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The 510(k) Process Does Involve a Relevant Safety Review, Despite What You May Have Read or Heard

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Although it may seem facially obvious that evidence relating to the regulatory pathway for introducing a medical device into the market is relevant to the safety and efficacy of the device and reasonableness of the manufacturer's conduct, there is surprising controversy regarding the admission of evidence relating to FDA's clearance of a medical device via its 510(k) process in the context of a product liability lawsuit. This "controversial" evidence can take the form of the 510(k) clearance itself, the choice to utilize the 510(k) process, FDA's actions leading up to clearance, and interactions between the device manufacturer and FDA concerning the device both before and following clearance. As discussed herein, the controversy largely results from significant misconceptions regarding the intent of FDA's 510(k) review. Contrary to some cursory discussions of the 510(k) process found in the case law, FDA does in fact review 510(k) applications in the context of the overall safety of the final product. Understanding this fact — and getting judges and juries to understand it — is the key to putting a medical device manufacturer's conduct during the regulatory process into the proper context.

Much of controversy regarding the admissibility of 501(k) evidence flows from an unfortunate discussion of the intent of the 510(k) process in United States Supreme Court decision *Medtronic v. Lohr*, a case which had nothing to do with the admissibility of such evidence.[1] In *Lohr*, the Court held that plaintiff's product liability design defect claims were not preempted by the MDA.[2] The device manufacturer argued that plaintiff's claims were preempted because FDA found its device to be "substantially equivalent" to an earlier device and because FDA had authority to exclude the device from the market but chose not to do so.[3] The Court disagreed, asserting that the device manufacturer "exaggerates the importance" of 510(k) clearance because "the § 510(k) process is focused on equivalence, not safety" and the device at issue "has never been formally reviewed under the MDA for safety or efficacy."[4]

The Court would reiterate this notion in *Riegel v. Medtronic, Inc.*, another federal preemption case: "While § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence."[5] These narrow and sweeping characterizations of the 510(k)

1 518 U.S. 470 (1996).
2 *Id.* at 491-92.
3 *Id.* at 492.
4 *Id.* at 492-93.
5 552 U.S. 312, 323 (2008) (internal citation and quotation marks omitted).

process have had a profound impact on trial court decisions concerning admissibility of 510(k) evidence. Unfortunately, they brush aside the truth about FDA's intent --in FDA's own words.

As both *Lohr* and *Riegel* demonstrate, the major misconception concerning the 510(k) process is the misinformed notion that the process does not involve a safety and efficacy analysis. This notion is simply incorrect. Indeed, the Supreme Court has stated in *Buckman v. Plaintiffs' Legal Committee*[6] that the 510(k) process is in fact concerned with safety and effectiveness. There, the Supreme Court pointed out that pre-market approval and § 510(k) clearance are both intended "to ensure . . . that medical devices are reasonably safe and effective."[7] This is not only accurate, it actually understates FDA's concerns with safety during the 510(k) process.

As an initial matter, § 510(k) submissions must include "an adequate summary of any information respecting safety and effectiveness."[8] This can include "information, including appropriate clinical or scientific data . . . that demonstrates that the device is as safe and effective as a legally marketed device" and information demonstrating that the device "does not raise different questions of safety and effectiveness."[9] These are safety inquiries on their face and clearance necessarily requires that FDA found that the manufacturer's submissions were adequate.

Moreover, in 1995, FDA issued a Guidance that plainly detailed that a safety and efficacy analysis was a critical part of the 510(k) process.` The 1995 Guidance, discussing the "Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices," included an FDA-modified matrix that designated the type of testing needed for various medical devices, including a flow chart for the selection of biocompatibility testing for 510(k) devices. In the Background section, FDA explicitly acknowledged that the purpose of biological evaluation of medical devices is to conduct an evaluation of the final product's safety compared to its efficacy:

> Biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The device materials should not, either directly or through the release of their material constituents: (i) produce adverse local or systemic effects; (ii) be carcinogenic; or, (iii) produce adverse reproductive and developmental effects. Therefore, ***evaluation of any new device intended for human use requires data from systematic testing to ensure***

6 531 U.S. 341 (2001).
7 *Id.* at 349-50.
8 21 U.S.C. §360c(i)(3)(A).
9 21 U.S.C. §360c(i)(1)(A).
10 *See* Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," G95-1 (Rockville, Department of Health and Human Services, FDA May 1, 1995) (the "1995 Guidance"). This Guidance was effective for all submissions that were received by FDA on or after July 1, 1995. It remained effective until September 14, 2016, when it was superseded by "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," (the "2016 Guidance") which is discussed further herein.

that the benefits provided by the final product will exceed any potential risks produced by device materials.[11]

It is worth breaking down this important statement:

First, FDA expressly states that it requires testing "to determine potential toxicity from contact of the component materials of the device with the body." This belies the notion that the 510(k) process does not examine the safety of the device by virtue of its contact with the body. It plainly does. Indeed, FDA next cautions that "the device materials should not, either directly or through the release of their material constituents [ ] produce adverse local or systemic effects." This is clearly a safety evaluation.

Second, FDA places this review squarely in the context of balancing safety with efficacy. FDA explains that it requires biological evaluation for "***any*** new device intended for human use." There is no 510(k) exception to "any." FDA goes on to explain its intent is "to ensure that ***the benefits provided by the final product will exceed any potential risks produced by device materials.***" This is a classic risk/benefit analysis that is central to design-related causes of action in many jurisdictions. Manufacturers should be permitted to produce evidence that they met this FDA standard even if it is not dispositive under a preemption analysis.

Were these statements about safety evaluation not clear enough, FDA's 1995 Guidance further states that a range of "appropriate tests for biological evaluation of a medical device… may not be sufficient ***to demonstrate the safety of some specialized devices.***" FDA then recommends additional tests depending on "[t]he specific clinical application and the materials used[.]"[12] Again, this is clearly a safety analysis.

FDA further states that "[s]ome devices are made of materials that have been well characterized chemically and physically in the published literature and have a long history of ***safe use,***" and goes on to state "FDA reviewers are advised to use their scientific judgement [sic] in determining which tests are required for the demonstration of substantial equivalence under section 510(k)."[13] Of course, FDA reviewers would necessarily need to determine whether the materials used in a device "have a long history of safe use" in order to judge which tests are required for the demonstration of substantial equivalence.[14] To make that point more clear, FDA requires that the "manufacturer must document the use of a particular material in a legally marketed predicate device or a legally marketed device with comparable patient exposure."[15]

In Attachment A to the 1995 Guidance, FDA recommends specific safety tests depending

11 1995 Guidance at 3 (emphasis added).
12 *Id.* at 4.
13 *Id.*
14 *Id.*
15 *Id.*

on the device, including for cytotoxicity, sensitization, irritation or intracutaneous reactivity, system toxicity (acute), sub-chronic toxicity (sub-acute toxicity), genotoxicity, implantation, and haemocompatibility. In Attachment B, FDA recommends supplemental evaluation tests for consideration, including for biological effects such as chronic toxicity, carcinogeniety, reproductive developmental, and biodegradable.

In Attachment C, FDA provides a "Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s." This is unquestionably a safety review, both in terms of the evaluation of the device's toxicology profile compared to marketed devices and the potential need for additional testing.

FDA just replaced the 1995 Guidance last month, meaning the 1995 Guidance was relevant for any device cleared during that period.[16] Yet in FDA's September 2016 Guidance, once again FDA could not have stated its intent to evaluate the overall safety of medical devices more clearly:

> [E]valuation of any new device intended for human use requires information from a systematic analysis ***to ensure that the benefits provided by the device in its final finished form will outweigh any potential risks*** produced by device materials over the intended duration and use of the device in or on the exposed tissues.[17]

The 2016 Guidance reiterated FDA's purpose "to determine the potential for an unacceptable adverse biological response resulting from contact of the component materials of the device with the body."[18] The Guidance specifically discusses the "use of risk assessments for biocompatibility evaluations," and specific considerations for an array of biological safety testing.[19]

FDA explains: "the biological evaluation of a medical device (or a material component of such) should be conducted within the framework of a risk management process."[20] FDA goes on to state, considering the material components, manufacturing processes, clinical use of the device, anatomical location, and frequency and duration of exposure:

> ***[T]he potential risks from a biocompatibility perspective should be identified.*** Such risks might include chemical toxicity, unacceptable biological response to physical characteristics of the device, and aspects of manufacturing and processing that could alter the physicochemical characteristics of the device, which could lead to changes in the

16 *See* "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," (Rockville, Department of Health and Human Services, FDA June 16, 2016) (the "2016 Guidance").
17 *Id.* at 15.
18 *Id.* at 1.
19 *Id.* at 3.
20 *Id.* at 5.

> biocompatibility response. Once the risks have been identified, the sponsor should assess what information is already available regarding those risks and identify the knowledge gaps that remain. Considering the potential biological impact, a plan should be developed to address the knowledge gaps either by biocompatibility testing or other evaluations that appropriately address the risks. ***The interpretation of the overall biocompatibility evaluation should be considered in the appropriate benefit-risk context.***[21]

Once again, as in 1995, FDA makes clear in 2016 that a "benefit-risk context" is a fundamental part of its evaluation of medical devices.[22] There is no exception for the 510(k) process to be found anywhere in FDA's 1995 or 2016 Guidances. To the contrary, the 510(k) process is expressly included within the overall evaluative framework. FDA notes, for example, that for "the purposes of a biocompatibility evaluation, leveraging information from other marketing applications could be appropriate in support of 510(k)s, PMAs, *de novos*, HDEs, and initiation of IDEs."[23]

FDA makes this point repeatedly in the 2016 Guidance in ways directly relevant to a "substantial equivalence" analysis, noting (i) "[a]n assessment of potential biocompatibility risk should include not only chemical toxicity, but also physical characteristics that might contribute to an unwanted tissue responses," (ii) "changes in manufacturing and processing parameters can also have an impact on biocompatibility," (iii) "[w]hen leveraging data from experience with a particular device for a new device submission to FDA, it is important to understand how the tested device compares to the device under consideration. In general, the more similar the tested device and device under consideration are, including their intended use, the more applicable the risk information is likely to be," and (iv) "experience with device components made using the same formulation and processing (e.g., for devices within a product family) will be more applicable than experience with device components made by a different manufacturer where the formulation and processing are unknown."[24]

FDA similarly reiterated its intent in a 2010 510(k) Working Group Report:

> [T]he 510(k) program has changed significantly since its inception. The MDA established the premarket notification process as a simple check to assure proper device classification. Through various statutory and regulatory modifications over time, it has become a multifaceted premarket review process that is expected to assure that cleared devices, subject to general and applicable special controls, ***provide reasonable assurance of safety and effectiveness,*** and to facilitate innovation in the medical device industry.[25]

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21 *Id.* at 6.

22 For example, FDA notes "In certain situations, a sponsor may propose to use a material that has known toxicities but where the material could be acceptable for the end use. In this case, the risk assessment should include consideration of the intended use population that will use (e.g., protective mask for clinician) or be treated with the device and a discussion of potential benefits of using the chosen material as well as potential mitigations that have been considered (e.g., hermetically sealing)." 2016 Guidance at 8.

23 *Id.* at 16 n.21.

24 *Id.* at 7.

25 510(k) Working Group, Preliminary Report and Recommendations, at 34 (August, 2010), *available at* www.fda.gov/.../cdrh/.../ucm220784.pdf

As demonstrated above, principles of safety and efficacy clearly underlie the substantial equivalence determination in every 510(k) review. Likewise, 510(k) evidence can reveal FDA's thought process on device safety, efficacy, and as to whether warnings are sufficient. This evidence is also directly relevant to the reasonableness of the manufacturer's conduct and to rebut plaintiffs' oft-repeated argument that FDA clearance is nothing more than a meaningless rubber stamp.

CONCLUSION

Despite the relevance of 510(k) evidence on many issues at the heart of product liability cases, many courts exclude such evidence reasoning that it will waste time and confuse the jury. Judges worry about the burden of additional regulatory experts and a resulting "trial within a trial."[26] These concerns should not tip the scale in favor of exclusion. The trial judge as gatekeeper of evidence can manage the presentation of 510(k) evidence so as not to waste time and confuse the jury.[27] Any potential confusion about the meaning of 510(k) clearance in terms of the jury's finding of negligence or product defect can be addressed with a limiting instruction.[28]

Medical device products cases involve claims of product safety and the adequacy of device warnings, and the regulatory process that makes possible the marketing of these devices is a significant piece of the puzzle. It is not a "trial within a trial" -- it often is the heart of the trial. Further, if plaintiffs are permitted to argue that device manufacturers have taken "short cuts" or somehow "gamed" the regulatory system in order to rush its device to market, or if plaintiffs introduce evidence of FDA Warning Letters, Material Data Safety Sheets, or adverse event reports concerning the subject device, evidence of 510(k) clearance and correspondence with FDA can be critical rebuttal evidence.

Prejudice resulting from such an uneven presentation of regulatory evidence can have profound impact on the jury; it can mean the difference between winning and losing a case.[29] Given FDA's own statements regarding the safety evaluation that is part of the 510(k) process, courts should not rely on inapposite precedent or an incomplete understanding of the process to deny defendants the ability to present their conduct in the relevant context.

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26 *See, e.g.,* Order in *Kransky v. DePuy Orthopaedics, Inc.* No. BC456086 (Cal. App. Ct. July 21, 2016); *Huskey v. Ethicon, Inc.,* 2015 WL 4944339, at *13-14; *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.,* 2015 WL 5145546, at *14–15; *In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.,* 2013 WL 4508339, at *2 .

27 *See, e.g., Lillebo v. Zimmer Inc.,* No. 03-2919, 2005 U.S. Dist. Lexis 2563, at *15 (permitting expert testimony regarding "the general nature of the approval and regulatory process, the FDA's general expectations with respect to testing and marketing of new products, Zimmer's actions in that respect, and [expert] opinion as to whether those actions were reasonable or appropriate"); *Block v. Woo Young Med. Co. Ltd.*, 937 F. Supp. 2d 1028, 1047 (D. Minn. 2013) (finding admissible testimony concerning "the general nature of the FDA's approval and regulatory process" and "the FDA's general expectations" regarding a 510(k)-cleared product).

28 *See, e.g., Musgrave,* 2011 WL 4620767 at *5 ("This Court's gatekeeper role is not intended to supplant the adversary system or the role of the jury; rather, vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.")(internal quotation marks omitted).

29 *See C.R. Bard v. Cisson,* 810 F.3d 913 (upholding exclusion of 510(k) evidence in pelvic mesh action resulting in verdict for plaintiff); Brief of Amicus Curiae Federation of Defense & Corporate Counsel in Support of Appellant C.R. Bard. Inc., No. 15-1102, 2015 WL 1814659, at *22 (4th Cir. 2015) (citing two DePuy hip implant cases, the first of which 510(k) evidence was excluded and resulted in a verdict for plaintiff (*Kransky v. DePuy,* BC456086 (Mar. 2013, Cal. Super. Ct., Los Angeles County), and the second of which 510(k) evidence was admitted, resulting in a defense verdict (*Strum v. DePuy,* 2011-L-009352 (Cir. Ct., Cook County, Ill.))).

APPENDIX

Survey of Case Law on Admissibility of 510(k) Evidence

A. Cases Excluding Admission of 510(k) Evidence

- ***In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig.,* 810 F.3d 913 (4th Cir. 2016).** The Court held that the District Court did not abuse its discretion in excluding 510k clearance as unduly prejudicial. *Id.* at 919. The Court agreed with the rationale "that bringing in such evidence would result in a 'mini-trial'" and that "having a 'mini-trial' could easily inflate the perceived importance of compliance and distract the jury from the central question before it-whether [the] design was unreasonable based upon any dangers it posed versus the costs required to avoid them." *Id.* at 921-22. The Court stated: "[w]hile 510(k) clearance might, at least tangentially, say something about the safety of the cleared product, it does not say very much that is specific." *Id.* at 922.

- **Order in *Kransky v. DePuy Orthopaedics, Inc.,* No. BC456086 (Cal. App. Ct. July 21, 2016).** The appellate court affirmed the trial court's exclusion of 510(k) evidence. The trial court held that clearance had little probative value on the issue of defect, and it would be confusing to the jury and unnecessarily confusing to explain the difference between 510(k) and approval. On appeal, the court found that Montana law does not regard regulatory compliance as being relevant to a strict liability claim, and agreed that the presentation of 510(k) evidence would have been "expansive, complicated, and time consuming." *Id.* at 10. It cited *Medtronic v. Lohr* for the notion that approval was a "rigorous" process while clearance "focused on equivalence, not safety." *Id.* at 11.

- ***In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.,* No. 11-md-02272, 2015 WL 5145546, at *14–15 (N.D. Ill. Aug. 21, 2015).** The court excluded expert testimony concerning the extent to which 510(k) clearance establishes a device's safety, stating that "[t]he regulations make plain that § 510(k) clearance does not constitute FDA approval of the device as safe and effective." *Id.* at *14 (citing 21 C.F.R. § 807.97). The court also held that even if expert testimony on the 510(k) clearance process would have probative value, which was "a matter not free from doubt" the court found it was "substantially outweighed" by the danger of misleading the jury, finding a "significant risk that jurors may be led to believe that 510(k) clearance…is equivalent to a finding of non-negligent design, which is an incorrect statement of law." *Id.* "In short, the FDA's finding of substantial equivalence, as a matter of law, is not a safety determination, and simply has too little probative value on the issue of whether the [device] was defective, and whether those defects injured [plaintiff]. And beyond the concern that the testimony may be more prejudicial than probative, it appears all but certain that the testimony would create 'undue delay' and create a trial within a trial." *Id.* at *15.

- ***Huskey v. Ethicon, Inc., et al.,* No. 2:12-cv-05201, 2015 WL 4944339, at *13-14 (S.D.W. Va. Aug. 19, 2015).** The court excluded 510(k) evidence, holding that it had

"no relevance" based on *Medtronic, Inc. v. Lohr*. In addition, the court found that any potential relevance was outweighed by the danger of unfair prejudice, in that "[j]urors are likely to believe that FDA enforcement relates to the validity of the plaintiffs' state law tort claims, which it does not. Furthermore, the jury may attach undue significance to an FDA determination, and [ ] alleged shortcomings in FDA procedures are not probative to a state law products liability claim." *Id.* at *14.

- ***Sanchez v. Bos. Sci. Corp.,* No. 2:12-cv-05762, 2015 WL 631289, at *2 (S.D.W. Va. Feb. 12, 2015)** (finding 510(k) evidence inadmissible "because of its potential to confuse the issues and mislead the jury").

- ***Lewis v. Johnson & Johnson,* 991 F. Supp. 2d 748, 754 (S.D.W. Va. 2014)** (holding, like in *Huskey*, that "evidence of FDA clearance and enforcement should be excluded as irrelevant under Federal Rule of Evidence 402 and misleading under Rule 403").

- ***In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.,* No. 2:10-md-02187, 2013 WL 3282926, at *2 (S.D.W. Va. June 27, 2013).** The court excluded 510(k) evidence "because of the danger of misleading the jury, confusing the issues, and unfair prejudice." The court was concerned that, "[g]iven the parties' filings throughout this case, it is abundantly clear that there would be a substantial mini-trial on the 510(k) process and enforcement should it be allowed. In short, this evidence poses a substantial risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims, and if such evidence comes in via expert testimony, the expert would effectively be offering a legal conclusion."

B. Cases Admitting 510(k) Evidence

- ***Block v. Woo Young Med. Co. Ltd.,* 937 F. Supp. 2d 1028, 1047 (D. Minn. 2013)** (finding admissible testimony concerning "the general nature of the FDA's approval and regulatory process" and "the FDA's general expectations" regarding a 510(k)-cleared product).

- ***Retractable Technologies, Inc. v. Becton,* No. 2:08-cv-16-LED-RSP, 2013 WL 11322723, at *2 (E.D. Tex. Aug. 29, 2013)** (admitting 510(k) evidence in case alleging violation of antitrust law and false advertising, stating: "Because the jury will be hearing extensive evidence about 510(k) clearance, there is no danger of undue prejudice from testimony concerning RTI's 510(k) process, and it is relevant to put in context the relationship between the 510(k) process and the safety of a given device.").

- ***Huggins v. Stryker Corp.,* No. 09-1250, 2013 U.S. Dist. Lexis 41260, at *43 (D. Minn. Mar. 25, 2013)**. Although the Court stated that "[s]ome courts have recognized that the simple denial of 510(k) clearance, without more, does not necessarily mean that a device is unsafe or that a manufacturer should know it poses certain risks,"

it stated that Plaintiff "does not rely solely on the fact that the FDA denied Stryker's 510(k) applications." *Id.* at 990. The Court noted that Plaintiff presented evidence "that the FDA reviewer told Stryker as part of the denial that the safety of pain pumps for use in the synovial space was not established" and "evidence regarding Stryker's alleged marketing of pain pumps for intra-articular use following these denials." *Id.*

- ***Strum v. DePuy Orthopaedics, Inc.,* No. 2011 L 009352, 2013 WL 3184765, at *1 (Ill. Cir. Ct. Mar. 8, 2013).** The court denied plaintiff's motion to exclude evidence that FDA gave 510(k) clearance to the DePuy ASR Orthopedic Hip Implant System without opinion. Plaintiffs filed a motion *in limine* to exclude evidence of 510(k) clearance, arguing that clearance was not relevant to device safety (citing *Lohr*), and that any probative value was outweighed by the potential that jurors would confuse 510(k) clearance with FDA approval of device safety. *See* Plaintiff's Motion *in Limine* to Exclude All References To The Food And Drug Administration ('FDA'), Including Evidence and Argument That The FDA Gave 510(k) Clearance To The DePuy ASR Orthopedic Hip Implant System., 2013 WL 3171926 (Ill. Cir. Ct. Feb. 4, 2013)).

- ***Musgrave v. Breg, Inc.,* No. 2:09-CV-01029, 2011 WL 4620767 (S.D. Ohio Oct. 3, 2011).** The Court held that the device manufacturer could introduce evidence that FDA cleared its pain pump device for intra-articular use. *Id*. at *3. The Court reasoned that such a prohibition would "preclude the jury from hearing all of the evidence." *Id.* The Court further reasoned that "[a]s Breg correctly points out, Plaintiffs may argue about what it means, but they cannot keep the jury from hearing the fact that the FDA cleared a general indication for use for the [pain pump], and that Breg understood that general clearance to include orthopedic and intra-articular uses. The Court concludes that the probative value of this evidence is not substantially outweighed by the danger of confusion of the issues or misleading the jury." *Id.*

- ***McClellan v. I-Flow Corp.,* No. 07-cv-01309, 2010 WL 3954092 (D. Or. Oct. 7, 2010).** The court admitted the entire 510(k) regulatory file, including the 510(k) application, FDA "Reviewer Memo" and Clearance Letter. The court noted that the FDA reviewer memo states: "The labeling for this device is adequate….It includes appropriate warnings, contraindications, and notes for the safe use of this device." *Id.* at *2. The Reviewer Memo did not constitute inadmissible hearsay because "the documents depict the FDA's activities in reviewing 510(k) applications and include factual findings resulting from [FDA's] review of I–Flow's 510(k) application, an investigation made pursuant to authority granted by law." *Id.* In addition, the court found the 510(k) evidence relevant to the indications for which the device was cleared and the presence of FDA's concerns for safety and efficacy. *Id.* at *4. Finally, the court rejected the unfair prejudice argument, stating that "[t]he fact that admission of the Memo may, depending on how it is viewed, prejudice the viability or credibility of I–Flow's position or witnesses is not the type of prejudice that warrants exclusion of the evidence. In sum, any prejudice that I–Flow may suffer does not substantially outweigh the probative value of this evidence." *Id.* at *6.

- ***Lillebo v. Zimmer Inc.,* No. 03-cv-02919, 2005 U.S. Dist. Lexis 2563, at *15 (D. Minn. Feb. 16, 2005).** The Court permitted expert testimony regarding "the general nature of the approval and regulatory process, the FDA's general expectations with respect to testing and marketing of new products, Zimmer's actions in that respect, and [expert] opinion as to whether those actions were reasonable or appropriate." *Id.*

- ***Corrigan v. Methodist Hosp.,* 874 F. Supp. 657 (E.D. Pa. 1995).** The court found that use of the device "could be relevant to an informed consent claim; therefore we do not exclude evidence as to their FDA regulatory status." *Id.* at 658. The Court also held that the admission of FDA regulatory status would not unfairly prejudice the Defendant under FRE 403. *Id.* The Court stated that "[i]n this case, one of the underlying issues . . . is whether the [device was] deemed experimental by the FDA. Evidence on this matter is, therefore, relevant and probative." *Id.*

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