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IN THIS ISSUE

CDRH Updates Guidance on Refuse-To-Accept Policies for 510(k)s, PMAs

The CDRH clarified its policy on the criteria it intends to use in assessing whether a 510(k) or premarket approval submission will be accepted for review.

The agency's current Refuse to Accept policies for 510(k)s and PMAs include an early review against specific acceptance criteria with the goal of informing the applicant within 15 days if submissions are deemed complete and, if not, to identify the missing elements in the submissions, according to final guidances that supersede guidances the agency issued on Jan. 30, 2018.

Both the guidance includes checklists and clarify the necessary elements that devicemakers should include in a complete 510(k) and PMA submission.

The process is applicable to all devices reviewed through the 510(k) notification process, the FDA said, including its new abbreviated 510(k)

(See **CDRH**, *Page 2)*

Australia Issues Draft Guidance On Regulatory Scheme for Personalized Devices

Australia's Therapeutic Goods Administration is seeking feedback from devicemakers on how personalized devices should be regulated.

The guidance defines personalized medical devices as those devices that are manufactured for a particular patient, including 3D-printed devices. These devices are currently covered under the custom-made medical device definition.

In a November 2017 consultation paper, the TGA noted the increasing use of 3D printing for medical applications was raising concerns about the adequacy of the current regulatory framework to mitigate risks to patients and to meet requirements for health care providers and manufacturers.

Stakeholders said the TGA needed to improve the existing regulations for custom-made device regulations because they are too broad (*IDDM*, June 4, 2018).

(See **Guidance**, *Page 6)*

CDRH, *from Page 1*

review process, which was renamed the Safety and Performance Based Pathway.

The 510(k) refuse to accept (RTA) policy is separated into two stages, quantity vs. quality. The first stage, acceptance review, allows the FDA's review staff to determine whether the submission is complete before conducting a substantive review in which the actual quality of the data is assessed.

Past guidances on the policy focused on defining broad issues or principles, and the checklists "dealt largely with administrative elements but did not address specific content that is essential for 510(k) review," which in turn led to an "inefficient use of resources and frequently lengthened review times," the agency said.

An initial review of completeness enables early interactions as the submitters can be informed of missing elements in a 510(k) deemed incomplete within 15 days after the agency receives the submission.

The checklist in the final guidance includes new statements of compliance for clinical investigations to include updated rules for good clinical practice (GCP) device compliance that became effective Feb. 21.

For example, for each clinical trial conducted in the U.S., the submission should include a statement of GCP compliance or a brief statement of the reason for noncompliance.

Similarly, for each trial conducted outside the U.S., the submission should either include a statement that the investigations were conducted in accordance with GCP requirements or a waiver request. Alternatively, the submission would include a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected.

The new checklist also includes statements on whether the device uses FDA-recognized voluntary consensus standards or non-FDA recognized consensus standards.

Like the 510(k) guidance, the updated PMA guidance includes new sections that include statements of GCP compliance for clinical investigations. It also adds a section on whether the device uses FDA-recognized voluntary consensus standards or non-FDA recognized consensus standards. Otherwise, the guidance is the same as earlier guidance issued in January 2018.

The FDA has been revamping its 510(k) program over the last year. It recently issued guidance on an expanded abbreviated 510(k) clearance program that would allow companies to show a new product's substantial equivalence to an existing device using performance criteria rather than directly comparing the device's performance to a predicate device.

The agency said the new pathway should be less burdensome than the longstanding abbreviated 510(k) route to market. The new pathway provides increased certainty regarding the likelihood of clearance for qualifying devices that should mean a shorter time to 510(k) clearance (*IDDM*, Feb. 1).

Read the final 510(k) guidance here: www.fdanews.com/02-28-19-510kguidance.pdf.

Read the final PMA guidance here: www.fdanews.com/02-28-19-PMAguidance.pdf.

Massachusetts Devicemaker Hit for Discrepancy Investigation Reports

The FDA cited Acorda Therapeutics' Chelsea, Massachusetts manufacturing facility for its handling of discrepancy investigations observed during a June 4-18, 2018 inspection.

The agency found that the firm's quality unit had multiple discrepancy investigations from 2016 to 2018 that exceeded their one-month closure target dates, including seven relating to environmental monitoring, a facility investigation and a deviation and calibration out of tolerance discrepancy.

Additionally, the firm didn't request extensions for six of seven marketed product complaint investigations during the same time period that went over their 30-business day closure target dates.

The firm's SOP for internal quality system audits was also not up to par, as it didn't reuire that audits would be conducted by individuals who had no direct responsibility for the activities being audited.

Read the Acorda Therapeutics Form 483 here: www.fdanews.com/02-25-19-acordatherapeuticsinc483.pdf. — James Miessler

FDA Warns Total Thermal Imaging For Unapproved Screening Device

The FDA warned La Mesa, California-based devicemaker Total Thermal Imaging for marketing an unapproved device for breast cancer screening.

The agency rapped the company for marketing its Thermography Business Package as a sole screening device for breast cancer and other diseases. The company's website and brochures claimed the product is intended for early detection and diagnosis of diseases including breast cancer, heart disease, deep pain thrombosis and reflex sympathetic dystrophy/complex regional pain syndrome.

The firm lacked the required premarket approval to sell such devices and it had not notified the FDA of its intent to distribute it, the agency said.

The infrared camera included in the package was cleared for a certain intended use, but the clearance of a component does not permit the marketing of the entire package, the agency said.

"The FDA is concerned that patients will rely on unapproved claims that thermography may be used as a sole screening device for breast cancer and not get screened with mammography, which is proven to save lives by detecting cancer and prompting patients to seek appropriate treatment," said FDA Commissioner Scott Gottlieb.

The warning letter also faulted the company for lacking design control procedures or procedures to ensure all purchased or received products conform to specified requirements.

Read the Total Thermal Imaging warning letter here: www.fdanews.com/02-28-19-TotalThermalImaging.pdf. — Zack Budryk

Sarstedt Called Out For Inadequate Documentation

The FDA rapped Newton, North Carolina devicemaker Sarstedt after a June 28 to July 2, 2018 inspection revealed deficiencies in its document change and labeling procedures.

The company's device master record change approval forms for box art updates to the S-Monovette, a blood collection system, failed to list revisions or a control number for various updates. The agency said that the firm's management couldn't show that the currently used version is the approved document.

The inspection report form for the Monovette's labeling machine was not reviewed and cleared by quality control before being issued. In addition, the agency found the facility didn't ensure that all labels and labeling used for each production batch were documented in the device history record.

The firm also failed to properly investigate a complaint regarding an out-of-tolerance scale used for batch production. The facility also failed to identify all lots that may have been impacted by the scale.

Read the Sarstedt Form 483 here: www.fdanews.com/02-25-19-sarstedtinc483.pdf. — James Miessler

MITA Urges FDA to Clarify Servicing And Remanufacturing Differences

The Medical Imaging & Technology Alliance is calling on the FDA to establish a framework that distinguishes between servicing and remanufacturing activities for medical imaging devices.

Currently, as defined by the FDA, third-party medical device servicers are not required to have controls in place to determine if their servicing activities constitute remanufacturing.

The agency does regulate the remanufacturing of medical devices, but it does not regulate servicing activities and has few safeguards in place to ensure that servicing activities do not cross over into uncontrolled and unregulated remanufacturing.

This lack of oversight poses an increased risk to public health and thus the safety of patients and device users, MITA said.

Servicing and Remanufacturing White Paper

The alliance lists detailed descriptions of the types of activities that would constitute servicing and remanufacturing in a new white paper, which recommends that organizations adopt appropriate quality management systems to ensure servicing and remanufacturing activities are properly performed, documented and regulated.

"It is important that a sound process and clear definitions are in place to ensure that servicing activities are clearly distinguished from remanufacturing and all stakeholders understand the differences," MITA said.

Medical device "servicing" should be defined as preventative maintenance, calibration or repair of a finished medical device after distribution for purposes of maintaining it within or returning it to the safety and performance specifications established by the original equipment manufacturer to meet its original intended use, MITA said.

The white paper stressed that servicing cannot change the intended use of a device from its original purpose.

In a May 2018 report to Congress, the FDA said it intended to develop draft guidance on remanufacturing of medical devices. But the agency rejected a push to impose additional regulations on third-party servicers of medical devices, saying there was insufficient evidence to justify imposing new requirements. Instead, the agency called for developing voluntary standards rather than mandating specific regulations.

That stance angered many industry stakeholders. AdvaMed called it "disappointing" and urged Congress to step in to "require third-party servicers to follow FDA quality systems, adverse event reporting, and registration regulations" (*IDDM*, May 18, 2018).

In December 2018, the FDA held a public workshop to further discuss the distinction between servicing and remanufacturing to better inform the development of future guidance. The workshop was accompanied by the release of the agency's white paper, which acknowledged the need for clarification between the two activities.

Previous industry comments suggested that inadequate servicing of devices related to adverse events and deaths, but the agency maintains that they were a result of remanufacturing rather than servicing.

The FDA said it considers servicing as the repair or preventative maintenance on a finished device after distribution to return it to the specifications established by the original equipment manufacturer to meet its original intended use. Remanufacturing is processing, conditioning, renovating, repacking, restoring or any act done to a finished device that significantly changes the device's performance or safety specifications or intended use.

There is an overlap between the regulatory definition of remanufacturing and the standard for when a 510(k) is required for a change to a legally marketed device, which could change safety or effectiveness in the intended use, the FDA said (*IDDM*, Nov. 2, 2018).

CDRH's priority list for fiscal year 2019 includes releasing a draft guidance on this issue.

Read the MITA white paper here: www.fdanews.com/02-28-19-MITA.pdf.

A Smoother 510(k) Process: Strategies, Tips and Best Practices

As the FDA seeks to improve the 510(k) process, companies need to keep up with the evolving approval options. In a recent FDA News webinar, Mary Vater, a medical device consultant with Medical Device Academy, offered tips to help navigate the changes.

The FDA is going to be pushing more product down the more rigorous and expensive De Novo pathway, Vater said, especially for broadened indications or new technologies applied for the same indications. "Through the 510(k) program, a lot of product codes and a lot of devices have evolved small steps at a time, and now, the device you have going back four or five predicates, doesn't look anything like the original predicate," she said.

The agency also plans to establish a 510(k) pathway for a safety and effectiveness determination. "This would mean that they're relying less on predicates and more on stand-alone safety and effectiveness, similar to the PMA or the De Novo," she said. "They want to make sure that 510(k)s are advancing technology [that is] safer or better-performing than what's out there [and] meets modern performance-based criteria that has been established or recognized by the FDA and that reflects current technological principles."

The agency is also conducting several pilot programs. For example, the Quality in 510(k), also called the QUIK review, focuses on product codes that are well-understood by the FDA. The agency is testing its eSubmitter software and wants to speed up the review process by ensuring more consistency in formatting, making it easier for the FDA to review it. That could reduce the clock from 90 days to 60, Vater said.

The Special 510(k) pilot expands the types of changes eligible for the program. "There are some design and labeling changes that were previously reviewed as traditional, and they may now be eligible for Special," Vater said. "So, if you already have a product and are just making a change, then you might push for the Special 510(k), whereas it may have previously been a traditional." This pilot has a 30-day review clock.

Another pilot is tackling the use of third-party reviewers—companies outside of the FDA that review submissions and make clearance recommendations. The FDA has expanded the third-party review expansion pilot to permit the review of many Class II devices that were not previously eligible.

"There are some pros and cons to using third-party reviewers," Vater said. "If you just really need a fast review, sometimes it's worth the extra $10,000 that it costs to hire a third-party reviewer.

Another change that has both pros and cons is the evolving pre-submission meeting. Gone are the days when FDA would take a quick phone call to answer a question. The new in-person meetings are more time-consuming but they can be a company's most useful tool in preparing 510(k) or De Novo submissions, Vater said.

To make the most of them, review and approve your design inputs first, she said. At the latest, schedule it at a design freeze or before a long-term clinical study. "The sweet spot is when you have your device descriptions fully developed, you know what your product's going to look like, you know what it's going to do, you know how it's going to be used, and you also have identified your predicate and the testing that you would like to perform in order to demonstrate equivalence with your predicate, as well as safety and effectiveness

(See **510(k)***, Page 6)*

Good Pre-Submission Meeting Questions

- Does the FDA have any concerns regarding the selected predicate?
- Is the justification to not do xyz testing acceptable?
- Does the FDA agree with "worst-case" rationale?
- Does the FDA support the decision to use a Third Party Reviewer?
- Does the FDA support the decision to file a Special 510(k)?
- Does the FDA support the decision to participate in a Pilot program?
- Does the FDA anticipate any revision changes to relevant standards?

Source: *Medical Device Academy*

Guidance, *from Page 1*

The current regulations "can result in some significant risks for patients receiving high risk custom-made devices such as permanent implants," because they don't have the same level of regulatory oversight as similar conventionally manufactured devices, the TGA said.

The proposed changes would allow the TGA to enter and inspect custom-made device manufacturing sites, and sponsors of overseas-manufactured custom-made devices would need to provide annual reports to the agency about the devices they supplied.

Documentation about implantable custom-made devices would need to be retained for at least 15 years compared to the current five-year retention. In addition, a manufacturer's statement about a custom-made device would have to be provided to the patient receiving the device.

The TGA's guidance proposes adopting the International Medical Device Regulators Forum definitions that would result in personalized medical devices being grouped into three categories:

- Custom-made medical devices;
- Patient-matched medical devices; and
- Adaptable medical devices.

Medical devices that fit the harmonized definition of custom-made, which is more detailed than the current Australian definition, would still be eligible for the exempt status, with limited regulatory oversight.

The patient-matched category of devices, which currently falls under the custom-made definition in Australia, would no longer be eligible for this exemption, and instead would require third party regulatory oversight.

The TGA plans on introducing a framework for regulating medical device production systems that allow providers to produce lower-risk personalized devices for treating their patients without the need for manufacturing certification.

Read the guidance here: www.fdanews.com/02-28-19-TGAguidance.pdf.

510(k), *from Page 5*

if there are any differences … before you spend all the time and money to do this testing that they may or may not agree with," Vater said.

The meetings can result in pleasant surprises, she added. In one case, a company requested a pre-sub meeting for a device it thought would be a Class 2 device. But the FDA said, based on that meeting, that the device could be classified as Class I exempt product. "That saved the client a ton of time and money, and they got to market so much quicker than if we hadn't had that pre-sub meeting," she said.

"I'll be honest. Maybe 50 percent of the time you don't get a ton of value. You'll get some good feedback. You might get your questions answered. But 50 percent of the time you will hit gold like I have in several of my projects where it has really just made a world of difference in the project itself."

Access the webinar FDA's Plan for Modernizing The 510(k) Pathway here: www.fdanews.com/products/57162. — Gienna Shaw

Brain Implant Trials May Need To Include Home Use for IDEs

Sponsors of brain implant trials seeking an investigational device exemption may be asked to demonstrate that their devices can work in "realistic home use environments," the FDA said in a draft guidance.

In general, the FDA doesn't grant IDEs for brain implants because it considers them significant-risk devices. But the agency may consider granting exemptions to trials of implants aimed at repairing catastrophic spinal damage or lost limbs if sponsors can show in their protocols that their trials approximate "realistic home-use environments."

The guidance notes that the FDA is not likely to give an IDE to trials involving patients with histories of seizure, intellectual impairment, "clinically relevant memory problems," psychosis or a chronic psychiatric disorder.

You can read the draft guidance here: www.fdanews.com/02-28-19-Brainimplant.pdf.

AdvaMed Calls for Clarity of Privacy Rules for Informed Consent Waivers

AdvaMed urged the FDA to clarify whether or not patients in low-risk clinical trials involving devices will have to sign privacy waivers even if they don't have to sign informed consent documents.

Late last year, the agency issued a rulemaking notice, implementing provisions in the 21st Century Cures Act, allowing the FDA to waive informed consent requirements for some low-risk trials.

In a written comment to the agency, AdvaMed said it's worried that sponsors, sites or researchers may still be on the hook for privacy waivers under the Health Insurance Portability and Accountability Act (HIPAA). It wants the agency to provide clarification or advisory text for sponsors, investigators and institutional review boards (IRBs) "to carefully consider the specific data elements to be collected as part of the research" in order to determine the applicability of HIPAA privacy requirements.

"While retrospective collection of anonymized data or research on anonymized biospecimens obtained in a previous research study, would not typically require consent under the Privacy Rule, many low-risk, retrospective, post-market clinical follow-up studies may require collection of PHI and, therefore, may still require subject authorization under the Privacy Rule," the group says.

Most industry groups seemed sanguine about the proposed consent waivers but Public Citizen said it had worried that "clinical investigators inappropriately will seek, and IRBs inappropriately will grant, waivers of informed consent for clinical investigations that involve greater than minimal risk to the subjects."

APPROVALS

Axonics' Sacral Neuromodulation System Gains Further Clearance

Axonics received the CE Mark for full-body MRI conditional labeling for its sacral neuromodulation device, used to treat urinary and bowel dysfunction.

The device is the only implantable sacral neuromodulation device that has received full-body MRI conditional labeling for European marketing.

With the clearance, patients receiving an MRI scan anywhere below the head no longer need to have their neurostimulator explanted before they undergo the scan.

Axilum Cleared by FDA For TMS-Cobot TS MV

The FDA granted 510(k) clearance to Axilum Robotics' TMS-Cobot, a device that helps position and orient the MagVenture TMS therapy system.

The TMS-Cobot includes a proprietary optical tracking system that enables the user to control, in real-time, the MagVenture's position, orientation and contact. The device can also compensate for patient head movement.

The MagVenture, which delivers transcranial magnetic stimulation, has been cleared by the

(See **Approvals**, *Page 8)*

Approvals, *from Page 7*

FDA for the treatment of major depressive disorder in patients who have not seen satisfactory improvement from antidepressant drugs.

iVascular's Microcatheter Gains CE Mark

iVascular's Navitian coronary microcatheter received a CE Mark for supporting and handling a guidewire during the treatment of chronic total occlusions (CTOs).

The device is cleared to help navigate guidewires in the case of a near-to-complete blockage of a coronal artery. It is also approved to exchange guidewires and inject radiopaque contrast media or saline solutions.

The microcatheter's braided pattern improves its flexibility and resistance to kinking, and its hydrophilic coating allows for high trackability in small, complex arteries.

Edwards Lifesciences Gains CE Mark for Mitral Repair Device

Edwards Lifescience gained the CE Mark for its Pascal transcatheter valve repair system for treating mitral regurgitation, the leakage of blood back through the mitral valve.

The device is designed to reduce mitral regurgitation, caused when the heart's left ventricle contracts and the valve fails to close tightly.

The system uses two contoured, broad paddles to pull the valve's two leaflets together, as well as a central spacer to fill the regurgitant orifice area.

FDA Clears Soft Tissue Visualization Addon for MRIdian SmartVision

The FDA granted 510(k) clearance for ViewRay's MRIdian SmartVision system, giving the go-ahead for the device's new soft tissue visualization capabilities.

The addon for the SmartVision MRI — which allows for high-definition imaging while removing risks of skin toxicities — gives enhanced contrast between different tissues to help clinicians with tissue visualization.

The new clearance enables the system to give faster, brighter and more detailed imaging for more precise targeting of tumors.

Abbott's HBV Surface Antigen Test Earns CE Mark

Abbott has been handed the CE Mark for its Determine HBsAg2 diagnostic test, a device used for detecting hepatitis B surface antigens in a patient's blood.

The portable diagnostic test — which provides results in 15 minutes — can be used with ease in any healthcare setting and has an analytical sensitivity of 0.1 IU/ml.

Patients can provide blood, plasma or serum for the diagnostic test to determine if they are infected with the virus and require treatment.

NuVasive's Magnetic Implant System Nabs Dual Clearance

NuVasive's Precice bone transport system has received both 510(k) clearance and the CE Mark for use in segmental bone loss treatment.

The Precice system is part of the company's NuVasive Specialized Orthopedics family of magnetically adjustable, limb-lengthening implants.

The magnetic implant can treat complex segmental defects in the tibia and femur caused by trauma or infection and allows patients to avoid many complications from external fixation systems.

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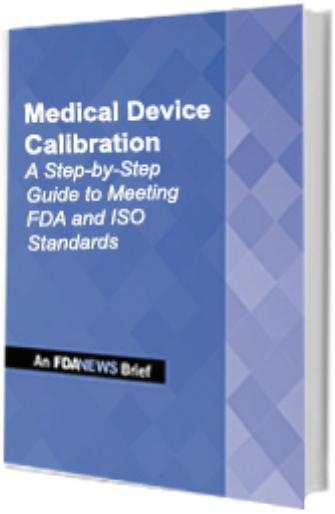

Medical Device Calibration: *A Step-by-Step Guide to Meeting FDA and ISO Standards*

Warning letter citing calibration failures are on the rise — indicating that the FDA is paying more attention to the issue.

Both the FDA and ISO have specific requirements for calibrating medical devices. And — they don't always line up. So devicemakers doing business in the US and abroad need a clear path to compliance if they want to avoid penalties.

Medical Device Calibration: *A Step-by-Step Guide to Meeting FDA and ISO Standards* provides a roadmap that walks devicemakers through each aspect of calibration requirements — showing where the FDA and ISO differ and where they match up — and explains how to combine them to endure full compliance.

You will learn:

- The role of monitoring and measuring in a medical device Quality Management System (QMS)
- Requirements for calibration in FDA's Quality System Regulation
- How to distinguish between accuracy and precision
- The role of traceability in a calibration program
- The audit requirements in both QSIT and MDSAP

The report defines key terms and concepts involved in calibration including proving that calibration practices can be traced back to recognized national and international standards.

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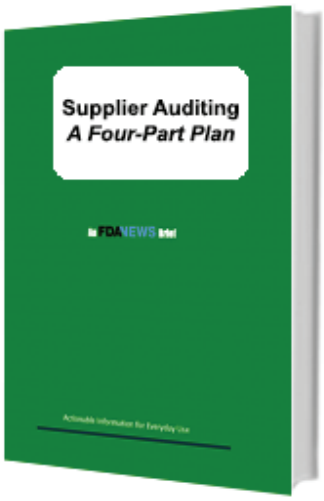

Supplier Auditing: *A Four-Part Plan*

You deal with hundreds of suppliers.

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- Decide who to audit. Start with risk assessment. Not every supplier needs a comprehensive annual audit. Some present bigger potential problems than others and should be monitored frequently. Others may be trusted long-standing contractors that you check up on only every few years. How can you know which is which?
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- Keep up with your suppliers. Maintain a file on each supplier — a dossier, if you will — and develop a list of those you have given your stamp of approval. Having these records on hand will be invaluable when FDA investigators start looking at your supplier management system.

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