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Date: January 15, 2011
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Northwestern Investigators Launch 510(k) Survey

Study Aims to Shed Light on Opportunities for Improving FDA Product Review Process

Evanston, Ill.—A team of investigators from Northwestern and Stanford universities is undertaking systematic collection of input from individuals involved in the design and development of medical products regulated through FDA's premarket notification (510(k)) pathway to market clearance.

Individuals with recent experience of the 510(k) process are being sought to participate in the industrywide survey by visiting the study's website at www.510k.net.

The online survey is intended to produce a statistically valid foundation for improving the product review process and to guide the development of new policies that will benefit medtech investors, companies, and patients alike.

The survey is part of "A Comprehensive Analysis of the FDA 510(k) Process: Industry Practice and the Implications for Reform," a study funded by the Institute for Health Technology Studies (InHealth), a nonprofit foundation that supports research and analysis into the role of medical technology in advancing healthcare and patient quality of life.

Principal investigator John H. Linehan, PhD, professor of biomedical engineering at Northwestern University, will lead the study along with collaborator Jan B. Pietzsch, PhD, consulting associate professor of management science and engineering and an advisory faculty member of the Biodesign program at Stanford University, and president and CEO of Wing Tech Inc., a technology consultancy.

The roughly 90-question anonymous electronic survey is geared toward individuals and companies that have been involved in developing a 510(k) product in the past three years, including entrepreneurs, academic physician-inventors, product developers, and regulatory affairs experts. The survey takes approximately 45–60 minutes and must be completed by February 21, 2011.

In recent years, the 510(k) process has come under fire from many directions. Advocates of a more rigorous premarket review process say that current processes may permit unsafe devices to make their way onto market. Meanwhile, the device industry maintains that current processes are both unpredictable and slow, inhibiting patient access to medical technology.

"Our previous research has demonstrated that regulatory requirements affect more than half of the steps

associated with medical device development and commercialization, from early-concept selection to postmarket surveillance," says Linehan.

FDA acknowledges that problems with the current 510(k) process are complicated, but the agency's efforts to reform the process are straining the relationships between innovators and regulators.

Most of the complaints registered against the 510(k) process have been anecdotal and lacking supportive evidence, says Linehan. "Studying the effectiveness of the 510(k) regulatory process, through which more than 90% of devices receive clearance, is crucial to ensuring future innovation and benefits to patients."

In a recent webcast, "Industry, Agency, and the 510(k) Process: An Industrywide Survey," the investigators discussed the regulatory background and context for the study. Other webcast participants included Larry G. Kessler, ScD, professor and chair of health services at the University of Washington (formerly director of FDA's Office of Surveillance and Biometrics), and Paul LaViolette, MBA, venture partner with SV Life Sciences (formerly chief operating officer at Boston Scientific).

Additionally, InHealth sponsored a special panel session at OneMedForum San Francisco 2011 featuring investigators who have recently conducted studies of FDA's 510(k) process. Video segments from the session can be accessed by visiting the InHealth website at www.inhealth.org.

To learn more about the study and participate in the 510(k) survey, visit www.510k.net.