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## *Medical Devices*

### **FDA Says ReGen's Knee Device Should Not Have Been Cleared for Marketing**

**T**he Food and Drug Administration Oct. 14 said that an orthopedic medical device used to treat knee injuries should not have been cleared for marketing in 2008 and that the agency will begin the process of rescinding the clearance.

The Menaflex Collagen Scaffold device, manufactured by ReGen Biologics Inc., was cleared for marketing under FDA's 510(k) clearance process, under which most devices reach the U.S. market; the more stringent premarket approval (PMA) process is used for the highest-risk devices.

In a 2009 report, FDA found it did not follow established processes, procedures, and practices in its premarket review and 2008 marketing clearance of Menaflex. However, the agency said at the time the device would remain on the market (184 HCDR, 9/25/09).

FDA said the decision to rescind the clearance follows a re-evaluation of the scientific evidence that was undertaken after the release of the 2009 report. Before beginning the rescission process, however, FDA said it has asked the product's manufacturer to meet with the agency to discuss the appropriate marketing pathway for the device and what data it would need to provide a reasonable assurance of safety and effectiveness. The device will remain on the market until the agency rescinds its clearance, FDA said.

In a 510(k) clearance, the applicant seeks to market the device based on predicate devices already on the market. FDA said it had concluded that the Menaflex device "is intended to be used for different purposes and is technologically dissimilar" from predicate devices on the market. These differences can affect the safety and effectiveness of the Menaflex device, FDA said. For example, instead of simply repairing or reinforcing damaged tissue like predicate devices, Menaflex is intended to stimulate the growth of new tissue to replace tissue that was surgically removed. Because of these differences, the Menaflex device should not have been cleared, the agency said.

According to FDA, a rescission prohibits the manufacturer from further U.S. marketing until the agency approves or clears a new marketing application or grants a classification petition. After FDA issues a rescission notice, a manufacturer has the option of re-

questing a regulatory hearing with FDA or choosing to voluntarily withdraw its marketing clearance.

FDA said "the circumstances surrounding the Menaflex device are unique," and the agency's decision does not affect the status of other devices on the market.

**Company Response, Attorneys' Perspectives.** In an Oct. 14 statement, Gerald E. Bisbee, chairman and chief executive officer of ReGen, said that in light of FDA's action, "the company is currently weighing its options."

Bisbee said, "The product has been approved and in use successfully in Europe for nearly 10 years with approximately 3,000 patients and there has never been a safety issue associated with the device."

Commenting on the FDA action, Bethany Hills, an attorney with Hodgson Russ in Buffalo, told BNA that while the agency's decision was unique, "this sort of action is exactly the type of thing that the medical device industry fears."

Hills said the action taken against ReGen clearly indicates FDA's willingness to retroactively change its decisions without a clearly defined process for doing so. "Not only does the lack of a predictable process create uncertainty post-clearance, the general impact of this action on investor and innovator behavior is likely to be continued uncertainty and decreased risk tolerance on the front end of the innovation/investment process," Hills said.

Hills also said that industry should take note of the fact that while a specific proposal to institutionalize rescission procedures was proposed in the agency's recent 510(k) reform recommendations issued in August, the action against ReGen "is taken without implementation of those proposed reforms and indicates FDA's willingness to move forward with certain reforms immediately."

Attorney Michael Gaba, with Holland & Knight in Washington, told BNA it appears "that FDA concluded the manufacturer understated the capability of the [Menaflex] device to enable it to qualify for 510(k) clearance and perhaps avoid" the lengthy premarket approval process. Gaba said FDA already has rescission authority to respond to a misrepresentation by a device company.

Gaba predicted the agency will tell the company to go through PMA for the device to keep it on the market.

The working group that prepared FDA's August report recommended the agency's devices office should "consider issuing a regulation to define the scope,

grounds, and appropriate procedures, including notice and an opportunity for a hearing, for the exercise of its authority to fully or partially rescind a 510(k) clearance.” The agency recently closed a comment period on the 510(k) report’s recommendations.

FDA’s rescission proposal from August also came under fire from a bipartisan group of House Energy and Commerce Committee members, who in an Oct. 12 letter to FDA said five of the proposed changes to the

510(k) process, including rescission authority, could prove disruptive and should be considered controversial (197 HCDR, 10/14/10).

BY NATHANIEL WEIXEL

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*FDA’s announcement is at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm229384.htm>.*