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Walking Down the Innovation Pathway With the FDA

Medical Device Law Update

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In February 2011, the Food and Drug Administration (FDA) and its Center for Devices and Radiological Health (Center) announced the Medical Device Innovation Initiative (Innovation Initiative), which will allow companies to achieve regulatory approval of ground-breaking medical devices quicker than ever before. *See CDRH Innovation Initiative*, U.S. Food and Drug Administration, Center for Devices and Radiological Health (Feb. 2011), available at the FDA website.

The United States is currently the world leader in developing medical devices. Bringing a cutting-edge medical device to market, however, is a time-consuming process. Currently, the majority of medical devices are approved under one of two processes: the premarket approval (PMA) process or the 510(k) process. An applicant seeking approval through the PMA process must demonstrate to the FDA a "reasonable assurance that the device is both safe . . . [and] effective." 21 U.S.C. § 360e(d)(2)(A). Upon a demonstration that the device is safe and effective, the FDA issues an order that allows the manufacturer to market the device as approved. *See Davenport v. Medtronic*, 302 F.Supp.2d 419, 426 (E.D. Pa. 2004). However, a device that is determined by the FDA to be the substantial equivalent of a "predicate device" may be marketed under a "510(k) notification" without further clinical study or the premarket approval that is required by the PMA process. 21 U.S.C. § 355(b)(1)(F). *See also In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1998 WL 964498 at *1 (E.D. Pa. Nov. 3, 1998).

Regardless of whether a device is approved via the PMA or the 510(k) process, a large percentage of a medical device's life is occupied by the time it takes to achieve regulatory approval. The Innovation Initiative calls for establishing an "Innovation Pathway" that will encourage innovation, streamline regulatory and scientific device evaluation, and expedite the delivery of novel, important, safe and effective innovative medical devices to patients. The Innovation Pathway will expedite this

review and reduce the cost of development of devices that are "truly pioneering technologies and that have the potential to revolutionize patient care or health care delivery, by providing earlier investment of FDA time and resources in these devices."

To be eligible for consideration under the Innovation Pathway, the FDA must determine that the device is radically different from any legally marketed medical device in the United States in its underlying technology or manner of use. The device must also be designed to either (1) significantly improve upon currently available treatment or diagnostics for life-threatening or irreversibly debilitating diseases or conditions; (2) treat or diagnose a life-threatening or irreversibly debilitating disease or condition for which no approved or cleared alternative treatment or means of diagnosis exists; (3) address an unmet public health need as identified by the Council on Medical Device Innovation; or (4) address an issue relevant to national security. The sponsor of a medical device may apply for the device to be approved under the Innovation Pathway, or a Center employee may suggest that a device be approved under the Innovation Initiative.

Once deemed eligible, the sponsor's device will be under the control of a special panel—the Center Science Council—and assigned a case manager tasked with identifying key scientific and regulatory issues as early as possible. Additionally, the device will be paired with specific subject matter experts. The experts, along with the sponsor, panel and case manager, will work to develop a roadmap and timeline for device development. The objective is to minimize unnecessary delays during development and regulatory approval by identifying and addressing difficult, unresolved regulatory science questions and obtaining advice from external experts during the early stages of product development and regulatory approval. The Center proposes that once the device completes preclinical and clinical stages of development, the regulatory reviewers will have 150 days to complete their review, which is approximately half of the time taken to review most PMAs.

The Center is kicking off the Innovation Initiative by selecting a brain-controlled upper-extremity prosthetic developed by the Defense Advanced Research Projects Agency to serve as a pilot device. The prosthetic—which is designed to restore near-natural arm, hand and finger function to patients suffering from spinal cord injuries, strokes or upper-extremity amputation—uses a microchip

implanted on the surface of the brain to record neuronal activity and decode the signals to actuate motor neurons that control the prosthesis.

In addition to the Innovation Pathway, the FDA and the Center seek to encourage the development of innovative devices by streamlining its currently existing *de novo* Pathway, leveraging device experience and data collected outside of the United States, and enhancing its horizon scanning of new medical device technologies.

On March 15, 2011, the FDA hosted a public meeting seeking comments and questions regarding the Innovation Pathway. A transcript of the comments is available at http://www.regulations.gov/

The Innovation Initiative, and its development of the Innovation Pathway, demonstrates the FDA's commitment to bringing new and pioneering medical devices to market in a timely manner. The FDA acknowledges, however, that the Innovation Initiative will largely be constrained by the FDA's budget. Accordingly, it will be imperative that the Innovation Pathway is used efficiently and economically in the development of the pilot device, the brain-controlled upper-extremity prosthetic.

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