



California Court Finds FDA-Approved “Investigational Medical Device” Preempts State Product Liability Law

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The California Court of Appeal recently held that the Federal Medical Device Amendments Act (MDA) of 1976¹ preempts state product liability common law claims that challenge the safety or effectiveness of an investigational medical device previously approved for clinical testing by the FDA. The applicable MDA preemption provision prohibits states from applying device rules that are different from or in addition to MDA “safety and effectiveness” requirements.² In *Robinson v. Endovascular Technologies, Inc.*³ (“*Robinson*”) the Court applied federal preemption to an Endovascular Technologies Ancure Endograft System (“AES”) that had received investigational device exemption (“IDE”) approval by the FDA. This particular class III device is a polyester endovascular tube graft that is surgically attached by metal hooks around the arterial wall of the descending aorta to treat abdominal aortic aneurysms.⁴

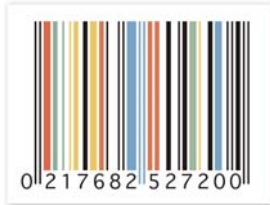
FDA Medical Devices Under the MDA

The MDA classifies medical devices as class I, class II or class III devices. Class III devices receive the greatest federal oversight, which can include FDA “premarket approval” for “safety and effectiveness.” Premarket approval requires full disclosure about the device’s safety and effectiveness, the identity of components and ingredients, the principles of operation, a description of the methods, facilities and controls for manufacture and installation and labeling. FDA premarket approval assesses all probable health benefits against any probable risks of injury or illness.

The 1976 MDA presents three options for a medical device manufacturer to seek FDA approval for human application. As noted, there is premarket approval for Class III devices. The MDA also “grandfathered” devices already on the market until the FDA could promulgate a regulation requiring premarket approval. Second, post-1976 devices can also seek approval under the section 510(k) “substantial equivalency” provision of the MDA. This permits a new device to avoid premarket approval if it is substantially equivalent to a pre-1976 device that was exempt from premarket approval. A third type of FDA approval for a Class III device is for clinical testing usage under an investigational device exemption. IDE applicants submit a plan for proposed clinical testing of the device with a report of all prior investigations, including data about the methods, facilities and controls used to manufacture, pack, store and install the device. The FDA determines whether the human risks are outweighed by the anticipated benefits and importance of the knowledge to be gained. Device manufacturers are required to report all investigational usage data so the FDA can evaluate progress, safety and effectiveness.

The Robinson Decision

Earlier cases have held that FDA premarket approval preempts legislatively enacted state statutes and regulations that are contrary to MDA safety or effectiveness provisions. The court in *Robinson* held that



FDA IDE approval preempts state product liability common law claims that are contrary to the safety and effectiveness provisions of the MDA.

In doing so, the court in *Robinson* relies on earlier decisions such as *Riegel v Medtronic, Inc.* (2008)⁵ in which the U.S. Supreme Court applied MDA preemption to a class III catheter device, allegedly designed contrary to state product liability common law. In *Riegel*, the catheter device had received FDA premarket approval. The Court in *Riegel* held that the MDA safety and effectiveness requirements for a catheter preempted state common law claims that invoked more stringent safety and effectiveness requirements. The Court noted that state product liability common law is subject to the preemption provisions of the MDA, because a jury could require a device to be safer but less effective, or less safe but more effective, than as approved by the FDA.

The *Robinson* plaintiff argued that an FDA IDE approved device should not preempt state law because IDE approval is akin to a section 510(k) substantial equivalence approval, which has been held not to preempt state law by the U.S. Supreme Court in *Medtronic, Inc., v. Lohr*.⁶ The court in *Robinson* rejected the plaintiff's position that FDA IDE approval lacks a specific finding of safety and effectiveness. The court noted that although the FDA cannot approve the safety and effectiveness of an experimental IDE device, the IDE process has rigorous procedures to determine if an experimental design is sufficiently safe and effective to proceed. IDE approval is not granted unless a device shows sufficient promise of eventually being proven safe and effective to justify usage before receiving premarket approval. The purpose of an IDE is to encourage the discovery and development of useful devices and to maintain optimum freedom for scientific investigators. The *Robinson* Court also explained why IDE approval should receive preemption status even though section 510(k) approvals do not. Once a section 510(k) approval determines that a post-1976 device is substantially equivalent to a pre-1976 device, this means only that the post-1976 device is no less safe and no less effective than the pre-1976 device. It does not assess the actual "safety or effectiveness" of the post-1976 device.

Conclusion

Under *Robinson*, both FDA premarket approval and the investigational device exemption approval of class III devices preempt state statutes, regulations or common law requirements that are contrary to the safety or effectiveness provisions of the MDA. The more easily attained MDA section 510(k) substantially equivalent approval will not preempt state statutory or common law that imposes safety or effectiveness requirements for medical devices.

Endnotes

- 1 21 U.S.C. § 360c et seq., to Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.)
- 2 MDA, § 360k(a).
- 3 190 Cal.App.4th 1490 (2010).
- 4 *Journal of Vascular Surgery* (2001) 33:S129-34.
- 5 552 U.S. 312.
- 6 518 U.S. 470.

For more information on the matters discussed in this *Locke Lord's QuickStudy*, please contact the author:

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