IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JOYCE LINK,	)	
Plaintiff ,	)	Case No. 06 C 5438
v.	)	
	)	Judge Virginia M. Kendall
ZIMMER HOLDINGS, INC., ZIMMER U.S., INC., AND ZIMMER, INC.,	)	
Defendants .	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Joyce Link ("Link") filed suit against Defendants Zimmer Holdings, Inc., Zimmer U.S., Inc. and Zimmer, Inc. (collectively "Zimmer") in the Circuit Court of Cook County alleging claims of strict liability, negligence and breach of warranty based on injuries she incurred as a result of a faulty knee replacement. Zimmer removed the case to this Court under 28 U.S.C. § 1332. Zimmer now moves for summary judgment, arguing that Link's claims are preempted by the Medical Device Amendments, 21 U.S.C. §§ 360c, *et seq*. ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. For the reasons stated below, this Court grants Zimmer's Motion for Summary Judgment.

STATEMENT OF FACTS[1]

On June 14, 2000, Link underwent a knee replacement surgery on her left knee during which Zimmer's "Natural Knee II" ("N-K II") was implanted in her knee. Def. 56.1 at § 3. In October of 2004, the N-K II was removed from Link's knee. *Id*. at § 4. Link alleges in her Complaint that the N-K II was removed to prevent further osteolysis caused by the N-K II. *Id*. at § 5. Link also alleges that the N-K II was defectively designed using materials that were "prone to wear." *Id*.

The N-K II is a Class III medical device and therefore subject to a rigorous premarket approval application ("PMA") process conducted by the Food and Drug Administration. ("FDA"). *Id*. at §§ 7-8. Zimmer submitted its original PMA application for the "Natural Knee System with Cancellous Structured Titanium" on January 12, 1994. *Id*. at § 9. As required by the FDA, Zimmer's PMA application contained detailed information regarding the design, manufacturing, quality control, marketing, and distribution methods proposed for the N-K II. *Id*. at § 11.

---

[1] On a Motion for Summary Judgment, Local Rule 56.1 requires that all parties submit factual statements supported by evidence on the record. L.R. 56.1. The nonmovant should submit "a response to each numbered paragraph in the moving party's statement, including, in the case of any disagreement, specific references to affidavits, parts of the record, and other supporting materials relied upon." L.R. 56.1(b)(3)(c).

Here, Link has completely disregarded the requirements of Local Rule 56.1. She has neither filed a response to Zimmer's Rule 56.1 Statement of Undisputed Facts nor a statement of additional facts. She has, seemingly instead, peppered references to various articles throughout her Response to Zimmer's Motion for Summary Judgment without submitting any of the referenced items into the record.

All facts set forth by a party moving for summary judgment are deemed admitted unless contraverted by the statements filed by the opposing party. L.R. 56.1(b)(3)(c), and failure of the nonmovant to respond to the movant's statements of fact as mandated by Local Rule 56.1 results in the admission of those statements of fact. *Smith v. Lamz*, 321 F.3d 680, 683 (7th Cir. 2003); *see also McCutcheon v. Zimmer Holdings, Inc.*, No. 06 C 6256, 2008 WL 3153442, at *1-2 (N.D.Ill. August 6, 2008) (deeming all statements of fact admitted under identical circumstances). As such, this Court deems all facts submitted by Zimmer admitted, and this Statement of Facts draws entirely from those facts.

Specifically, Zimmer submitted the following items, all of which were required by statute and regulation: 1) a statement of components, ingredients and properties and of the operation of the device, including pictorial representations, an explanation of how the device functions, the scientific concepts that form the basis for the device, and its physical and performance characteristics; 2) the methods, facilities and controls used in manufacturing, processing, packaging and storing the device, aimed at allowing the FDA to make a judgment regarding quality control; 3) a description of the properties of the device relevant to diagnosis and treatment of medical conditions; 4) the results of nonclinical laboratory studies; 5) the results of all clinical studies; 6) the results of all published reports regarding the safety and effectiveness of the device; and 7) all proposed labeling, instructions, literature and advertising regarding the device. *Id*. at § 9. On May 21, 1996, Zimmer submitted an Amendment to their PMA application seeking to include the second generation Natural Knee system as well as the N-K II System, the system about which Link complains, to its PMA application. *Id*. at § 10.

The FDA took considerable time reviewing the PMA application, raised questions, and required additional submissions from Zimmer. *Id*. at § 12. On March 21, 1997, the FDA approved the application for the Natural-Knee and N-K II systems. *Id*. at § 13. Such approval represents a specific federal determination that the N-K II is safe and effective. *Id*. at § 18.

The approval limited the systems to prescription use in accordance with 21 C.F.R. § 801.109 and FDA labeling requirements. *Id*. at § 14. It also included three mandatory conditions of approval: 1) submission of a supplemental PMA for FDA approval prior to making any changes that would change the safety or effectiveness of the devices; 2) submission of annual post-approval reports to the FDA pursuant to the requirements of 21 C.F.R. § 814.84; and 3) submissions of

Adverse Reaction Reports and Device Defect Reports under relevant circumstances. *Id*. at § 15. In addition, the PMA required Zimmer to complete a post-approval study to evaluate the nine year survivorship of the device. This requirement included the submission of annual progress reports including survivorship data and patient accounting until the completion of the nine-year study. *Id*. at § 16. FDA approval for the design and manufacturing process used for the N-K II continues to this day. *Id*.

When Link was implanted with the N-K-II device, Zimmer maintained the approval of the N-K II as a Class III medical device in compliance with MDA regulations and with continuing FDA supervision. *Id*. at § 17. The manufacturing records for the N-K II implanted in Link show that all its components were manufactured in compliance with FDA approved specifications. *Id*. at § 19.

STANDARD OF REVIEW

Summary judgment is proper when "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 judgment as a matter of law." Fed. R. Civ. P. 56(c). In determining whether a genuine issue of fact exists, the Court must view the evidence and draw all reasonable inferences in favor of the party opposing the motion. *Bennington v. Caterpillar Inc.*, 275 F.3d 654, 658 (7th Cir. 2001); *see also Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 255 (1986). However, the Court will "limit its analysis of the facts on summary judgment to evidence that is properly identified and supported in the parties' [Local Rule 56.1] statement." *Bordelon v. Chicago Sch. Reform Bd. of Trustees*, 233 F.3d 524, 529 (7th Cir. 2000).

DISCUSSION

The Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act imposed detailed federal oversight onto the introduction of new medical devices onto the market. *Riegel v. Medtronic*, 128 S. Ct. 999, 1003 (2008). The level of federal oversight varies depending on the risks the devices present. *Id.* Class III devices, such as the N-K II, are given the greatest oversight and are subjected to a rigorous premarket approval process. *Id*. at 1004.

The MDA includes a provision that expressly preempts state law. *Id*. at 1006. It states:

> "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. § 360c et seq. As such, this Court must determine whether (1) the Federal Government has established requirements applicable to the N-K II and if so (2) whether Link's common-law claims are based on requirements imposed by the State of Illinois with respect to the N-K II that are "different from or in addition to" the federal requirements and relate to safety and effectiveness.[2] *Riegel*, 128 S.Ct. at 1006; *Mitchell v. Collagen Corp.*, 126 F.3d, 902, 909 (7th Cir. 1997); *McCutcheon v. Zimmer Holdings, Inc.*, No. 06 C 6256, 2008 WL 3153442, at *3 (N.D.Ill. August 6, 2008).

---

[2] Link argues that this analysis does not apply to her case because Zimmer did not fully and honestly disclose the potential risks of the N-K II to the FDA during the PMA process and because the particular defect at issue was not identified until after the N-K II received premarket approval. First, this Court notes the extensive and ongoing nature of the PMA process, *see Riegel*, 128 S.Ct. at 1004-05, as well as the fact that the majority in *Riegel* did not discuss exceptions among Class III medical devices that received PMA approval. Regardless, and more importantly, Link has not submitted any admissable statements of fact or any evidence to support this claim, and thus it cannot create a material dispute of fact that could persuade this Court to refuse to apply *Riegel*.

The PMA Process is a Federal Requirement Applicable to the N-K II

A federal "requirement" that warrants preemption only occurs under the MDA where the regulation at issue is specific to a particular device. *Riegel*, 128 S.Ct. at 1006-07 *citing Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495, 501 (1996). That is, general requirements reflecting concerns of device regulation at large do not warrant preemption under the MDA. *Id*. The PMA process as applied to Class III medical devices by the FDA constitutes a federal "requirement" specific to an individual device as defined in the MDA. *Id*. at 1007 (PMA process applied to a balloon catheter); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 487-88 (7th Cir. 2005) (PMA process applied to a brain implant); *Mitchell*, 126 F.3d at 911 (PMA process applied to a collagen product used to fill in soft tissue under skin). The PMA process is essentially federal safety review specific to individual devices, and the FDA grants premarket approval only to individual devices that it determines provide a reasonable assurance of safety and effectiveness. *Riegal*, 128 S.Ct. 1007. During its review, the FDA weighs competing considerations related to a particular device, reaches a conclusion, and implements "that conclusion via a specific mandate on manufacturers and producers." *Mitchell*, 126 F.3d 911 *citing Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir. 1997). For example, here, the FDA approved the N-K II, but only for prescription use and only if Zimmer fulfilled three mandatory conditions of approval, including the submission of extensive post-approval materials. Def. 56.1 at ¶¶ 14-16. *See, e.g.*, *McMullen*, 421 F.3d at 488 (FDA required specific warnings and required manufacturer to track all device recipients). Further, an approved device must be manufactured "with almost no deviations" from the specifications approved by the FDA during the PMA process. *Riegal*, 128 S.Ct. 1007.

Here the N-K II, a Class III medical device, underwent the rigorous and individualized PMA process as dictated by the MDA. Def. 56.1 at ¶¶ 7-8, 10, 13. Zimmer submitted extensive application materials and answered questions related to its application and the FDA eventually approved the application, although it placed limitations on its approval, including requiring post-application safety-related submissions. *Id*. at ¶¶ 9, 11, 15-16. This approval is a federal determination of the safety of the N-K II. *Id*. at ¶ 18. No facts indicate that this approval has been questioned or repudiated by the FDA. As such, like the devices in *Riegal* and *Mitchell*, the N-K II has been subjected to, and achieved, a specific federal requirement. *See, McCutcheon v. Zimmer Holdings, Inc.*, No. 06 C 6256, 2008 WL 3153442, at *3 (N.D.Ill. August 6, 2008) (PMA process as applied to the N-K II amounted to a federal "requirement" under the MDA).

Link's Common Law Claims are State Requirements Related to Safety and Effectiveness that Differ from the Federal Requirements

Because the PMA process implemented by the FDA constitutes a federal "requirement" as defined in the preemption provision of the MDA, this Court next evaluates whether Link's common law claims of strict liability, negligence and breach of warranty are state requirements which relate to safety and effectiveness and are "different from or in addition to" the federal requirements as imposed by the PMA process. *Riegel*, 128 S.Ct. at 1006.

Safety and Effectiveness of products are the specific targets of the state common-law claims of negligence, strict liability and breach of warranty at issue here. *Id*. at 1007. Further, these common law claims qualify as state "requirements" under the MDA. *Id*. at 1007-08 (strict liability, breach of implied warranty and negligent design, testing, inspection, distribution, labeling, marketing, sale and manufacture claims constituted state requirements) *citing Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992) (common-law liability is premised on a legal duty and is

designed to govern conduct); *McMullen*, 421 F.3d at 487 (failure to warn claim constituted a state requirement); *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1247-48 (strict liability and breach of implied warranty claims constituted state requirements). As such, Link's state law claims of negligence, strict liability and breach of warranty are preempted to the extent that they differ from the relevant federal requirements. *Riegal*, 128 S.Ct. at 1011.

Link's Claims are State Requirements Different from or In Addition to Federal Requirements under the MDA

Link's claims would not be preempted if they were "parallel" to the federal requirements; that is, here, if they offered damages for failure to comply with FDA regulations. *Id*. at 1011 (claims premised on a violation of FDA regulations would not be preempted); *Chambers*, 109 F.3d at 1248 (negligent manufacturing claim not preempted because it alleged that manufacturer failed to comply with procedures approved and required by FDA); *Mitchell*, 126 F.3d at 914 (allegations of failure to meet standards of PMA process would not be preempted). In order to be considered parallel to federal regulations, the state requirements must be "genuinely equivalent" to the federal requirements. *McMullen*, 421 F.3d at 489.

Here, Zimmer established that it complied with the PMA process as required by the MDA, received approval and continues to comply with the ongoing requirements of that approval. Def. 56.1 at ¶¶ 9-11; 17. To the extent that Link puts forth facts that could be construed as questioning Zimmer's compliance with the PMA process, those facts are not properly filed and supported by the record. *See footnote 1, supra*. As such, any finding holding Zimmer liable under Link's theories despite their conformance with the federal requirements imposes a state requirement different from the applicable federal requirements. *Riegal*, 128 S.Ct. at 1011 (claims including strict liability, negligence, and breach of implied warranty amounted to state requirements different from federal

requirements); *Mitchell*, 126 F.3d at 913 (claims of negligence and strict liability amounted to state requirements different from federal requirements). During the PMA process, the Federal Government weighs competing interests related to a given product, makes a determination about how those considerations should be resolved, and does so via a specific mandate. *Mitchell*, 126 F.3d at 911 citing *Papike*, 107 F.3d at 741. The application of differing common-law standards necessarily undermines that careful analysis. *See Chambers*, 109 F.3d at 1248 (claims "set up a direct collision with federal policy because the FDA has already decided, rightly or wrongly, that a particular device can be sold" subject only to requirements it has imposed).

Link argues that *Riegal* does not apply to her claims. First, she argues that the *Riegal* analysis should not apply because Zimmer did not fully and honestly disclose all information relevant to the safety of the N-K II to the FDA. It is undisputed, however, Zimmer submitted the results of all clinical and nonclinical laboratory studies and the results of all published reports regarding the safety and effectiveness of the N-K II to the FDA during the PMA process. Def. 56.1 at ¶ 9. Regardless, any allegations that Zimmer committed a fraud upon the FDA are also preempted and therefore cannot provide the basis for Link's claims. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (claim that defendants made fraudulent representations to FDA regarding intended use of bone screws preempted).

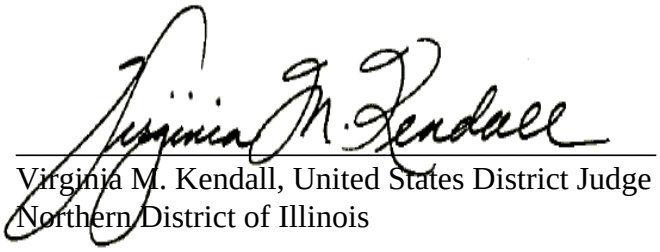
Second, Link argues that her situation falls outside of those contemplated in *Riegal* because the N-K II's defects came to light after it received premarket approval from the FDA. In so arguing, she relies on Justice Ginsburg's dissent in *Riegal*, arguing that *Riegal*'s holding does not address "the preemptive effect of § 360k(a) where evidence of a medical device's defect comes to light only *after* the device receives premarket approval." *Riegal*, 128 S.Ct. at 1013

(Ginsburg, J. dissenting). This argument also fails. Indeed, this Court need not even reach the issue of whether *Riegal* applies in situations where defects are discovered after premarket approval because the record is devoid of admissible evidence that such a situation exists here.

Link also argues that regardless or whether *Riegal* would otherwise apply, this Court should not follow its holding because it violates Congress's intent in passing the MDA. To this end, she asserts that Congress is considering the passage of a new medical device act to "correct" *Riegal*. This Court declines to alter its ruling based upon alleged congressional motivations in conflict with the Supreme Court's ruling or upon a potential law that may or may not be passed by Congress at an unknown point in the future. Indeed, "it is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available - the text of the statute - suggests that the solicitude for those injured by the FDA-approved decives, which the dissent finds controlling, was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of all 50 states to all innovations." *Riegal*, 128 S.Ct. at 1009.

Therefore, Link's claims are preempted by federal law. *Riegal*, 128 S.Ct. at 1011 (state common law claims preempted as to a balloon catheter approved through the PMA process); *Mitchell*, (state law claims preempted as to collagen injections approved through the PMA process); *McCutcheon*, No. 06 C 6256, 2008 WL 3153442, at * 4 (identical state law claims preempted as to same device at issue here) *compare Chambers*, 109 F.3d strict liability and breach of implied warranty claims preempted but negligent manufacture claim involved failure to follow FDA requirements and therefore not preempted). For the reasons stated above, Zimmer's Motion for Summary Judgment is granted.

So ordered.



Virginia M. Kendall, United States District Judge
Northern District of Illinois

Date: November 26, 2008