

# DOES RIEGEL V. MEDTRONIC, INC. AFFECT YOU?

March 28, 2008

Yes, probably more than you realize. On February 20, 2008, in *Riegel v. Medtronic, Inc.*, the U.S. Supreme Court found that common law tort claims challenging the safety and effectiveness of devices that require premarket approval (PA) under the Medical Device Amendments of 1976 (MDA) are preempted by federal law. This case does not apply to devices that are marked under a premarket notification, also known as a §510(k) devices.

After *Riegel v. Medtronic, Inc.*, §510(k) device manufacturers continue to be vulnerable to state law tort claims including, but not limited to, claims alleging strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, or sale of the devices.

In *Riegel v. Medtronic, Inc.*, the plaintiff brought state tort claims against the manufacturer, Medtronic, despite the fact that the medical device, a balloon catheter, was used incorrectly in a patient for which it was contraindicated (the catheter was not to be used for patients with diffuse or calcified stenoses, but Mr. Riegle's coronary artery was diffusely diseased and heavily calcified). Obviously, if the Supreme Court had ever reached the merits of the case, it may have been a "winner" for Medtronic. However, the Supreme Court first needed to address whether the plaintiff was barred from bringing the claims at all.

The MDA includes a pre-exemption clause that prohibits a state from establishing a "requirement" that is different from, or in addition to, a federal FDA requirement that relates to the safety or effectiveness of a device. The Supreme Court found both that (1) the PMA process established the requisite devicespecific federal FDA requirements and (2) the state tort claims were sufficiently related to impose different or additional legal requirements for the same device. The effect is that state tort law claims are pre-empted (i.e., barred) and only the federal FDA requirements remain. Therefore, while the full ramification of this Supreme Court case remains to be seen, it is now far less likely that devices that have received PMA approval from the FDA will be the subject of state tort law cases.

Device manufacturers need to be realistic, however, since Riegle's holding does not extend to 510(k) devices. In 2005, the FDA authorized the marketing of 3,148 devices under §510(k), but granted PMAs to only 32 devices. Since the bulk of

## Attorneys

Julia Hilliker

## Practices & Industries

Business Litigation

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devices marketed in the United States are §510(k) or §510(k)-exempt devices, medical device manufacturers should continue to actively prepare for and monitor the risks of state law tort claims. State law tort claims, although limited to a plaintiff's damages, can be very costly to medical device manufacturers. Companies should maintain a responsive complaint procedure that directly and smoothly link to an effective, well-documented corrective and preventive action process. Medical device manufacturers should carefully assess any responses to requests for documents and view the Medical Device Reporting (MDR) procedure as both an FDA requirement and a potential source of publicly available information for plaintiffs bringing tort claims.

If you would like further information on *Riegel v. Medtronic, Inc.*, your state tort claim risks, structuring a complaint to the FDA regulatory system, or evaluating whether your product should seek either a PMA or 510(k), please contact Bethany Gilbert or Julia Hilliker.