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IN THIS ISSUE

FDA Explains When to Submit a 510(k) For a Change to an Existing Device

FDA is shedding some light on when changes made to a cleared device necessitate a new 510(k) premarket notification.

The draft guidance issued Friday addresses the extent to which an existing 510(k) clearance covers labeling or product changes before a new notification is required. A companion document covers the same subject for software changes.

The guidance uses flowcharts with questions to simplify the process of determining whether a change mandates a new filing. There are six series of charts, each focusing on separate issues that manufacturers may face. These include:

- A main flowchart, with major changes that may be made to an existing device;
- Labeling changes;
- Technology, engineering, performance and materials changes made to a device and IVDs;
- Materials changes; and

(See **510(k)**, *Page 2)*

FDA: Request Small Business Status Before Submitting FY2017 Applications

Devicemakers seeking small business status for fiscal year 2017 should apply before submitting any product applications, a new FDA guidance advises.

Businesses with gross receipts or sales of $100 million or less for the most recent tax year qualify for a "significant reduction" in user fees, the FDA said. Those with $30 million or less qualify for a one-time waiver of the fee for their first-ever PMA application, BLA application, product development protocol or premarket report.

For fiscal 2017, the Premarket Application (PMA, BLA, PDP) fee for standard businesses is $234,495 while small businesses pay $58,624. The establishment registration fee remains the same for both small businesses and standard businesses (*IDDM*, Aug. 1).

(See **Small Business**, *Page 4)*

510(k), *from Page 1*

- Considerations for risk assessments of modified devices.

FDA regulations and federal law require manufacturers to submit a new 510(k) whenever a device will be "significantly changed or modified in design, components, method of manufacture or intended use," states the guidance. Significant changes that require premarket notification include, changes that affect the safety or effectiveness of the device and modifications in the intended use of the device.

The agency recommends that devicemakers consider the risk presented by the modification when determining if they should submit a new 510(k). Updates to the guidance include:

- Guiding principles, including recommendations for manufacturers to conduct a risk-based assessment in order to determine whether a modification could significantly affect the safety or effectiveness of the device.
- Updated sections and flow charts to provide more clarity to manufacturers on when they likely are required to submit a new 510(k) for labeling, materials, technology, engineering and performance changes.
- Examples of specific device changes that likely require a new 510(k) and ones that likely do not in order to help guide manufacturers during their own decision-making on whether to submit a new premarket notification.

The agency asks companies to weigh not only the change itself, but the intent of that change, when deciding whether to refile a 510(k). For example, if a manufacturer modifies a device with the intent to significantly improve its safety or effectiveness, "a new 510(k) is likely required." Changes that are not intended to significantly affect the safety or effectiveness of a device, however, should still be evaluated to determine whether it could impact the device's performance.

The draft guidances generally follow the same structure as earlier versions, but provide updates to ensure that devices with significant modifications are not being sold or distributed without FDA review. On the software side of things, the document addresses changes such as:

- Updates to software made due to a continually changing environment;
- Updates to correct faults; and
- Modifications made to improve performance or maintain performance.

Additionally, design changes classified as software modifications under the quality system regulation include: fixes to bugs, hot patches, software changes or tweaks.

"Medical device technology evolves quickly, and not all changes made to marketed devices alter their safety profile or require our review," stated CDRH Director Jeffrey Shuren.

Both documents emphasized that their recommendations do not apply to combination products, but devices only.

The guidance on 510(k) submission for an existing device can be found here: www.fdanews.com/08-05-16-510kExistingDevice.pdf. The complimentary guidance on software updates can be found here: www.fdanews.com/08-05-16-510kSoftware.pdf. —– Joya Patel

GSK, Verily Establish Bioelectronics Joint Venture

GlaxoSmithKline and Verily Life Sciences have formed a joint venture in the device space called Galvani Bioelectronics.

The companies plan to research, develop and commercialize bioelectronic medicines by harnessing electrical signals in the body to treat chronic diseases. GSK will hold a 55 percent equity interest in the new joint venture, and Verily will hold 45 percent.

Bioelectronic medicine aims to tackle chronic diseases using miniaturized, implantable devices that can modify electrical signals that pass along nerves in the body.

Initial work will center on inflammatory, metabolic and endocrine disorders, including type 2 diabetes.

Guidance Seeks to Harmonize IEC, FDA Standards for X-Ray Devices

The FDA is attempting to harmonize performance standards with International Electrotechnical Commission standards for certain x-ray imaging devices.

The agency hopes to streamline the review process by providing recommendations on how devicemakers may meet FDA standards by conforming to IEC standards.

The agency said in draft guidance released Aug. 3 that it believes conformance to certain IEC standards would provide the same level of or improved protection from electronic radiation as Electronic Product Radiation Control (EPRC) regulatory standards.

Conformance to IEC standards would also be sufficient to meet 510(k) requirements for certain devices.

Industry had expressed concern about overlapping requirements that are submitted to the FDA and EPRC for products that are both devices and electronic products. The agency addressed this overlap with guidance on ultrasound devices, laser products and computed tomography dose index devices in previous guidance.

The newly released guidance addresses diagnostic x-ray imaging systems and their major components. These devices are generally classified as Class I or II devices.

The guidance lists specific products for which conformance to IEC standards would be sufficient to meet 510(k) premarket notification requirements. Those devices include diagnostic x-ray beam limiting devices, spot-film devices and radiographic film and cassette changers.

Although a declaration of conformity to recognized conformance standards could suffice to sidestep 510(k) submissions, the FDA would still need to review the test data addressed by the standards.

Device manufacturers would submit a declaration of conformity that is based on a GMP compliant testing program, the FDA said, and the manufacturer's quality system should address radiation safety and conformity to standards through design controls. Testing results should be documented and placed in the firm's records.

The agency said that the policy described in the draft guidance would not apply if "FDA finds that a manufacturer's testing program does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic parts comply with the appropriate standards."

By declaring conformance with IEC standards, devicemakers are asserting that they have established design specifications that relate to radiation emission, the guidance said. The guidance does not change the FDA's policy toward enforcing correction of defects, the guidance said.

Comments on the draft guidance are due Nov. 1. Read the guidance here: www.fdanews.com/08-03-16-Xrayguidance.pdf. — Tamra Sami

FDA Seeks Consumer Advocates To Serve on Device Panels

The FDA is asking consumer organizations to nominate representatives to serve on FDA device advisory panels.

The agency said it wants to include the views of the broader population, and is encouraging consumer organizations to help select representatives to serve on its Ear, Nose and Throat Devices Panel; the Medical Imaging Advisory Committee; and the National Mammography Quality Assurance Advisory Committee.

Consumer representatives should demonstrate ties to consumer and community-based organizations, and be able to analyze technical data and to discuss the benefits and risks. The representative should be able to represent the consumer perspective on issues and actions before the advisory committee and to serve as a liaison between the committee and interested consumer association.

Read the FDA notice here: www.fdanews.com/08-05-16-FDArequest.pdf. — Tamra Sami

Small Business, *from Page 1*

Requests for small business status for fiscal 2017 must be submitted by Sept. 30. If the status is granted, it will expire Sept. 30, 2017. Devicemakers should submit a new MDUFA Small Business Qualification and Certification each year to qualify as a small business, the guidance advises.

For both U.S.-based and foreign applicants, the FDA will review the application and supporting documents within 60 days. If a business qualifies, the FDA's decision letter will assign a Small Business Decision number that should be provided anytime a discount or waiver is sought.

U.S. businesses applying for small business status should submit:

- A completed Form FDA 3602 for FY 2017;
- A copy of their original federal income tax return for the most recent tax year;
- A separate federal income tax return for each U.S. affiliate; and
- A certified Section III of Form 3602A for each foreign affiliate.

Foreign businesses should take several steps in the following order:

- Complete Sections I and II of Form FDA 3602A for FY 2017;
- Submit Form FDA 3602A for FY 2017 to their national taxing authority, which completes Section III of that form;
- Receive the updated form back from the national taxing authority; and
- Submit the completed Form FDA 3602A to the FDA.

Companies with foreign affiliates should submit a separate certified Section III of Form FDA 3602A for each foreign affiliate. If the company has U.S. affiliates, it should send a U.S. federal income tax return for each of them.

The guidance is available at www.fdanews.com/08-04-16-smallbusiness.pdf. — April Hollis

Winning Device EU Marketing Approval
Seven Steps to Writing Clinical Evaluation Reports

An FDANEWS Publication

If you want to market your device in Europe, you need to provide clinical evidence that the product is safe and effective. But if your development phase didn't include clinical trials, how can you make that argument?

EU regulations require devicemakers to submit a clinical evaluation report (CER) that presents data culled from development of approved devices similar to theirs and explains how the findings apply to their own product.

It's a tall order and a lengthy process, but a well-crafted CER can pay off in a marketing authorization certificate.

This FDAnews Brief walks you through the process of developing and writing a CER with a 7-point model that ensures you cover all the bases and have the greatest chance of success.

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UK Issues Safety Alerts For Infant Warmers, Ventilators

The UK's Medicines and Healthcare products Regulatory Agency issued safety warnings on two pediatric products manufactured by Germany's Dragerwerk AG & Co.

A risk of a heating element overheating and releasing hot particles that could result in fire triggered the MHRA to issue warnings on Dragerwerk's Babytherm infant warmer.

The agency alerted healthcare professionals that the infant warmer poses a fire risk in skin-temperature mode. The action affects the Babytherm 8004/8010 infant warmer. Healthcare professionals were advised to use the manual mode rather than the skin-temperature mode to avoid risk.

The agency also issued safety alerts for a Draeger Medical pediatric ventilator due to a risk of rebreathing exhaled gases.

The alert affects the VentStar Oxylog3000F (P) 190 disposable pediatric ventilation circuit. Healthcare professionals were advised to return ventilation circuits manufactured up to and including March 2016, because they may leak at the check valve.

Read the safety alerts here: www.fdanews.com/08-04-16-ventilatoralert.pdf. — Tamra Sami

FDA Launches Pilot Program to Streamline Combination Product Work

The FDA hopes to improve the review process for combination products with a pilot program that will address institutional drawbacks to developing combination products.

The newly unveiled pilot effort will start in select offices within CDER, CBER and CDRH before gradually spreading to all offices within the three centers sometime next spring.

This program, dubbed the intercenter consult request process, addresses policy and review problems associated with approving a product that falls under multiple regulatory categories, such as a drug-device combination. In the past, the agency noted issues with the timeliness of reviews for combination products.

Under the program, the agency is adopting a tiered consultation approach to speed interactions across centers involved in the oversight of these products. Through this approach, the agency intends to connect drugmakers with the appropriate experts for consultations.

The pilot program also establishes timelines for centers and submissions related to the identification of combination products and completion of consultations. In addition to a timeline, the agency is spelling out the roles and responsibilities for each of the participating centers when reviewing combination product submissions.

The agency will track these consultations through a single system electronically that provides detailed information on the combination product. The goal is to ensure reviewers always have access to the latest information. — José Vasquez

TGA Updates Instructions For Use for ADVIA Centaur Assays

Australia's Therapeutic Goods Association is updating Siemens Healthcare Diagnostics' Instructions for Use statement for its prostate-specific antigen assays used with ADVIA Centaur systems.

The update will clarify the utility of the PSA assay, the TGA said, noting that the ADVIA Centaur/XP/XPT PSA assay is intended to be used as an aid in detecting prostate cancer and in monitoring and managing prostate cancer patients.

The agency was advised that PSA measurements at values <0.2 ng/mL are being used to monitor some patients for biochemical recurrence of prostate cancer post-radical prostatectomy. The PSA assay should not be used to predict disease recurrence solely based on serial PSA values, the agency advised.

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TriMed Warned on MDRs, CAPAs, After Device Issue Leads to Surgery

TriMed, a maker of implantable bone fixation systems, failed to report a device failure that required surgery to remove the device, according to an FDA warning letter.

In February 2014, the company learned about the breakage of an implanted fixation plate, which was associated with the need for surgery, according to the June 30 letter. But the Santa Clarita, Calif., company had not submitted an MDR for the event at the time of the FDA's March 2016 inspection.

Posted on the FDA's website Aug. 2, the warning letter cites two other complaints that linked the company's osteotomy device and pin plate with a malfunction.

It notes that a malfunction of long-term implantable devices is reportable. However, TriMed did not submit MDR reports within 30 days of receiving or becoming aware of the events.

No Evidence

Additionally, the FDA saw "no evidence to justify whether the malfunctions would not be likely to cause or contribute to a death or serious injury, if they were to recur."

The company's MDR procedure did not set up systems for timely and effective identification, communication and evaluation of events that might fall under MDR requirements.

Further, TriMed's nonconforming product procedure did not require non-conformances to be evaluated to see if an investigation was needed, and it did not require the company to document any investigations that were conducted.

CAPA procedures also drew the FDA's attention during the inspection.

In September 2015, TriMed initiated a CAPA referencing non-locking semi-tubular screw plate screws that were passing through the hole of the semi-tubular bone plates, allowing the screws to pass through the plates. It received plates from the field during that month but did not submit a written report of the removal to the FDA, the letter says.

TriMed's CAPA procedures did not include a requirement to analyze sources of quality data, including complaints documented in the error log, non-conformances documented in the material review board log and returned products documented in the returned goods authorization log.

Missing Documentation

In addition, one CAPA was initiated in September 2015 to address complaints of non-locking screws that were passing through the hole of the plate.

The CAPA appeared to have been implemented in early October 2015 and deemed effective in February 2016; however, there was no documentation to show the corrective action — revising the dimension of the screw hole — was effective.

The corrective action plan notes that other bone plates using the same threaded screw hole could have the same issue, but the CAPA does not list the affected products or provide documentation that effective corrective actions were taken for all products affected. Meanwhile, TriMed did not document the failure mode of non-locking screws passing through the hole of bone plates during surgeries in its risk analysis for the Supracondylar Elbow Implant System.

The warning letter also notes that some finished products shipped to a customer did not include records showing completion of certain activities required in the device master record for the Wrist Fixation System, Radiocarpal Fusion System and Ulnar Osteotomy System.

TriMed told *IDDM* that the company has taken all the necessary actions and submitted the required documentation within the FDA's deadline.

The warning letter is available at www.fdanews.com/08-03-16-TriMed.pdf. — April Hollis

Japan's Mitaka Kohki Lands 483 for Numerous Quality System Failures

Japan's Mitaka Kohki failed to establish design control procedures, CAPA procedures, equipment calibration procedures, and documentation was found lacking for numerous critical processes during an inspection of the Tokyo-based facility.

The plant produces high-resolution microscopes used in surgery, and the firm had not established procedures for design control for its Point Setter models that were cleared under 510(k) notifications.

The firm had not established quality data sources to be analyzed to detect recurring quality problems, and no data analysis had been performed. No corrective and preventive actions had been initiated despite numerous complaints of movement of the Mitaka arm during surgery.

Moreover, procedures for receiving, reviewing and evaluating complaints by a formally designated unit had not been adequately established. For example, the firm failed to document two complaints from hospitals that the point setters didn't have holding power, which resulted in a recall of the Mitaka Point Setters in April 2009.

The agency also found fault with the firm's purchasing controls and device history records and procedures. The 483 noted that the device history record didn't demonstrate that the device was manufactured in accordance with the device master record and 21 CFR 820.

The firm did not respond to a request for comment. Read the Form 483 here: www.fdanews.com/08-05-16-Mitaka483.pdf. — Tamra Sami

Process Validation, MDR Lacking at Biotronik's Berlin Facility, 483 Says

The FDA found process validation, medical device reporting and other quality system failures at Biotronik's Berlin facility during a recent inspection.

The six-item 483 said that the firm didn't validate its hydrophilic coating process used to manufacture the Selectra catheter lead introducer system used to facilitate lead implantation in the heart.

"Your firm's validation process is inadequate in that it failed to demonstrate consistency of the coating process because it only included one device, and did not include the testing of coating integrity, coating adhesion or thickness, and failed to conduct the effects of upper and lower limits of parameters such as cycle time," the 483 said.

Biotronik did not submit medical device reports within the required 30 days of becoming aware that a device had malfunctioned and could contribute to a death or serious injury, the agency said. It noted at least four examples that involved delamination of the Teflon coating during a procedure, and none of the events were reported.

Suppliers were also not property vetted and evaluated, the agency said, noting that the firm's Select Supplier procedure requires evaluation prior to becoming an approved supplier, but the firm didn't document evaluations of its component suppliers.

The 483 noted three suppliers that had been used since 2009 but there was no documentation indicating they had been evaluated.

The FDA also cited the firm for not establishing adequate design input procedures. For example, the firm had not adequately defined design input for adhesion/durability and thickness of the hydrophilic coating on the Selectra catheters, the inspector said.

The agency also found fault with the facility's sampling plans, and said that a statistical rationale was not provided to justify the sampling method for inspections of incoming raw materials.

The firm did not respond to a request for comment by deadline. Read the Form 483 here: www.fdanews.com/08-05-16-Biotronik483.pdf. — Tamra Sami

BRIEFS

Gore's Tigris Vascular Stent Approved

Gore has received premarket approval from the FDA for its Tigris vascular stent.

The device features a combination of flexible fluoropolymer and single-wire nitinol and is designed to adapt to the natural movement of the knee. Study data on the product showed a 0 percent rate of fractures versus 27 percent on the control arm.

Alcon's Cypass System Approved

The FDA approved Alcon Laboratories' CyPass System – a tiny stent implanted into the eye to drain fluid in patients with glaucoma.

The CyPass System consists of a micro stent that is pre-loaded into a stent-delivery tool. The stent is designed to control intraocular pressure (IOP) by creating a drainage pathway from the anterior chamber to the outermost layer of the eye.

Clinical trials in 374 patients implanted with the device saw 72.5 percent achieve IOP compared to 58 percent who received cataract surgery alone.

510(k) Clearance for Hydrocodone Assay

The FDA granted 510(k) clearance for Thermo Fisher Scientific's immunoassay for detecting hydrocodone.

The DRI Hydrocodone Assay is a homogeneous enzyme immunoassay featuring requisite sensitivities that meet the newly proposed Substance Abuse and Mental Health Administration guidelines using a 300 ng/mL cut-off.

The DRI Hydrocodone Assay is reactive to the major metabolites hydromorphone and hydromorphone-glucuronide and uses liquid, ready-to-use reagents, which can be run in both qualitative and semi-quantitative modes.

Boston Scientific Recalls Lotus Valves

Boston Scientific has issued a recall for Lotus valve devices with issues with release mandrel breakage.

The release mandrel is a delivery system component connected to the release pin.

The company said it has received numerous reports of catastrophic vessel trauma associated with damaged versions, including three reported patient deaths.

BTG's DC Beads Now Class III Devices

DC Bead and DC Bead M1 have been reclassified as Class III medical devices.

These devices are embolic drug-eluting beads capable of loading and releasing compatible chemotherapeutic agents.

These drug administrators are the only drug-eluting beads with CE Mark approval for filling with doxorubicin and irinotecan.

FDA Grants Market Clearance for Permaseal

Micro Interventional Devices received FDA clearance for the company's first product, a transapical access and closure device.

The Permaseal device allows surgeons to access and close the left-ventricle without suturing the myocardium.

Clinical trials indicated that the device shortened operating time and hospitalization.

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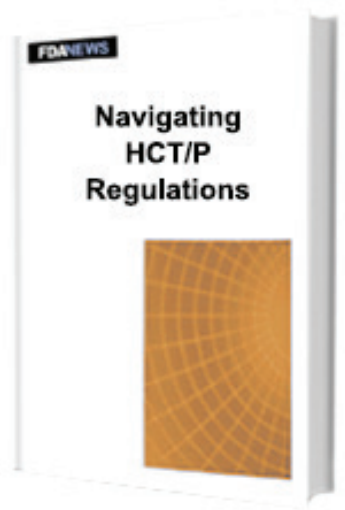

Navigating HCT/P Regulations: *Risks and Opportunities for Drug and Device Manufacturers*

The regenerative medicine industry is rapidly growing and, with major court decisions, new and significant FDA guidance, and government enforcement actions, the regulatory landscape is more complex than ever.

With this management report, you will learn what uses of human cells and tissue are regulated and when the FDA requires an HCT/P to go through the marketing approval process including:

- The three criteria the FDA uses to determine whether an HCT/P falls under its jurisdiction.
- The four draft guidances in which the agency establishes its regulatory policy.
- Two court cases that have helped shape regulation of regenerative medicine.
- The distinction between two classes of HCT/Ps and which one is quickest to market.
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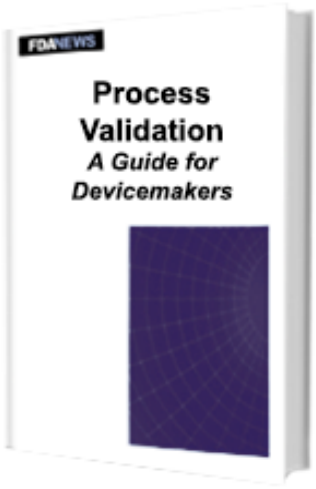

Process Validation
A Guide for Devicemakers

When must a process be validated? That is the first crucial question devicemakers must answer. But with no clear guidance from the CDRH, finding the answer can be difficult.

The new FDAnews management report — **Process Validation: *A Guide for Devicemakers*** provides you with the answers. This report will walk you through each point in the decision-making process, including how to determine if a product can be "fully verified," and how FDA inspectors define that term.

In it, you'll also find a valuable in-depth overview of all of the currently applicable regulatory guidelines that have an impact on process validation for devices, including those from three key sources: the FDA, the International Organization for Standardization (ISO) and the Global Harmonization Task Force (GHTF).

Process Validation: *A Guide for Devicemakers* teaches the proper application of the regulatory requirements that lead to successful process validation, and also offers advice on the practical issues confronting validation compliance by using real-life anecdotes and scenarios.

You also get invaluable extras, such as checklists for IQ, OQ and PQ — and hundreds of pages of appendices, including the invaluable *Medical Device Quality Systems Manual: A Small Entity Compliance Guide*, which is no longer available from the FDA.

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