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IN THIS ISSUE

FDA Plans to Modernize 510(k) Clearance Pathway

The FDA announced a proposed overhaul of its 510(k) review process that would begin with a shift in focus to predicate devices that are ten years old or less.

Commissioner Scott Gottlieb said the agency wants to promote the use of more modern predicates in order to compare devices to the benefits and risks of newer technology.

Almost 20 percent of current 510(k) clearances are based on predicates that are more than a decade old, meaning that they're being compared to older technology during review and may not be seeing constant improvement, "the hallmark of health technologies," Gottlieb said.

"The most impactful way that we can promote innovation and improved safety in the 510(k) program is to drive innovators toward reliance on more modern predicate devices or objective performance criteria when they seek to bring new devices to patients," he said.

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

Health Canada Proposes Streamlined Process for Priority Review Requests

Health Canada is proposing a new streamlined priority review request mechanism that would significantly reduce burdens on devicemakers.

Under the proposal, devicemakers would be able to request a priority review when they submit their device license applications, so a separate priority review request would no longer be required.

The agency previously issued an interim policy for priority review applications in 2000, which prioritized Class III or Class IV device applications intended to diagnose or treat serious, life-threatening or severely debilitating conditions.

Under the interim policy, the device needed to show substantial clinical evidence that the device diagnoses or treats a condition

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FDA Releases Draft Guidances On Blood Glucose Monitors

The FDA issued separate draft guidances on blood glucose monitors used in health care settings and on over-the-counter products used in the home. When finalized, they will replace guidances the agency issued in 2016.

The guidances were revised based on "additional feedback from stakeholders requesting more clarification on design considerations and recommended standards," the agency said.

The revised drafts include recommendations for what to include in 510(k) submissions, as well as suggestions for performance studies. Some revisions just clarify existing agency recommendations, while others include new information, such as a revised list of known or potential substances whose presence interferes with an analytical procedure and generate incorrect results.

Read the blood glucose test guidance here: www.fdanews.com/11-29-18-OTCGlucoseTests.pdf.

Read the OTC blood glucose test guidance here: www.fdanews.com/11-29-18-BloodGlucoseTests.pdf.

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for which there is no device currently licensed in Canada, or the device had a significant risk-benefit improvement over an existing device "that is not adequately managed by existing products marketed in Canada," the agency said.

Although the intent of the interim policy provides faster access to new innovative devices for Canadians, the request process is "unnecessarily complex," the agency said, adding that consideration should be given for unforeseen or unmet urgent health need such as a pandemic in granting priority reviews.

Under the new proposal, a priority review would be granted to a Class III or Class IV medical device intended to diagnose or treat a serious, life-threatening or severely debilitating disease or condition where there is substantial clinical evidence that the device:

- Provides effective treatment or diagnosis of a disease or condition for which no medical device is currently licensed in Canada;
- Provides significant risk-benefit improvement over existing therapeutic or diagnostic devices for a disease or condition that is not adequately managed by existing products marketed in Canada; or
- Responds to an unforeseen or unmet urgent health need.

The agency invited comment on the proposal until Jan. 25, 2019.

Read the notice here: www.fdanews.com/11-29-18-HealthCanada.pdf.

510(k), *from Page 1*

To that end, in the next few months CDRH is considering publishing an online list of cleared devices that demonstrated substantial equivalence to predicate devices more than ten years old, to encourage sponsors to develop devices that keep pace with modern improvements and advancements. Gottlieb said the agency will seek stakeholder input before it publishes a list.

"We don't believe devices that rely on old predicates are unsafe, or that older devices need to be removed from the market," Gottlieb said. "However, we believe that encouraging product developers to use more modern predicates… would help the overall product environment continue to evolve in the direction toward more modern performance standards."

The Medical Device Manufacturers Association said it is currently reviewing the FDA's proposal and it called for a cautious approach to the program's modernization.

"We must be vigilant that any changes made to a system that has worked so well for so many patients carefully balances safety and innovation, and does not adversely impact America's innovators as they seek to improve patient care," MDMA said. — James Miessler

FDA Boosts Foreign Device Inspections By 243 Percent

The FDA has increased its foreign device inspections by 243 percent since 2007, according to a new quality and enforcement report.

Medical device manufacturing has become "an increasingly global enterprise," with more than 21,000 registered manufacturers located in 106 countries, the agency said. It conducted 2,952 device inspections in 2017, representing a 46 percent increase since 2007.

In addition to FDA inspections, the agency received nearly 600 Medical Device Single Audit Program (MDSAP) reports from 2013 to 2017. The program involves conducting a single quality management audit to satisfy requirements in multiple jurisdictions.

The FDA highlighted its targeted, risk-based enforcement approach to address specific areas of concern.

For example, CDRH received 56,000 adverse events reports associated with infusion pumps from 2005 to 2009, and it launched an infusion pump improvement initiative in 2010. As part of that effort, CDRH conducted 496 inspections of infusion pump manufacturing facilities and issued 40 warning letters to infusion pump manufacturers.

The agency reported that its enforcement activity led to an initial three-fold increase in voluntary recalls, but an 82 percent reduction in annual medical device reports since 2015.

A similar effort was spearheaded for automated external defibrillators. The agency conducted 115 inspections, 39 of which were for AED manufacturing facilities, and it issued six warning letters as a result of those inspections.

Under 21 CFR Part 806, device manufacturers are required to report to the FDA on any correction or removal of a medical device if the correction was initiated to reduce a risk to health posed by the device. Devicemakers with Part 806 inspectional observations reported 20 percent more voluntary recalls in the year following the inspection, according to the report. In addition, the firms were eight times more likely to report a recall following an inspection.

Over the past decade, the FDA flagged adverse event reporting inspectional observations at more than 2,000 medical device companies. In 2017, firms cited for adverse event reporting violations reported more than three times the number of medical device reports compared to the year prior to inspection, the agency said.

The FDA took a more aggressive approach to issuing warning letters beginning in 2008, and reaching a peak in 2012 when it issued 189 warning letters. In recent years, the agency has focused more on resolving issues and on firms with severe violations or those who fail to follow through on their corrective actions.

The more interactive approach has resulted in a drop in the number of warning letters issued. Between 2008 and 2017, 82 percent of firms corrected observed violations on follow-up inspections.

CDRH launched a voluntary quality appraisal pilot in 2018 aimed at raising baseline regulatory compliance. Under the pilot, certified third-party teams conduct quality system maturity appraisals at the manufacturing sites.

To date, 18 firms have undergone 32 appraisals. Most participants said the appraisal was helpful to the firm and 86 percent said it had a positive impact on quality. CDRH is considering developing a formal appraisal program to complement its oversight activities.

Read the report here: www.fdanews.com/11-29-18-FDAInspections.pdf.

FDA to Leverage Patient-Generated Data for Medical Devices

Nearly half of clinical trials for medical devices fail to reach their enrollment goals and the FDA wants to know why.

The FDA's Patient Engagement Advisory Committee (PEAC) met in mid-November to discuss new ways of getting patients not just

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enrolled in device trials, but active in helping to shape them. Last week, the agency released a PEAC discussion document for stakeholder comment on patient engagement in trials and said trials designed with patient input may be "more likely to enroll and retain patients, collect information meaningful to patients and other key stakeholders, and be successfully completed."

Some participants in the Nov. 15 meeting wondered if there are other ways of "listening" to patients. Potential patient sources of health data include social media, sensor technologies — such as fitness watches, arrhythmia monitors and weight scales — and patient-reported data.

Unlike the traditional health data gathered in clinical settings, patient-generated health data are recorded by the patient, who can decide how to share or distribute the information. The information can lead to more effective regulatory decision making, as well as enable the FDA to detect safety risks and take appropriate actions earlier, the PEAC noted, in background documents released for the public meeting.

Seventy-two percent of adult internet users have searched online for health information, 32 percent have posted about health experiences, and user-generated content on blogs and message boards is commonly used by patients for support, the committee said, adding that surveillance on these resources could help inform the FDA's postmarket process for adverse outcomes, issuing recalls and signal management.

One study discussed by the PEAC compared the timelines of identifying adverse events using social media with other sources and "found that the events would have been detected earlier if social media listening was part of the medical product surveillance process."

Real-world evidence, according to PEAC, offers "an immense new set of information about medical devices." Under the right conditions, real-world evidence could support the approval of a new device, or the expansion of indications for devices already on the market, the committee said.

Patient privacy was a central focus of the Nov. 15 meeting. Researchers using internet-connected digital health technology and social media to identify individuals from under-represented populations who could be included in clinical trials for medical devices "should adhere to strict privacy practices," the committee cautioned. To facilitate this, the FDA should create a framework for the type of data that can be used; develop standards for data collection consent; and use social media as a tactic for data collection rather than a stand-alone strategy.

Next steps for the FDA, the committee said, include standardizing how data is collected, used and applied in various situations. The committee also urged the FDA to develop its own social media and website channels, webinars and patient organizations to communicate information about medical devices.

Read the PEAC discussion document on patient engagement in medical device clinical trials here: www.fdanews.com/11-30-18-PatientEngagement.pdf. — Tiffany Winters

FDA Hits Microlight for Deficient Complaint Handling

The FDA flagged Microlight's Sugar Land, Texas facility for its complaint handling procedures, in a Form 483 after conducting two inspections.

The firm's documented service complaints — which were categorized as warranty repairs between January 2016 and June 2018 — were actually complaints regarding possible malfunctions of components of the firm's Class IIIb laser medical devices and were not handled by the company, the agency found.

For example, the facility did not service or repair components involved in complaints of its Microlight Class IIIb lasers, such as possibly malfunctioning batteries.

Approximately 37 out of 51 warranty service records in 2018 were "complaints received due to a failure of the device to meet a specification, but there was no documented evidence that an investigation was conducted," the agency said.

Microlight's CEO said that components are not serviceable or repaired by either Microlight Corporation of America or their third party service contractor.

Additionally, service records in which repairs were made didn't have documentation or results for the tests completed, which were needed to assure each device operated as intended after being repaired.

For example, after requesting the test and results data for the service repair of an ML-830 SmartLaser — which was tested by the firm's third party contractor — the service repair form lacked a required document number, and the service complaint had no test or inspection data.

The firm's vice president of operations said the firm received 84 complaints in 2016, 103 complaints in 2017 and 23 complaints in 2018. The FDA investigator asked to review the complaints, but the records were not provided.

"I was unable to observe documented evidence that these complaints were reviewed, evaluated or investigated for adverse events" including MDR reportability or accidental radiation overdose, the investigator said.

Additionally, the firm's former and current complaints procedures were missing key elements, such as reviews of all complaints to determine if an investigation is needed and investigations of all complaints involving a device's failure to meet specifications.

Read the full Microlight Form 483 here: www.fdanews.com/11-29-18-microlightcorpofamerica483.pdf. — James Miessler

Nebraska Devicemaker Slammed For Design Project Documentation

The FDA cited devicemaker Streck for failing to document certain design elements for its Cyto-Chex blood collection tubes, serving the company a Form 483 after a September inspection of its La Vista, Nebraska facility.

The investigator noted that the firm failed to fully document the design requirements for its Cyto-Chex blood collection tubes, which didn't include how to construct the tube from inert materials.

The facility also failed to adequately document design outputs, including documentation for the tube's rubber stopper design, composition and material properties. It also didn't state whether the stopper was made up of materials with low extractables and low outgassing properties.

In addition, verification of the blood collection tubes' activities was not fully documented, as the firm did not complete verification data to identify potentially interfering substances extracted and/or outgassed from the tube. It also didn't complete validation studies to specifically test for potential assay interference caused by such extractions.

The firm also lacked direct test methods to verify the concentration of the chelating agent ethylenediaminetetraacetic acid (EDTA) in the final product.

Read the full Streck Form 483 here: www.fdanews.com/11-29-18-streck483.pdf.
— James Miessler

FDA Issues Draft Guidance for Dual 510(k), CLIA Waiver Applications

The FDA released draft recommendations for device sponsors on study designs to generate data to support a dual application for a 510(k) clearance and a waiver under the Clinical Laboratory Improvement Amendments (CLIA).

The agency believes the dual approach is in many instances the least burdensome and fastest way for manufacturers to get a CLIA waiver and 510(k) clearance for new in vitro diagnostic devices.

The draft guidance recommends that applicants use the MDUFA IV commitment letter to discuss planned designs for studies that support both the 510(k) clearance and the CLIA waiver.

"A Dual Submission should contain the same information as a complete 510(k) and CLIA Waiver by Application," the guidance states. Content related to comparison and reproducibility studies may overlap, so a single set of comparison and reproducibility studies may be used to support both 510(k) clearance and CLIA Waiver by Application, the agency says. All other content "that would otherwise be included in separate, sequential 510(k) and CLIA Waiver by Application submissions should be included in a Dual Submission," according to the draft.

The dual submissions should also include a description and a determination that the device qualifies as "simple;" a risk analysis, including the identification of potential sources of error; a description of failure-alert and fail-safe mechanisms; flex studies demonstrating insensitivity of the test system to environmental and usage variations under stressful conditions; comparison and reproducibility studies; clinical performance studies; and proposed labeling.

Read the draft guidance here: www.fdanews.com/11-29-18-Waiver.pdf. — Zack Budryk

APPROVALS

Philips' Ventilator System Gains CE Mark

Philips received CE Mark approval for its V60 Plus ventilator system, used for early interventions into respiratory failure.

The system features both noninvasive ventilation and high flow therapy, which allows it to be used with changing patient conditions without having to switch devices.

The device allows for quick therapy and interface transitions and lessens the time physicians need to use for equipment set up.

Implanet Receives CE Mark For Jazz Cap System

Implanet received the CE Mark for its Jazz Cap System, a device for securing screws in poor-quality bone.

The single-use, sterile implants were developed for the main purpose of supporting the treatment of degenerative conditions in adult patients.

The system includes a set of implants consisting of a screw, a band and the company's patented locking mechanism.

PerkinElmer Earns CE-IVD Mark For Prenatal Testing Device

PerkinElmer earned a CE-IVD mark for its Vanadis non-invasive prenatal testing (NIPT) platform.

The test allows patients to screen for trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) and trisomy 13 (Patau syndrome).

The device measures maternal plasma via targeted fluorescent labeling and the counting of specific cfDNA fragments, removing data-intensive steps required by gene sequencing or microarray testing.

Millar Gains CE Mark Expansion For Pressure Catheter

Millar received an expansion of its Mikro-Cath pressure catheter CE mark to include airway and intra-compartmental pressure measurements.

The pressure catheter previously received European approval for making cardiovascular

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pressure measurements, and it received FDA clearance in March 2017 for the expanded indications.

The expansion allows physicians to continuously monitor patient compartment pressure and accurately diagnose acute compartment syndrome, a medical emergency usually caused by internal bleeding or swelling tissue that can lead to permanent muscle damage.

Mesa Biotech Gains 510(k) Clearance for RSV Test

The FDA granted Mesa Biotech 510(k) clearance for its Accula respiratory syncytial virus (RSV) molecular point-of-care test. The test received the CE Mark in Europe earlier this month.

The test diagnoses RSV, which is highly contagious and frequently affects young children and elderly adults, who experience more serious complications from the virus.

The test is designed for use with the company's polymerase chain reaction testing platform, which was specifically made for point-of-care infectious disease diagnosis.

FDA Clears Astura Medical's Spinal Fixation System

Astura Medical's Olympic posterior spinal fixation system has been granted 510(k) clearance by the FDA.

The top loading thoracolumbar, sacral and iliac fixation system offers surgeons a range of posterior spinal fixation instruments and implants to provide fixation during spinal fusion.

The device is made up of preassembled polyaxial and monoaxial screws, rods, rod connectors and crosslinks.

E-Motion Earns CE Mark For Stimulation Therapy System

E-Motion Medical received the CE Mark for its stimulation therapy system, a device intended to treat patients with acute gastrointestinal dysmotility.

The digestive systems of patients with acute gastrointestinal dysmotility have muscles that do not function properly in terms of strength, speed or coordination.

The device gives off "unique patterns" of electrical stimulation to the patient's esophagus using a tube. The stimulation delivered by the system causes the esophagus to contract, restoring the digestive system's natural function and promoting gastrointestinal functioning.

OrthoXel Cleared for Femoral Nailing System in Europe

OrthoXel received the CE Mark for its Apex femoral nailing system, marking another clearance for the device after it recently received a nod from the FDA.

The device, used for fixating femoral fractures, gives physicians numerous locking options, such as the company's patented micromotion for controlled axial movement that encourages callus formation.

Varian's Cancer Treatment System Receives Chinese Approval

Varian's Halcyon system has been given the go-ahead from the China National Medical Product Administration (NMPA), allowing the company to market the cancer treatment system.

The device has already received approvals in the U.S., EU, Japan, India and Brazil.

The image-guided radiotherapy offers advanced treatments for lung, breast, prostate, head, neck and other forms of cancer.

Medical Device Supplier Initiates Recall of Bipolar Pacing Leads

Florida-based medical device company Oscar issued a Class I recall for certain lots of its temporary bipolar pacing leads.

The TB Unshrouded Bipolar Pacing Leads are used to stimulate or pace the heart to increase a patient's heart rate. They are placed into a vein and advanced until the tip touches the inside of the heart.

The company said that in certain lots of the pacing leads, the connector cap housing may shift and expose the internal wire, risking loss of connectivity or breakage during cable movement that could prevent the external pulse generator from pacing, which could be fatal.

BRIEFS

TGA and Philips Sign MOU Over Defibrillator Supply

Australia's Therapeutic Goods Administration and Philips Electronics have entered into a memorandum of understanding under which Philips has agreed to notify the agency of any anticipated shortage of parts associated with its HeartStart MRx defibrillator and to provide service as needed.

Philips advised the TGA in May 2017 that the HeartStart MRx would no longer be supplied, but it continues to be used and supported in hospitals, clinics and ambulances across Australia.

Under the agreement, Philips has agreed to continue service until Dec 31, 2022, and it will meet with the TGA twice yearly and report adverse events as required under normal operations.

TGA Issues Guidance On Regulation of Menstrual Cups

Australia's TGA advised sponsors that menstrual cups no longer need to be included on the Australian Register of Therapeutic Goods (ARTG).

Prior to July 1, menstrual cups were required to be listed on the register, but listing is no longer required for these products. However, menstrual cups are required to comply with Therapeutic Goods Order No. 99 — Standards for Menstrual Cups 2018 before they can be supplied in Australia.

The TGA advised sponsors that they should notify the TGA to de-list the products from the registry or they will need to pay applicable fees.

Under the regulatory requirements, manufacturers should be able to demonstrate that the materials are in compliance with relevant standards, the agency says.

The guidance lists requirements for design, packaging, labeling on both the package and the information leaflet. Reporting adverse events associated with the device remains mandatory.

India Recalls Allergan's Ozurdex Intravitreal Implant

India's Central Drugs Standard Control Organization (CDSCO) recalled Allergan's Ozurdex 700 mg intravitreal implant because a single loose silicone particle may become detached from the needle sleeve during administration of the implant and may be delivered into the eye.

The defect was discovered during a routine manufacturing inspection. The 300 micron silicone particle originated from the needle sleeve. Additional testing by Allergan found two to four percent of defective units, but defect rates as high as 22 percent have been reported.

Although the root cause of the defect has not yet been determined, Allergan identified a corrective action that eliminates creation of the particle and is implementing the correction before releasing additional stock.

Allergan said the silicone particle "is not expected to degrade, and it will remain permanently in the vitreous cavity unless removed." The company warned that a corneal adverse reaction could not be ruled out (*IDDM*, Oct. 15).

Allergan said that for some patients the benefit of the product might outweigh the risk.

CDSCO directed Allergan India to recall all defective lots imported into India, which included seven batches manufactured between 2016 and 2018.

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EU MDR Compliance: *A Checklist for Meeting Manufacturing, Safety and Performance Requirements*

The new EU Medical Device Regulation is massive… complex… and confusing… and you must be ready to comply by May 26, 2020.

When the European Union revised its system of rules for medical device manufacturers in 2017, it replaced a longstanding set of directives on specific topics with one large document that covers all aspects of making devices in EU countries.

Not only did they consolidate all the rules, they gave them greater weight. Previously, medical device directives provided guidance but did not have the force of law. The new MDR, however, contains mandates that are legally enforceable by EU member countries.

The FDAnews report **EU MDR Compliance** can help. Our editors have combed through the regulations, picking out the most minute compliance points and building them into a checklist of 200+ requirements you can use to confirm that you are satisfying all the EU mandates for device manufacturing. The report provides:

- Definitions of key terms in the EU MDR
- Knowing where to find specific requirements in the 150+ page regulation
- Checklists that walk you through every aspect of manufacturing, safety and performance requirements
- A training tool for employees new to the regulations

EU MDR Compliance: *A Checklist for Meeting Manufacturing, Safety and Performance Requirements* is the tool that collects all the requirements, explains them and itemized them in an easy-to-use form to ensure compliance.

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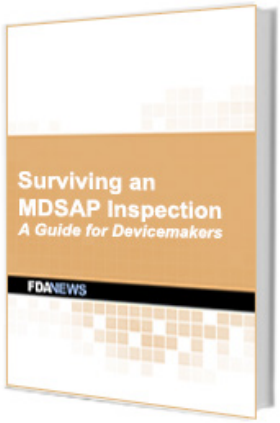

Surviving an MDSAP Inspection: *A Guide for Devicemakers*

Currently, Australia, Brazil, Canada, Japan and the United States are participating in the MDSAP program. If you pass one MDSAP inspection you'll be ready to pursue marketing authorization in five separate countries.

But, if you're going through MDSAP for the first time your experience will be very different from regulatory inspections you've gone through in the past.

- You'll know exactly when and how often to expect an audit
- You'll know exactly how long the audit will be
- You'll know exactly what questions the auditor will ask

The prescriptive nature of the MDSAP model makes it relatively easy to prepare for an audit — if you know what to expect. **Surviving an MDSAP Inspection** provides all the information you'll need to understand the MDSAP model. You'll learn:

- The standard schedule for and duration of audits
- Specific areas auditors will examine and questions they will ask
- Different types of audits involved, such as initial certification, surveillance, desk and site audits
- How to create a checklist to make sure all your bases are covered
- The MDSAP grading system and how nonconformance issues can be escalated — and consequences of getting a bad grade

The management report also includes a copy of the MDSAP Companion document — the official guide — auditors will follow.

Order your copy of **Surviving an MDSAP Inspection: *A Guide for Devicemakers*** and know what to expect from an MDSAP audit and how to prepare for it.

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