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CALIFORNIA HEALTHCARE INSTITUTE

510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device (FDA-2013-N-0430-0001)

June 11, 2013

The California Healthcare Institute (CHI) welcomes this opportunity to present our views to the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) regarding "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device."

Description of CHI

CHI represents the broad biomedical sector of the California economy and unites more than 275 of California's leading universities and private research institutes, venture capital firms and life sciences companies in support of biomedical science and biopharmaceutical and medical technology innovation.

California is home to nearly 1,200 medical technology firms, more than any other state in the nation. The 72,000 medical technology jobs in California represent almost 20 percent of the total U.S. medical technology workforce as well as the largest segment (47 percent) of the total 153,000 California life sciences jobs, including medical technology, biopharmaceuticals, and research, testing and medical labs. It is also, most significantly, the source of many of the medical technologies that improve patient and public health around the world such as in diagnosing and treating diabetes, cardiovascular disease, cancer, hearing and vision loss, pain management and numerous other diseases and conditions.

Why CHI has a Unique Perspective

CHI represents the entire continuum of medical technology innovation in California. This includes basic research undertaken in our state's universities and private research institutes, which is then spun-out to venture capital-backed start-up firms. In fact, the vast majority of the medical technology companies in California are such smaller, venture capital-backed firms with fewer than 50 employees. In 2012, California-based firms received $1.113 billion in medical technology VC investment, or 44 percent of the total $2.525 billion in total medical technology venture capital nationwide. These smaller entrepreneurial firms are then themselves often the source of new technologies or technology advancements for larger multinationals headquartered not only in California but across the nation.

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Importance of 510(k) to CHI Members

The 510(k) Premarket Notification process is the clearance mechanism by which the vast majority of CHI member company medical technologies are brought to market. It is a long-standing, proven mechanism that recognizes the oftentimes iterative and incremental nature of medical technology innovation and allows medical device developers to bring new products to market because they are substantially equivalent to existing, or predicate, devices that have already been shown to be safe and effective in actual clinical practice. In the last year alone, nearly 4,000 new devices were cleared under the 510(k) process, benefiting physicians and the patients in their care.

Determination of Need for Additional Information Regarding 510(k) Modifications

Similar to other organizations (e.g. AdvaMed), CHI notes several important factors related to device changes:

- The manufacturer is best qualified to determine whether or not a change "could significantly affect the safety or effectiveness" of a device;
- The incorporation of the language "could significantly affect the safety and effectiveness of a device" into the FDA's 1997 guidance document was intended to more specifically define the scope of changes required submitted to the Agency; and
- The Agency's 1996 Quality Systems Regulation (QSR) is intended to be an integral part of a manufacturer's change assessment evaluation in determining when a new 510(k) is required.

Recognizing this, CHI supports the view that the Agency's 1997 guidance document and 1996 QSR, with some certain modifications, should continue to be the appropriate foundation for determining when a premarket notification should be submitted for a modification or change to a legally marketed device.

In particular, CHI agrees with others (e.g. AdvaMed) that the following recommendations would address the requirement in Section 604 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) to clarify how to leverage existing quality system requirements to reduce premarket burden, facilitate continual device improvement, and provide reasonable assurance of safety and effectiveness of modified devices:

1. An explicit requirement in the guidance document that when a change is made to a specification, method, or procedure, each manufacturer should evaluate the change in accordance with an established procedure to determine if the submission of a premarket notification is required, and to require the retention of records of this evaluation and its results.

2. An explicit requirement in the guidance document for each manufacturer to establish a procedure within its quality system to ensure that after the design requirements are established and approved, changes to the design, both pre-production and post-production are also reviewed, validated (or verified where appropriate), and approved.
3. Explicit statements at every stage of the guidance document that the responses to each question in the decision trees must be made based on the results of validation testing (or verification testing, where applicable) undertaken in compliance with the requirements of 21 CFR 820. This would provide assurance to the Agency that the questions in the 1997 guidance document are not being arbitrarily answered; rather, that they are being addressed through an FDA-sanctioned process and documented accordingly.

Conclusion

CHI supports robust FDA and regulatory systems, including the 510(k) process, that provide innovative and safe and effective products to patients. We appreciate this opportunity to share our perspectives regarding improvements to the 510(k) device modifications process and look forward to future opportunities to engage with FDA on this issue.

Thank you for consideration of our views.