safe and effective for its intended use,” and that therefore any claims based on the safety or efficacy of the device must be preempted. (Def. Brief at 17.) Defendant has submitted volumes of exhibits in support of its argument that the FDA carefully considered the approval, and that the PMA Supplement was exhaustive. For example, defendant submits exhibits indicating that St. Jude provided at least five “addendums” to the PMA Supplement. Each supplement addressed specific concerns voiced by FDA officials or consultants.

Despite this evidence, plaintiffs assert that FDA approval was improperly secured and unlawfully maintained. In support of this argument, plaintiffs submit the affidavits of three experts.⁷ The gist of those affidavits is that St. Jude concealed information from the FDA, and that had that information been made available, the FDA would not have approved the valve. Plaintiffs suggest that because their claims are premised on the contention that St. Jude failed to comply with FDA regulations, there is no preemption. *See Brooks*, 273 F.3d at 798 (“a claim of failure to comply with FDA regulations is not preempted by the MDA, since such a state claim imposes no requirements different from, or in addition to any federal requirement”) (internal quotation and citations omitted).

⁷These affidavits are the subject of a motion to strike, which is addressed below.

Plaintiffs also argue that although the approval was ostensibly PMA approval, in reality the FDA used a 510k-type approval (the much less intensive approval described above). The 510k process was at issue in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (hereinafter “*Lohr*”) a case in which the Supreme Court determined that plaintiff’s claims were not preempted. Citing *Lohr*, plaintiffs argue that because 510k approval is based on equivalence, not safety, their claims are not preempted. Finally, plaintiffs alternatively argue that the express preemption of 360k(a) cannot apply, because the device approved is actually a drug or drug/device combination, not a device. The distinction between drug and device, plaintiffs argue, is one for the Court. Plaintiffs suggest that the FDA never determined that the Silzone valve was a device, rather than a drug/device combination. Even if the FDA made such a determination, plaintiffs continue, this Court owes no deference to it because Congress, and not the FDA, divided medical implements into categories of either drug or device.

ANALYSIS

I. Standard of Review

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment “shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56. Only disputes over facts that might affect the outcome of the suit under the governing substantive law will properly preclude

the entry of summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Summary judgment is not appropriate if the dispute about a material fact is genuine, that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Id.* Summary judgment is to be granted only where the evidence is such that no reasonable jury could return a verdict for the nonmoving party. *Id.*

The moving party bears the burden of bringing forward sufficient evidence to establish that there are no genuine issues of material fact and that the movant is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The nonmoving party is entitled to the benefit of all reasonable inferences to be drawn from the underlying facts in the record. *Vette Co. v. Aetna Casualty & Surety Co.*, 612 F.2d 1076, 1077 (8th Cir. 1980). However, the nonmoving party may not merely rest upon allegations or denials in its pleadings, but it must set forth specific facts by affidavits or otherwise showing that there is a genuine issue for trial. *Forrest v. Kraft Foods, Inc.*, 285 F.3d 688, 691 (8th Cir. 2002).

II. Preemption Principles

The Supremacy Clause of the United States Constitution provides that the “Laws of the United States . . . shall be the supreme Law of the Land.” U.S. Const. art. VI, cl. 2. The principle of preemption is the application of this clause, resulting in the rule that any “state law that conflicts with federal law is ‘without effect.’” *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Preemption is disfavored in areas of historic importance to the states’ police powers—areas such as public health and safety. *Kemp v. Medtronic,*

Inc., 231 F.3d 216, 222 (6th Cir. 2000). *See also Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (no presumption against preemption where plaintiffs' claims involved medical devices, but were more accurately characterized as "fraud on the FDA" claims because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied") (internal quotation omitted).

Preemption is typically understood as having two types—express and implied. Express preemption is found when Congress "pre-empt[s] state law by so stating in express terms." *Hillsborough County, Fla. v. Automated Med. Labs, Inc.*, 471 U.S. 707, 712-13 (1985) (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525). Implied preemption, in turn, 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. *Id.* Conflict preemption occurs

[e]ven 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.

Id. (internal quotations omitted).

"Central to determining questions of preemption is divining Congress' intent." *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000) (citing *Cipollone*, 505 U.S. at 517-18). Courts must be careful to avoid the "unintended encroachment on the authority of the States" and therefore "will be reluctant to find pre-emption" where the subject is one "traditionally governed by state law." *CSX Transp., Inc. v. Easterwood*, 507 US 658,

663-64 (1993). Where Congress has included an express preemption provision in a statute, courts historically have not looked beyond it to consider implied preemption. *Kemp*, 231 F.3d at 222. However, since *Buckman Co. v. Plaintiff's Legal Comm.*, it is clear that express and implied preemption are not mutually exclusive. Therefore, the Court discusses both express and implied preemption.

A. Express Preemption—Section 360k

At issue in these cases is the express preemption provision of the MDA, which states:

[N]o 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) (emphasis added).

1. What is a “requirement”

Courts have struggled to divine Congress’s intent in § 360k—specifically, courts have differed in the understanding of what was meant by the term “requirement” in the context of a “requirement” imposed by a State (or political subdivision). Some courts have reasoned that “requirement” is intended to encompass only State legislative, statutory “requirements.” *See Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997) (interpreting *Lohr* and holding that “requirement” meant only state statutory requirements). Others determined that the term “requirements” was intended to include

common-law tort claims as well. *See, e.g., Martin*, 254 F.3d at 579-83; *Kemp*, 213 F.3d at 224.

These differing understandings stem from the Supreme Court's discussion of "requirements" in *Lohr*. Justice Stevens, writing for a plurality, rejected as "implausible" the medical device manufacturer's suggestion that "any common-law cause of action is a 'requirement' which alters incentives or imposes duties 'different from, or in addition to,' the generic federal standards." *Lohr*, 518 U.S. at 486-87. Justice Stevens discussed the language of § 360k, the legislative history, and the fact that members of both houses "were acutely aware of ongoing product liability litigation" when the section was enacted. *Id.* at 487-491. Stevens concluded that § 360k "simply was not intended to preempt most, let alone all general common-law duties enforced by damages actions." *Id.* at 491. Despite this discussion, Stevens did not "respond directly" to the plaintiff's contention that common-law duties are **never** requirements within the meaning of § 360k and that the statute therefore never pre-empts common-law actions. *Id.* at 502-03.

Justice Bryer, writing separately, noted that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." *Id.* at 504. Bryer used the example of a federal regulation of hearing aids requiring a two-inch wire, and a state regulation requiring a one-inch wire. The state regulation would clearly be pre-empted, Bryer reasoned, therefore a jury award of damages based on the one-inch wire would also be pre-empted. *Id.*

The Supreme Court has revisited its holding in *Lohr* to insinuate that the term “requirement” in the MDA applies to tort claims as well as particular state statutory “requirements.” See *Geier v. American Honda Motor Corp.*, 529 U.S. 861, 867 (2000) (“a majority of this Court has said that . . . a provision that uses the word ‘requirements’—**may** well expressly pre-empt similar tort actions.”). (Emphasis added) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 502-04 (1996) (plurality opinion); *id.* at 503-05 (Breyer, J. concurring in part and concurring in judgment); *id.*, at 509 –12 (O’Connor, J. concurring in part and dissenting in part)); *American Honda Motor Corp.*, 529 U.S. 861, 897 (2000) (Stevens, J. dissenting) (“And in *Medtronic v. Lohr*, we recognized that the statutory reference to ‘any requirement’ imposed by a State or its political subdivisions **may** include common-law duties.”) (citations omitted) (emphasis added). Despite this language, there has been no explicit holding by the Supreme Court, in the medical device realm, that any particular common law claim has constituted a “requirement.”

Equally difficult has been determining what constitutes the federal requirement. At least two approaches have been put forth. Some courts have applied a process-oriented definition to the term “requirement.” See, e.g., *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997). Those courts reason that the PMA process itself, without more, constitutes the “requirement” mentioned in the statute. Another approach is to look at the device specific edicts from the FDA, and consider those edicts the “requirements” of 360k.

Some Courts have held that the PMA process itself is a federal “requirement” imposed by the MDA. *See Mitchell*, 126 F.3d 902 (holding that unlike the 510k process, the PMA process can constitute the sort of specific federal “requirement” that can have preemptive effect under the MDA); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (same). There is a division of authority, however, and the Eleventh Circuit has reached the opposite conclusion. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir.) *reh’g* and *reh’g en banc* denied (1999) (holding that the PMA process itself is not a “requirement” and reasoning that the ordinary construction of the language of 360k and use of the term “requirement” in the broader statutory context and the FDA regulations contemplate the imposition of some identifiable precondition that applies to the device in question); *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802 (W.D. Va. 2002) (holding that PMA approval represents only a finding that the device manufacturer has reasonably assured the FDA of the safety and effectiveness, and also finding that PMA approval **does not** provide any indication of what, if any, specific substantive requirements the FDA may have applied to reach that result); *Webster v. Pacesetter, Inc.*, 171 F. Supp. 2d 1, 19 (D.D.C. 2001) (rejecting argument that PMA process amounts to a “requirement”); *Quillin v. American Hosp. Supply Co.*, 1997 WL 382095 (N.D. Okl., March 31, 1997) (PMA process does not constitute a “requirement” for the purpose of determining whether a plaintiff’s state common law claims are preempted). The Supreme Court has not addressed the issue.

Prior to *Lohr*, the Eighth Circuit had held that the PMA process itself constituted a “requirement.” *See Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994).

However, in *Brooks v. Howmedica*, the Eighth Circuit, sitting *en banc*, retreated from that broad holding. See *Brooks v. Howmedica*, 273 F.3d 785, 795 (8th Cir. 2001), *cert. denied*, 535 US 1056 (2002) (noting that the *Martello* holding “requires some modification” to be consistent with the Supreme Court’s decision in *Lohr*). The *Brooks* Court did not hold that the PMA process itself amounts to a requirement. Instead, the *Brooks* Court carefully compared the plaintiff’s claims with the federal requirements and determined that “[t]he failure to warn claim [plaintiff] Brooks seeks to assert could impose state requirements which conflict or interfere with these federal directives. Because these ‘particular state requirement[s] threaten[] to interfere with . . . specific federal interest[s],’ *Lohr*, 518 U.S. at 500, 116 S. Ct. 2240, Brooks’ claim is preempted by the MDA.” *Id.* at 798 (alteration and internal quotation in original).

B. Applying express preemption

1. *Medtronic, Inc. v. Lohr*

In *Medtronic, Inc. v. Lohr*, the Supreme Court first discussed whether the MDA preempts particular common law tort claims. 518 U.S. 470 (1996). The plaintiff in *Lohr* had received a pacemaker (a Class III device) that had been approved under the 510k process. Plaintiff asserted claims of negligence and strict liability against the manufacturer, alleging defendant had failed to use reasonable care during production. The Court, in a plurality opinion, held that none of plaintiff’s claims were preempted. Specifically, the Court held that the MDA does not preempt state or local requirements that are equal to, or substantially identical to, requirements imposed under federal law.

Similarly, the Court held that plaintiff's claims were not preempted to the extent that they alleged that the manufacturer failed to comply with duties equal to, or substantially identical to, federal requirements.

In response to the defendant's preemption argument, the *Lohr* Court emphasized that it would be "to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct,' and it would take language much plainer than the text of § 360k to convince us that Congress intended that result." *Id.* at 484 (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)). The Court went on to note that, "[n]othing in 360k denies [States] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 495.

Lohr generated confusion as the circuit courts attempted to discern its specific holding, and apply it in subsequent cases, including cases in which plaintiffs were injured by devices that had been approved through the full PMA process, and cases in which plaintiffs pled alternate theories of liability. *See Kemp*, 231 F.3d at 221 (noting that "[C]ourts of appeals that have confronted the issues of preemption arising under the MDA have struggled mightily with *Lohr's* language in the effort to discern its holding" and further noting that "[t]his appeal presents fractious issues which have sharply divided the various circuit courts which have considered them."). *Compare Kemp*, 231 F.3d 216 (granting summary judgment to pacemaker manufacturer on preemption grounds) *with Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (facts and legal theories almost indistinguishable, but refusing to find plaintiff's claims preempted).

2. *Brooks v. Howmedica*

In *Brooks v. Howmedica*, 273 F.3d 785 (8th Cir. 2001), *cert. denied*, 535 U.S. 1056 (2002), the Eighth Circuit, sitting *en banc*, reversed its panel decision, and denied relief to a former orthopedic surgical nurse who had been injured by repeated on-the-job exposure to toxins released as she mixed bone cement.⁸ The *Brooks* court held that plaintiff's claims of negligent failure to warn and failure to comply with federal labeling regulations were expressly preempted.⁹ In reaching this conclusion, the court discussed the extensive regulation to which defendant was subject, and noted that the approval process "included review by the FDA of the proposed design and content for all Simplex labels" and that "the FDA drafted the language that was used in the package insert." The court also emphasized that the case involved "ascertainable requirements" taking the form of "a series of mandates regarding the label" issued by the FDA. Under the *Brooks* analysis, such mandates amount to the federal "requirement" with which state "requirements" must not conflict.

The *Brooks* court articulated a "three-step test" to determine if a plaintiff's state law claim is preempted—first, discern the federal requirement imposed on a medical

⁸It is noteworthy that the plaintiff in *Brooks* was in a different position than the typical plaintiff—that is, plaintiff Brooks was not a recipient of the medical device at issue, rather, her injuries were caused by mixing the bone cement to prepare the device for surgery.

⁹The Eighth Circuit mimicked the Supreme Court in declining to address the "other" preemption category—that is, the Supreme Court in *Buckman* stated in a footnote that because it found plaintiffs' claims impliedly preempted, it would not address express preemption. In *Brooks* the Eighth Circuit, also in a footnote, noted that "because we find express preemption, we do not address any potential issue of implied preemption." *Id.* at 792 n.7.

device manufacturer; next, determine the state requirement; finally compare the two to see if there is conflict. *Id.* at 794 (“*Lohr* instructs that state requirements—including common law duties—are preempted **to the extent that they interfere with specific federal requirements**. The state and federal restrictions must be ‘carefully compar[ed]’ to ascertain whether there is interference between them—that being the ‘overarching concern’ of the test articulated by Justice Stevens and joined in by Justice Breyer.”) (emphasis added) (quoting *Lohr*, 518 U.S. at 500).

C. Implied preemption — *Buckman Co. v. Plaintiffs’ Legal Committee*

After *Lohr*, the Supreme Court next examined the issue of preemption in the MDA context in *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, plaintiffs injured by orthopedic bone screws brought suit alleging that defendant, a regulatory consultant, had made fraudulent representations to the FDA in order to obtain approval to market the devices. The *Buckman* Court declined to address whether express preemption applied, holding that plaintiffs’ “fraud on the FDA” claims were **impliedly** preempted. The Court noted that the FDA itself is charged with policing fraud on it and has a variety of enforcement options that allow it to make “a measured response to suspected fraud.” *Id.* at 350. Therefore, the state fraud on the FDA claims conflicted with the FDCA—specifically, permitting plaintiffs’ claims would conflict with the FDA’s responsibility to police fraud consistently with its judgment and objectives.

In *Buckman*, despite the express preemption provision of 360(k) the Court found implied preemption applicable. In doing so, the Court did not clarify the confusion

surrounding the appropriate use of implied versus express preemption. In fact, the Court specifically “express[ed] no view on whether the[] claims [were] subject to express preemption under 21 U.S.C. § 360k.” *Id.* at 348 n.2. The failure to address whether both types of preemption could apply is significant, because, until *Buckman*, an oft-cited rule was that where express preemption applied, courts would not use the implied preemption theory. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (“Congress’ enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.”) (citations omitted). The *Buckman* Court also chose not to specify whether preemption analysis differs depending on the process through which the at-issue devices was approved (510k, PMA, or IDE).

Though instructive,¹⁰ *Buckman* is distinguishable on several important grounds. First, the device approved in *Buckman* was approved via the 510k process, not the PMA/PMA Supplement process. In addition, the bone screws at issue in *Buckman* were being used “off-label” (they were approved for use in long bones, but were being used in back surgeries), an important distinction because Congress has repeatedly and explicitly noted that the FDA is not designed to interfere with practice of medicine. Plaintiffs in *Buckman* made only “fraud on the FDA claims.” The Court specifically noted that states do not have a traditional interest in policing fraud on government agencies. The Court

¹⁰ Defendant, while distinguishing a case from the Tenth Circuit, suggests that where a different method of approval is at issue (such as the 510k approval), the case “does not inform the issues before this Court.” (Def. Brief at 10 n.5.) The Court disagrees with this characterization, and finds useful those cases that involve other types of FDA approval, including *Buckman* and *Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997).

also emphasized that the MDA set up a comprehensive scheme for policing fraud, and that consumers could petition the FDA to take action against suspected wrongdoing. The harm complained of in *Buckman* was the fraud itself, as allegedly perpetrated by the consulting group, not the plaintiffs' personal injuries. In fact, the manufacturer of the bone screws had settled with plaintiffs before the case was appealed to the Supreme Court. See Daniel W. Sigelman, *Is Fraud-on-the-FDA a Dead Letter After Buckman v. Plaintiffs' Legal Committee?*, 2 ATLA-CLE 2483 (2001) (noting that AcroMed Corporation, maker of the devices at issue, settled after Third Circuit's opinion). The remaining defendant was an FDA consultant who was not responsible for the design of the device, only for the manner in which the application was presented to the FDA.

III. Discerning the Federal "Requirements"

The parties understandably dispute the fundamental issue of what constitutes "requirements" of federal law in this case. This dispute is predictable, given the conflicting authority in both federal and state courts, as discussed above. The Court notes theoretical and practical difficulties in the "process" approach. Accepting the "process" argument—that the PMA Supplement process itself is a requirement—makes it difficult as a practical matter to find any claim that is not preempted. On a more theoretical level, this broad immunity is not consistent with Congressional intent in enacting the MDA, *see generally Lohr*, 518 U.S. at 490-92 (discussing congressional history), and is also not consistent with the presumption against preemption in areas of traditional state control (such as health and safety). *See id.* at 475 ("Throughout our history the several States

have exercised their police powers to protect the health and safety of their citizens.”). Despite these shortcomings to the process approach, a majority of federal courts have held that the PMA/PMA Supplement process itself is a “requirement.” *See supra; see also Am. L. Prod. Liab.* 3d § 91:16.

The Court finds that, given the language of § 360k and the implementing regulations¹¹, the Supreme Court’s rationale in *Lohr*, and the Eighth Circuit’s reasoning in *Brooks v. Howmedica*, PMA Supplement approval, without more, is not necessarily a “requirement” of federal law. The submission of a product to the FDA for pre-market supplement approval does not, in itself, amount to a specific federal requirement meriting preemptive effect. Instead, the Court will inquire whether the FDA, in this instance, has promulgated any ascertainable precondition to regulatory approval. The Court will carefully examine the potential “federal requirements” and then compare those requirements to the relevant state laws.¹²

¹¹ 21 C.F.R. § 808.1(d) “State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.”

¹² The Court will address only the “main” claims common to the majority of plaintiffs. By not addressing a particular claim, the Court is not expressing an opinion on whether that ancillary claim would amount to a conflicting “requirement.” However, defendant is not entitled to summary judgment on such claims, because defendant did not meet its burden of establishing that such claims conflict with a federal requirement.

IV. Discerning the State Requirements and Comparing for Conflict

A. Strict liability and negligence claims

Plaintiffs allege that the Silzone valve was defective in design and/or formulation in that when the valves left defendant's hands the risks exceeded the benefits. Alternately, plaintiffs argue that the valves were defective in design or formulation in that they were more dangerous than an ordinary consumer would expect when used in their intended or reasonably foreseeable manner. Plaintiffs also allege the valves were defective due to inadequate warning, and that defendant failed to provide adequate post-marketing warnings. In addition, plaintiffs allege the valves failed to conform to the representation of defendant (in that they were not safe for use by consumers), and plaintiffs allege defendant failed to adequately test the valves.

Defendant argues that these claims are necessarily pre-empted because the FDA approved the device, and any inquiry into the approval process is forbidden "second-guessing" of the FDA. Plaintiffs argue that these claims are not pre-empted because the claims do not rely on any state "requirement" different from any federal requirement. Plaintiffs suggest that because there was no "requirement" to continue selling Silzone after its safety was called into question, plaintiffs' strict liability (and negligence) claims cannot be preempted.

Device manufacturers are never "required" to sell devices, and therefore it seems that plaintiffs' first argument would totally eliminate preemption—a result that clearly is incorrect. Plaintiffs' next argument, however, is more persuasive. Plaintiffs note that the FDA encourages voluntary recalls and unilateral changes to warning labels. Although

the *Brooks* Court rejected an argument premising liability on the failure to update a warning, plaintiffs' argument is distinguishable. In *Brooks*, the Eighth Circuit examined the plaintiff's evidence to discern (1) whether the FDA was aware of that particular risk when approval to the warning language was granted and (2) whether that risk was scientifically established either at the time of approval, or at the time the suit was brought. This inquiry implies that if the FDA had not been aware of the risk, plaintiff Brooks' failure to warn claim would not have been preempted. Applying that reasoning here, plaintiffs would have to establish that defendant knew of the particular risks during the PMA Supplement process, and that the risk is scientifically valid. Plaintiffs claim to have evidence of both, and point to specific facts in the record demonstrating a dispute of material fact.¹³ Defendant has not, therefore, established that plaintiffs' strict liability failure to warn claims are pre-empted and summary judgment is inappropriate.¹⁴

Although the *Brooks* decision did not address a claim for design defect, the Court applies a similar rationale to deny defendant's motion for summary judgment as to those claims. As the Eighth Circuit explicitly stated in *Brooks*, a claim alleging failure to

¹³ Plaintiffs claim both pre-approval and post-approval evidence. Plaintiffs point to evidence that defendant misrepresented the results of animal tests to the FDA because defendant failed to report the death of one of the subject animals. In addition, plaintiffs cite public reports from the medical community of high rates of stroke and other thromboembolic events, as well as allegedly high explant patterns. Plaintiffs claim these facts establish knowledge on defendant's part that the valve was problematic, yet defendant did not report the problems to the FDA.

¹⁴ Defendant's argument would allow medical device manufacturers to wrongfully withhold data from the FDA, gain PMA or PMA supplement approval, and then be completely immune from liability based on that approval. This cannot be what Congress had in mind when it enacted the MDA because, in its judgment, medical device manufacturers needed to be more strictly regulated. See *Lohr*, 518 U.S. at 587 (noting that in the judgment of Congress the medical device industry needed more stringent regulation).

comply with FDA regulations is not preempted, because such a claim imposes no requirements different from or in addition to federal requirements. *Brooks*, 273 F.3d at 798-99. Preemption was nonetheless appropriate in the *Brooks* case, however, because the Eighth Circuit determined that plaintiff did not make such a claim. In contrast, plaintiffs here claim, and present evidence, that defendant “violated federal regulations . . . failed to meet regular reporting requirements, failed to report a known hazard to the FDA, [and] failed to comply with federal law in other respects.” *Id.* at 799. Therefore, to the extent that plaintiffs’ negligence and defective design claims hinge on violations of FDA requirements, the claims are not preempted, and summary judgment is not appropriate.

B. Implied and Express Warranty

Plaintiffs allege that defendant breached the implied warranty because the Silzone valve was not fit and safe for its intended use, the defects were present when the product left defendant’s hands and the valves were defective, unmerchantable and not fit for their intended purpose. To support their argument that the implied warranty claim is not preempted, plaintiffs point to section 808 of chapter 21 of the C.F.R. which notes that “[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 (**warranty of fitness**)).” (Emphasis added.) Since many states, including Minnesota, have adopted the U.C.C. implied warranty provision, it

appears that claims premised on the U.C.C. should survive preemption motions. *See Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330, n.5 (4th Cir. 1996) (“Although the [Supreme] Court did not address a claim for breach of implied warranty in *Medtronic [v. Lohr]*, we nevertheless determine that the reasoning of that decision requires a conclusion that state-law claims for breach of implied warranties are not preempted by § 360k(a).”). *But see Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997) (“If the [plaintiffs] meant to allege an implied warranty, it is preempted.”).

Similarly, plaintiffs cite several cases in which courts have explicitly held that express warranty claims are not preempted. Those cases seem correctly decided and the Court agrees that express warranty claims are not preempted, at least to the extent that the defendant makes express warranties in addition to the language (warranties or warnings) required by the FDA. *See Mitchell*, 126 F.3d at 915 (“As we noted in our earlier opinion, [express] warranties arise from the representations of the parties and are made as the basis of the bargain between them. A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA, and therefore we cannot say that such a cause of action is preempted.”). *See also Steele v. Depuy Orthopaedics, Inc.*, 2003 WL 22779079 at *14 (D.N.J. Nov. 20, 2003) (denying defendant’s motion for summary judgment on preemption grounds as to plaintiff’s breach of express warranty claims).

As evidence of particular express warranties that (allegedly) were breached, plaintiffs point to, among other things, an advertisement for Silzone which states, “With over 30,000 implants St. Jude Medical heart valves with Silzone coating continue our

tradition of excellent clinical performance.” Plaintiffs then note that in deposition, St. Jude employee Dr. Guzik admits that the “tradition of excellent clinical performance” was questionable. Plaintiffs argue this is a clear-cut example of a breach of express warranty. Plaintiffs also assert, and support with deposition testimony, that St. Jude sales representatives represented to heart surgeons that the Silzone valves were superior to the Masters Series because of the anti-microbial properties of the silver in the Silzone.¹⁵ Such a representation was expressly forbidden by the FDA. St. Jude disputes that it made such representations, and points to statements by St. Jude managers to that effect. This disagreement highlights the disputed material facts. Plaintiffs have pointed to specific, admissible evidence raising disputed issues of material fact on these claims. Therefore summary judgment on pre-emption grounds must be denied as to the breach of warranty claims.

C. Inadequate warnings and labeling

Plaintiffs call this an “easy call” arguing that because Minnesota’s duty to warn “requirements” mirror product manufacturers’ duties under the FDCA and the FDA, there is no conflict. The trouble with plaintiffs’ analysis is that the FDA, at least initially,

¹⁵ For example, a St. Louis thoracic surgeon averred that he implanted approximately fifty Silzone valves “because of its asserted anti-bacterial and anti-infection properties.” This understanding, he continues, “came in significant part from statements made to me by a sales representative of St. Jude Medical...[who] informed me that the Silzone valve was an improvement over the existing St. Jude Master’s Series valve because the Silzone coating on the valve sewing cuff would greatly reduce the incidence of post-surgery infection.” (Plaintiffs’ Appendix at Volume VI, Exhibit 21).

determined that the labeling constituted an adequate warning. In fact, the FDA drafted some of the language, and approved all of the language.

Plaintiffs' argument continues—"despite knowledge [of risks] SJM never made or even proposed a single change to the Silzone labeling." At first blush, this argument is identical to that rejected by the Eighth Circuit in *Brooks*. However, the plaintiff in *Brooks* could not show (or simply failed to show) that the FDA was unaware of the risks when the labeling was approved. Here, plaintiffs argue that they can demonstrate that the FDA was unaware of certain risks as the label language was updated. Defendant argues that plaintiffs' claims are nonetheless preempted, because to prove that the FDA was unaware of a given risk, plaintiffs will essentially have to prove fraud on the FDA—the inquiry rejected in *Buckman*. Defendant apparently would have the Court read *Buckman* so as to preempt any and all claims in which any inquiry into the FDA regulatory process is necessary.

It is difficult to accept such an expansive reading of *Buckman*, and such a reading would be difficult, if not impossible, to reconcile with the decision announced in *Lohr*. In addition, the *Brooks* Court had the benefit of the *Buckman* opinion, and nonetheless reasoned that the result might be different had plaintiff shown that the FDA was unaware of certain information. The Supreme Court in *Buckman* was addressing a cause of action emanating **exclusively** from federal regulations. This case does not present such a limitation. The critical distinction between *Lohr* and *Buckman* is not that a court or jury would have to examine what the FDA knew, and when it knew it. Instead the meaningful distinction is a fundamental difference in the very source of the cause of action. That is,

in *Lohr*, the cause of action was based in traditional state tort law; in sharp contrast, the cause of action asserted in *Buckman* depended entirely on the regulatory relationship between the federal government and the FDA. In that dispositive way, the instant case is more similar to *Lohr*, and entirely unlike *Buckman*. In this case, the inadequate labeling and failure to warn claims are based on traditional tort causes of action—causes of action that have normally been the exclusive province of states. For that reason, *Buckman* does not require preemption of these claims.¹⁶

Similarly, *Brooks* does not dictate a result in defendant’s favor. Unlike the plaintiff in *Brooks*, the plaintiffs here have alleged, and have supported with specific evidence, that the FDA was not aware of the risk that the Silzone valve presented. In short, plaintiffs have raised disputed issues of material fact such that their inadequate warning and labeling claims survive summary judgment on the ground of preemption.

D. Consumer fraud & deceptive trade practices statutes

Like state law requirements under the U.C.C., the applicable regulation expressly states that claims under state unfair trade practices are not preempted. 21 C.F.R. § 808(d). Citing *Buckman*, defendant argues that plaintiffs’ consumer fraud and

¹⁶Legal commentators have made a similar distinction. *See, e.g.*, Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 Washburn L. J. 549, 572 (2002) (“Under *Medtronic [v. Lohr]* and its predecessors, plaintiffs should ordinarily be able to base actions against manufacturers of risky products on traditional common law negligence and strict liability theories without fear of preemption. As cases based upon negligence and strict liability go forward, evidence of attempts by the defendant to manipulate the regulatory process through fraudulent or misleading means should be admissible even if wrongful manipulation may not support an independent claim for relief.”).

deceptive trade practices claims are really “fraud on the FDA claims” in disguise, and are therefore preempted. Again, the Court does not find that *Buckman* extinguishes plaintiffs’ claims at this stage of the litigation. Instead, the Court finds this case more analogous to *Dawson ex rel. Thompson v. Ciba-Geigy Corp., USA*, 145 F. Supp. 2d 565 (D.N.J. 2001). In that case, the Court rejected defendant’s preemption argument, noting:

Plaintiffs’ Complaint here does not allege a claim of “fraud on the FDA,” but rather alleges that Defendants deceived the public, including Plaintiffs. The Supreme Court in *Buckman* expressly distinguished “fraud on the FDA” claims from other state tort claims for fraudulent labeling, such as those that the Court had previously addressed in *Medtronic v. Lohr*, 518 U.S. 470 (1996). *Buckman*, 121 S. Ct. at 1020. ... *Buckman* thus clarified that traditional state tort law claims (even those which parallel FDCA requirements) are not necessarily preempted by the FDCA and are not necessarily the same as “fraud on the FDA” type claims. *Id.* Unlike the claims in *Buckman*, a finding of a violation of the FDCA is not a necessary element of Plaintiffs’ claims, which rely on traditional state tort principles. Plaintiffs are not claiming a violation of the FDCA; their claims are confined to traditional state tort and fraud claims, similar to those in *Medtronic*.

Id. at 573. The Court finds that reasoning persuasive, and therefore denies defendant’s pre-emption motion on the consumer fraud and deceptive trade practices claims.

E. Medical monitoring

In general, a medical monitoring plaintiff must establish exposure to a hazardous substance; that as a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease; that increased risk makes periodic diagnostic medical examinations reasonably necessary, and that monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial. The parties’ briefing did not address whether medical monitoring claims

impose requirements different from or in addition to those imposed by federal requirements, and the Court determines that such claims do not. Therefore, defendant's motion for summary judgment is denied as to plaintiffs' medical monitoring claims.

V. Drug, Device, or Both

Plaintiffs also assert that they have raised a disputed issue of material fact as to whether the valve is a device, or is a combination drug and device. This distinction is important because the express preemption principles and case law discussed above do not apply to combination products or to drugs (§ 360k by its terms applies only to devices). Plaintiffs base this argument on their experts' opinions that the silver sewn into the valve interacts with the body more like a drug than a device. Plaintiffs assert that the FDA never determined that the valve is a device, rather than a drug, but that even if such a determination had been made, the Court is not bound by the FDA's determination. *See Tarallo v. Searle Pharmaceutical, Inc.*, 704 F. Supp. 653, 658 (D.S.C. 1988) (reasoning that because Congress defined the terms "drugs" and "device" the Court is not bound by an administrator's determination); *see also Callan v. G.D. Searle & Company*, 709 F. Supp. 662, 666 (D. Md. 1989) (finding that Copper 7 IUD was drug due to release of copper ions).

Defendant briefly addresses this argument, and states the FDA expressly considered the drug/device issue and classified the valve as a device. The Court reviewed the exhibits defendant identified, and from those exhibits, it appears that the FDA *considered* the drug or device issue. In particular, one exhibit defendant identifies

is a portion of minutes from a June 1998 meeting, apparently of the Circulatory Systems Devices Panel of the FDA. Def. Appendix C, tab 32. That excerpt includes a discussion during which the drug/device distinction was addressed, but, at least in the portion submitted to the Court, there does not appear to be a conclusion or consensus reached. Defendant also suggests that all of Appendix C supports its argument that the FDA expressly determined that the valve is a device. The Court carefully reviewed the documents submitted in Appendix C, and did not uncover any indication that the FDA explicitly determined that the valve is a device, rather than a drug. The Court notes, however, that Appendix C does contain many instances of defendant making that assertion to the FDA, and the FDA continually referred to the valve as a device.

The Court owes no deference to an FDA “classification” where it is made simply for “administrative convenience” and does not reflect the considered view of the agency. *See Tarallo*, 704 F. Supp. at 658. The Court finds plaintiffs’ argument that the valve more closely resemble a drug/device combination to be intuitively persuasive. However, because the Court finds that plaintiffs’ claims are not pre-empted and this drug/device issue requires more extensive analysis, the Court will not decide at this time whether the heart valve with Silzone coating is a drug, a device or a combination.

VI. What approval? 510k or PMA Supplement

Plaintiffs finally argue that because the approval process here was more like the abbreviated 510k-equivalence process than the PMA Supplement-safety process, preemption should not apply. *See Brooks*, 273 F.3d at 794 (“Section 510(k) approval is a

mere grant to market; it imposes no “requirements” of its own.”) (Citing *Lohr*, 518 U.S. at 493). Plaintiffs suggest that the Court simply needs to determine that the FDA never made a determination of the efficacy of the Silzone coating.

The FDA, at least ostensibly, approved the valve via the PMA Supplement. (March 24, 1998 Letter from Susan Alpert, Director, Office of Device Evaluation stating “The Center for Devices and Radiological Health (CDRH) of the [] FDA has completed its evaluation of your premarket approval application (PMA) supplement.”). On the other hand, it is clear that the FDA never determined that the Silzone coating was “effective.” In fact, the FDA explicitly precluded defendant from making claims regarding the efficacy of the Silzone coating. *Id.* (“[T]he labeling of the device must not contain or imply any claims that the Silzone Coating is effective in reducing the incidence of endocarditis.”). Equally clear, nonetheless, is that the valve itself continued to be considered effective as a heart valve. The parties ask the Court to determine if issuing a PMA Supplement approval without making a finding of efficacy, invalidates the approval, transforms the approval into 510(k) approval, or is an abuse of agency discretion.

A separate, but related argument is that the approval, whichever approval it was, was lost when defendant failed to comply with FDA guidelines, or if not at that point, at least once the product was voluntarily recalled. “Please comply with the above guidelines. We do not want to do anything that will jeopardize our own FDA approval.” (Memorandum from Hosek to U.S. Sales Force at Plaintiffs’ Appendix Vol. VI, Ex. 79.)

The FDA classified St. Jude's actions as "a recall." The Administration noted, "We are assigning recall numbers to [Silzone valves] . . . We are classifying the firm's actions as a voluntary recall. We consider the devices to be adulterated and misbranded." (March 20, 2000, Memorandum from Cardiovascular and Neurological Devices Branch at Plaintiffs' Appendix Vo;. VI, Ex. 100.) Similarly, a March 22, 2000 letter from Edwin Dee to St. Jude noted, "We agree with your firm's decision to recall [listing of specific device identifying numbers] . . . We have reviewed your action and conclude that it meets the formal definition of a 'Recall'. This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market." (Plaintiffs' Appendix Vol. V, Ex. 24.)

Defendant suggests that this letter is "out of context" and that the Silzone valve in fact has never been recalled (specifically, counsel for St. Jude stated at oral argument that "[T]he adulterated and defective language that the plaintiffs pick on from the correspondence is drawn out of context. It doesn't represent any regulatory finding or conclusion."). The Court hesitates to characterize defendant's argument too harshly, however, it is difficult to read the FDA's March 20, 2000 and/or March 22, 2000 correspondence and find any ambiguity, regardless of context. The FDA clearly indicates that the device is "adulterated and misbranded." The recall is significant because it is "an alternative to [FDA] legal action to remove the product from the market." Despite defense counsel's arguments, St. Jude appears to recognize that the Silzone valve is not marketable absent additional approval from the FDA. *See Affidavit of Alan Flory* at Plaintiffs' Appendix, Vol. II, Tab. 2 (A) page 258. (Q: "The fact that the PMA

Supplement has not been withdrawn doesn't mean that you're perfectly free to go out and market this product again, unless FDA says you can do it. Isn't that fair?" A: "That's true. . . . Unless we put in a PMA supplement and notify [the FDA] that we have the clinical data that we said we would gather before we put it back on the market.")

The Court finds persuasive plaintiffs' argument that the Silzone valve no longer has FDA approval. At this time, however, the Court need not determine how the withdrawal of approval impacts plaintiffs' claims. Similarly, the Court will not resolve whether the Silzone valve's approval was via the PMA supplement or was 510k approval, because the Court has found that plaintiffs' claims are not pre-empted. The Court will not scrutinize such an involved issue without the benefit of thorough briefing on this specific question. The Court's research has revealed that plaintiffs' argument regarding types of approval (PMA versus 510k) is not novel, but the Court has been unable to find a reported decision in which a court **analyzes** the method of approval to determine independently whether the approval was PMA or 510k. *See, e.g., Steele v. Depuy Orthopaedics, Inc.*, 2003 WL 22779079 at *5 (D.N.J. Nov. 20, 2003) (acknowledging plaintiffs' argument that the approval at issue was more akin to the abbreviated 510k, and apparently rejecting the argument, but not discussing the issue).

MOTIONS TO STRIKE

I. Defendant's motion to strike affidavits of plaintiffs' three experts

Defendant moves to strike the affidavits of Gregory Wilson, Devin Healy, and Suzanne Parisian, arguing that the expert reports violate "fundamental rules of

evidentiary admissibility.” Defendant asserts four “compelling reasons” to strike the affidavits, including (1) the opinions are irrelevant, (2) the expert’s testimony is not the proper subject of expert opinion under controlling law, (3) the opinions are simply legal conclusions “recast as expert opinion,” and (4) the experts are not qualified.

For the purposes of this motion, the Court denies the motion to strike. The material is relevant, and the Court assures defendant that the Court will reach its own conclusions regarding the law and will not be misled by plaintiffs’ experts. The Court might well be more cautious in allowing a jury to consider such opinions. Finally, the Court finds that the experts are adequately qualified given each expert’s education, training and experience.

II. Plaintiffs’ Motion to Strike the Affidavits of Alan Flory and Diane Johnson.

Flory is an employee of St. Jude Medical. Johnson is a former FDA employee who is presented as having expertise in the field of heart valve regulation and the PMA process. Plaintiffs object on the grounds of hearsay and lack of personal knowledge. Plaintiffs note that in deciding a motion for summary judgment, the Court may not consider affidavits that do not satisfy the requirements of Fed. R. Civ. P. 56(e).

Plaintiffs argue that the information in Flory’s affidavit is based on hearsay. In addition, plaintiffs suggest that Flory admitted during deposition that he has no personal knowledge that St. Jude complied with every applicable FDA regulatory requirement as he averred. The basis for the objection to the Johnson affidavit appears to be lack of personal knowledge.

The Court denies the motion to strike for purposes of this summary judgment motion. Although the Court must not rely on evidence which would be inadmissible, it is not necessary to strike either affidavit. Plaintiffs have preserved their objections, and the Court can sift through the affidavits to determine what portions, if any, would be inadmissible and therefore will not be considered for the purposes of summary judgment. It appears to the Court that Johnson is offered as an expert, and therefore the personal knowledge objection is inapplicable.

III. Plaintiffs' motion to strike the attachments to defendant's reply brief

The Court granted defendant a significant page and time extension for its reply brief. Defendant used its full page allotment, and also attached additional argument, in the form of "charts" as exhibits. These exhibits are improper, and given the Court's reasonableness in granting the page and time extension, the Court finds defendant's additional argument in the guise of "exhibits" unfortunate. The Court therefore strikes the argumentative portions of the "charts" (specifically, the portions preceding the numbered tabs). However, the charts also serve as a table of contents, and the Court will continue to use the table of contents portion.

ORDER

Based upon the foregoing, the submissions of the parties, the arguments of counsel and the entire file and proceedings herein, **IT IS HEREBY ORDERED:**

1. Defendant's motion for summary judgment [Docket No. 67] is **DENIED**;

2. Defendant's motion to strike the affidavits of Gregory John Wilson, Kevin E. Healy, and Suzanne Parisian [Docket No. 219] is **DENIED**.

3. Plaintiffs' motion to strike the affidavits of Alan R. Flory and Diane Johnson [Docket No. 208] is **DENIED**.

4. Plaintiffs' motion to strike appendices to St. Jude's reply in support of motion for summary judgment [Docket No. 223] is **GRANTED in part and DENIED in part as described above**.

DATED: January 5, 2004
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge