

The FDA's 510(k) Approval Process in Medical-Device Litigation

By Troy Roberts – July 29, 2013

Any litigator knows evidence makes or breaks a case. One piece of admissible evidence may not determine a matter outright, but it may be that crucial nudge for a jury to tip the scales of justice for one side or the other. In medical-device trials, Food and Drug Administration (FDA) 510(k) regulatory approval may be that evidence. This dynamic was never more evident when two separate juries, one in March and one in April, determined whether or not DePuy's ASR XL metal hip implants caused injuries to the plaintiffs. At the conclusion of the March trial, the first in the ongoing ASR XL metal-hip litigation, a Los Angeles jury awarded the plaintiff an \$8.3 million verdict because the hip was defective and negligently manufactured. The next month, in Chicago, DePuy's second ASR XL hip trial resulted in a full defense verdict.

What made the difference? In Chicago, where the jurors found for the defense, the judge allowed evidence and testimony that DePuy fully complied with the FDA's 510(k) regulatory approval process. In Los Angeles, where the jurors found for the plaintiff, the judge did not. However, surely the respective cases did not hinge solely on the 510(k) evidence. Opposing sides presented weeks of evidence on many evidentiary issues, such as the plaintiffs' past medical history. But equally as sure, the 510(k) evidence (or lack thereof) played a role in determining the divergent outcomes. This article's purpose is to revisit the status of the FDA's 510(k) medical device approval process and to address related legal considerations.

The 510(k) Process

As early as 1906, Congress regulated medical devices. Initial regulations were not nearly as rigorous as we see today because medical devices in that era were relatively basic and safety was not a significant concern. Fast-forward to 1976. Medical devices had markedly evolved in their complexity and use. So had their potential harm to consumers. Applying consumer-protection policy at the time to medical devices, Congress passed into law more device-centric requirements. Created was our current three-tiered medical-device class system and the stringent premarket approval process (PMA). Based on market and social interests at the time, Congress also determined that certain medical devices could be eligible for "fast track" FDA approval, i.e., the 510(k) process.

The 510(k) process has developed significantly since 1976 due to similar transformative policy principles. Currently, according to the FDA's website, "a 510(k) is a premarketing submission made to the FDA to demonstrate that the [medical] device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval (PMA)." Under 510(k), a manufacturer's submission to the FDA may vary in scope and complexity, depending on the current status of the device, FDA consensus standards, and other

varying factors. Basically, a manufacturer designs and creates a medical device with the same intended use as a product already legally approved, and it then petitions the FDA for approval so that the manufacturer may introduce the new product to the general consumer. The manufacturer has to show that the product has the same technological aspects of the predicate device or that any new technological characteristics do not raise safety and effectiveness concerns.

The FDA generally has 90 days to review a manufacturer's 510(k) submission. However, the review process may exceed the 90-day time frame for varying reasons. Once the FDA approves a device, the manufacturer receives a decision letter, or order, approving the device for marketing in the United States. After approval, the FDA requires manufacturers to track certain medical devices once they enter the marketplace. Changes or modifications to an existing device require new FDA approval, usually through the 510(k) process.

Despite these proactive steps addressing consumer safety, the 510(k) process has been and continues to be a controversial consumer-safety policy. The battle lines in this respect have been clearly drawn.

Differing Opinions on the 510(k) Process and Their Effect

In 1996, the U.S. Supreme Court, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), weighed in on the FDA's PMA and 510(k) approval processes, albeit for preemption purposes. Pertinent here, the Court observed that the FDA spent on average about 20 hours evaluating each 510(k) submission, while for each PMA submission, which is generally required for the more potentially dangerous Class III medical devices, the FDA spent an average of 1,200 hours per PMA submission. The Court came to the obvious conclusion that PMA process was a much more rigorous safety test than 510(k) process. This conclusion forms part of the foundation on which the current 510(k) policy battle rages.

Opponents of 510(k) roundly criticize the 510(k) process's relative lack of FDA scrutiny compared with PMA or other potential approval processes. They argue that the 510(k) "substantially equivalent" test simply does not go far enough and, therefore, the 510(k) does not effectively safeguard consumers. For example, critics point to past instances where the FDA did not require distinct clinical trials or human testing for new 510(k) devices. To drive home their message, 510(k) opponents cite helpful statistical studies that address 510(k) Class I recall rates (recall classification for dangerous or defective products, a separate classification determination than that for types of devices). One exemplar study found that 71 percent of Class I recalls between 2005 and 2009 involved devices that had been approved through the 510(k) process. Other arguments are that the FDA does not have access to full information that the manufacturers possess and that the FDA is too understaffed to perform its mandate properly. And, of course, 510(k) opponents cite past blockbuster lawsuits relating to defective devices.

Meanwhile, 510(k) proponents maintain that the 510(k) process offers the proper balance between patient safety and consumer access. The medical devices eligible for 510(k) approval receive a proportional amount of scrutiny in relation to the dangers they pose. To support their position, 510(k) proponents also cite statistical studies. One study revealed that the 510(k) process has a 99.8 percent safety rate over a period of time similar to the one in the opponents'

studies—meaning that only 0.2 percent of 510(k) approved devices faced Class I recalls. They argue that this number and similar statistics depict the program’s success in weeding out unsafe devices while timely introducing in the market new and improved medical devices that save lives and improve consumer quality of life. In addition, the substantially equivalent standard is a logical demonstration of safety and effectiveness because the FDA has already vouched for the safety of the predicate devices. And, as noted above, the FDA *expressly* states the substantially equivalent standard addresses the issue of safety.

It is essential for practitioners to stay apprised of these policy arguments and the evolving nature of the policy itself to better prepare for the prosecution or defense of lawsuits. Furthermore, the differing points of view help set the stage for 510(k) evidentiary battles during medical device litigation. Whether it is a defendant presenting evidence to a jury that the FDA approved its product or a plaintiff presenting evidence of a particular device’s flawed 510(k) approval process, advantageous 510(k) evidence can be quite valuable.

510(k) Approval Process Considerations

Plaintiffs’ and defense attorneys must continually assess case-specific 510(k) evidence to determine its effectiveness for, or against, their client’s case. Whether the assessment is conducted prior to filing a complaint, during discovery, or prior to trial, practitioners must address 510(k) evidence and adapt their litigation strategy accordingly.

Medical-device defense attorneys by and large wish to present 510(k) compliance evidence before a jury. Such evidence shows that their clients played by the rules and worked hand in hand with a safety regulatory agency before selling their product on the open market. Ideally, defense counsel want a jury to equate the FDA’s 510(k) approval to society’s safety stamp of approval and find that the device manufacturer was a responsible member of society. Predictably, plaintiffs generally do not want 510(k) evidence presented to the jury. Like opponents of the process, plaintiffs’ attorneys argue the 510(k) substantially equivalent standard does not truly represent a viable safety standard, which, perhaps, the PMA standard does. They worry the jury may place considerable weight on the fact that the medical device passed “FDA safety standards,” albeit a less stringent standard.

To some degree, this dynamic played a role in DePuy’s trial victory in Chicago, where DePuy was permitted to present evidence that it complied with the 510(k) process. DePuy introduced testimony from a former FDA device compliance chief that DePuy thoroughly complied with the 510(k) process and that DePuy adhered to post-approval tracking requirements. It is not far-fetched to say that the lack of such evidence in Los Angeles made it much easier for the plaintiff’s counsel to depict DePuy as a corporation motivated more by profit than concern for consumer safety.

The two DePuy cases demonstrate that judicial 510(k) evidentiary determinations will vary. Practitioners must be cognizant of this and should closely evaluate each jurisdiction’s rules of evidence and case law to best structure their arguments for or against the admission of 510(k) approval. For example, a plaintiff should identify jurisdictional conditions and defendants in multiparty cases that would allow them to bring, or maintain, their case in a “friendly”

evidentiary venue, keeping in mind various removal techniques employed by defendants. Or a defendant may structure deposition examinations and discovery to better support their pretrial argument that 510(k) evidence should be allowed.

Practitioners must also evaluate 510(k) evidence specific to their case, such as the behavior or actions taken by a manufacturer during the 510(k) process. Evidence regarding the tone of a defendant's communications with the FDA, documents made available, willingness to comply, and other specifics during the submission review can have significant effects on a jury. For example, in April, a New York district court judge ruled the FDA could revoke the FDA 510(k) marketing clearance for ReGen's Menaflex knee implant despite having approved the device nearly two years earlier. The judge determined this particular manufacturer's 510(k) submission and approval had been so tainted by irregularities and political pressure that the FDA could legally rescind its approval. Imagine what would have happened if DePuy's ASR XL hip implant had gone through a similar approval process prior to its recall and subsequent litigation. Compensatory damages at the Los Angeles trial would have been the least of DePuy's worries. Instead, DePuy's cooperation with the FDA during the hip implant's approval process may have been the evidence that saved the day in Chicago.

If 510(k) evidence is allowed, there are tactical considerations. Take the voir dire process as an example. Parties might inquire into a potential juror's trust in the government to keep him or her safe or whether he or she could trust a manufacturer to present supporting documents regarding safety, design, or clinical trials to the FDA. The list of tactical considerations for practitioners goes on and on. The important point is that each practitioner must develop his or her own strategy tailored to a specific case and then tactically address 510(k) evidence.

Last, manufacturers can assist in their defense long before an alleged injury to a consumer. For instance, to make a 510(k) approval "safety" or "responsible" argument more powerful, device manufacturers could hire a neutral third party to steer their medical device through the 510(k) process. This approach could remove potentially damaging approval issues that a jury may attribute directly to the manufacturer. A jury may also consider the neutral party an additional layer of safety.

Conclusion

Manufacturers should consult with legal counsel to determine the most effective way to implement approval strategies for their devices, keeping in mind the risk of future lawsuits and the societal perceptions reflected in juries. Legal practitioners on both sides must keep a close eye on 510(k) legal matters because of the evolving consumer safety policy environment. Also, as shown in the ReGen Menaflex case, the legal landscape can radically shift in a single day. Preparation and knowledge are key; otherwise, a client may be on the wrong end of a jury decision.

Keywords: litigation, products liability, DePuy, medical devices, 510(k)

[Troy Roberts](#) is an associate at Snell & Wilmer L.L.P. in Phoenix, Arizona.