International Devices & Diagnostics Monitor

Vol. 2, No. 48
Dec. 5, 2016

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House Approves New Version Of 21st Century Cures Bill

The House voted 392-to-26 to approve a new version of its 21st Century Cures bill — nearly a year-and-a-half after it passed its first version — which seeks to streamline the FDA's review process for medical devices.

The legislation establishes a program to speed up development of devices featuring "breakthrough" technologies that are designed to diagnose or treat serious conditions and have no approved or cleared alternatives. The program builds on the FDA's Expedited Access Pathway, chiefly by permitting access to 510(k) devices (*IDDM*, June 10).

J.C. Scott, head of government affairs for AdvaMed, said the program exemplifies a welcome culture change at the FDA. "Ever since [Medical Device User Fee Amendments] III, there have been better interactions between the FDA and medical technologies that are going through the review process," he said. "Hopefully this bill and MDUFA IV will continue that positive trajectory."

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HHS OIG Work Plan Focuses On Recalled Devices, Cybersecurity

The Department of Health and Human Services' Office of Inspector General (OIG) next year wants to rein in Medicare costs associated with defective medical devices, examine the FDA's efforts to improve networked device security and crack down on Medicare payments for devices at high risk of fraud and abuse.

According to its 2017 work plan, the OIG will review Medicare claims to identify how much it costs replace recalled devices, given that medical device recalls nearly doubled from 2003 to 2012. The OIG also wants to look at expenses associated with replacing defective implanted devices, in light of previous findings that Medicare administrative contractors made improper payments for such replacements.

The OIG also said it will examine the FDA's premarket review of networked device cybersecurity controls, as well as

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Gregory Daniel, deputy director of Duke-Margolis Center for Health Policy, also said the breakthrough device provision is promising, but cited the need for a good way to track performance. He noted that the FDA is taking steps in that direction with the Medical Device National Evaluation System for health Technology (NEST), which will generate real-world evidence across the total product lifecycle of medical devices. "This is a perfect example of the value that NEST can bring," Daniel said.

The bill further requires the FDA to publish lists of Class I and Class II devices that no longer require 510(k) clearances. The lists are to be published every five years and public comments are to be allowed for the listed Class II devices.

The legislation also identifies five categories of medical software that would not be regulated as a medical device, including:

- Administrative support software, such as maintaining financial records;
- Programs designed to encourage a healthy lifestyle and are unrelated to the diagnosis and treatment of disease;
- Electronic patient records created by health care professionals and maintained by certified health information technology;
- Software for displaying clinical laboratory test results; and
- Software for displaying medical information about a patient, unless it processes or analyzes a medical image or signal from an in vitro diagnostic device.

The bill further requires the FDA to finalize its draft guidance on when a new 510(k) is required by November 2017 (*IDDM*, Nov. 11). In addition, it:

- Requires FDA reviewers to consider the least burdensome means necessary for demonstrating safety and effectiveness;
- Requires the FDA to recognize national or international standards for medical device review; and
- Removes the requirement that medical device trial sponsors always use a local institutional review board, which will allow the use of centralized models.

The Senate still has to pass the bill before it adjourns Dec. 16. The House originally passed it in July 2015. Its passage later stalled in the Senate, which produced 19 separate bills that made it out of committee but were not brought up for a full vote. However, Scott said that due to bipartisan support in the House and President Obama's endorsement, he is optimistic that the bill will pass the Senate.

The full, 996-page bill is available here: www.fdanews.com/11-28-16-CenturyCures.pdf.

Numerous Procedural Violations Leads To Form 483 for Hoggan Scientific

Hoggan Scientific LLC has been hit with a Form 483 after an inspection revealed a lack of adequate procedures for design control, corrective and preventive actions, complaint evaluation, and other issues.

Hoggan's Salt Lake City, Utah, facility was inspected in January and investigators discovered the manufacturer of diagnostic and measurement products failed to maintain several design control elements for its microFET 2 dynamometer; including a design development plan; inputs and outputs; review; verification and validation; and transfer.

Investigators also pointed out that Hoggan had not established procedures for analyzing quality data, investigating the cause of product nonconformities; and identifying; verifying; and implementing corrective and preventive actions.

Other observations include a lack of written procedures, device master record and procedures for quality audits that have not been maintained

In total 13 observations were mentioned in the letter. The full letter can be read here: www.fdanews.com/11-22-16-hogganscientificllc483.pdf.

Australia Proposes New Priority Review Pathway for Medical Devices

Australia's regulator outlined a new priority review pathway for medical devices and is asking industry for feedback on its proposal.

The recommendation is part of a regulatory overhaul intended to speed the review of "novel" medical devices and reduce regulatory burdens.

The Medicines and Medical Devices Review Panel also determined that an expedited review pathway should be consistent with the U.S. FDA's priority review pathway.

Current TGA mechanisms to accelerate approval include:

- Pre-submission meetings with the sponsors to identify gaps in clinical evidence prior to application submission;
- Guidance documents on preparing an application and what types of clinical evidence to include in a submission; and
- EU conformity assessments accepted by notified bodies in the European Union.

The FDA's pre-market approval assessment applies to new devices for which there are no existing predicate devices and it is considered to be "more rigorous in its clinical data requirements, while having a lesser regard for approvals outside of the U.S.," the proposal notes.

The TGA has watched the evolution of the FDA's priority review pathway and its expedited access pathway (EAP) closely, and it is not considering implementing the EAP model.

Criteria for Priority Reviews

Under the proposal, medical devices that seek designation for priority review should meet all of the following criteria:

- The device is intended to prevent, diagnose or treat a life threatening or seriously debilitating disease or condition;
- The device addresses an unmet clinical need in Australia; and
- The device must either represent a breakthrough technology or offer a major clinical advantage over existing technology. Or, if the device is an in vitro device, early availability in Australia would result in a major public health benefit.

When applying for a priority review, sponsors would agree to provide a full dossier to support conformity assessment if the device is designated as eligible for priority review.

The TGA requests comments on whether the criteria to restrict the pathway to novel devices is appropriate. It also asks sponsors whether they are likely to submit an application for a priority review designation.

When submitting the application, sponsors should indicate whether the device is a new device or for a new intended purpose. The application should also include expert opinion from a medical expert as to the novelty and patient need for the device.

Once the application is received, it would be assigned to a coordinator who would oversee the administrative process. The TGA would also publish a notice on its website that the sponsor is seeking a priority review.

Applications for priority review would be determined within six weeks of acceptance and sponsors would be asked to submit applications for conformity assessment as soon as possible after the designation is granted. The TGA would consider revoking a priority review designation if the conformity assessment is not submitted within three months after the assessment is granted.

Decisions for eligibility would be made by the Principal Medical Adviser and an appeal process would also be available to sponsors.

The agency is asking companies to provide feedback on the timelines proposed. It asks if sponsors would be able to submit a succinct argument for priority review designation that is independent of the full application process.

Interested parties may submit comments by Jan. 11, 2017. Read the notice here: www.fdanews.com/11-30-16-TGAprioritypreview.pdf.
— Tamra Sami

FDA Releases Final Guidance On Endoscope Cross-Contamination

Final guidance on reducing cross-contamination from irrigation valves and accessories for flexible gastrointestinal endoscopes adds a new section on testing for backflow prevention.

The guidance, released in draft form in January 2015, calls on makers of gastrointestinal endoscopes to consider risk-mitigation in device design or ensure their devices are reprocessed or discarded after each use to prevent cross-contamination during flexible gastrointestinal endoscopy procedures. The recommendations follow reports of backflow from irritation channels into water bottles and tubing when irrigation channels lacked a backflow-prevention mechanism (*IDDM*, Jan. 23).

The final guidance states that when testing the performance of a system incorporating backflow-prevention valves or other features for reducing the risk of cross-contamination, manufacturers should use worst-case scenarios for backpressure, pressure cycling, duration, concentration of chemical and microbiological markers, and other conditions.

The tests also should identify relevant factors that may influence fluid backflow, including pressures; fluid volumes; flow conditions; type and purpose of connections within the flow path; tubing lengths; and time of relevant procedures. Tests should include positive and negative controls and be adequately sensitive.

The guidance recommends that test reports describe the device system used, including the backflow-prevention valve function and its critical operational characteristics.

Other changes to the draft guidance were minor, including:

- Additional definitions and clarification of terminology;
- Inclusion of a diagram to illustrate the potential for contamination;
- Consolidation of two tables on recommended labeling and actions for components of irrigation systems; and
- Citation of new standards and FDA guidance documents.

Read the guidance here: www.fdanews.com/11-28-16-Endoscopeguidance.pdf. — Jeff Kinney

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procedures for dealing with the consequences of cyber-attacks.

In addition, the OIG will look at Medicare payments for devices that are at high risk of fraud and abuse; including hyperbaric oxygen therapy; intensity-modulated radiation therapy; positive airway pressure device supplies; orthotic braces; and nebulizer machines and supplies. The OIG also will determine whether it is cheaper to rent or purchase some relatively inexpensive devices such as bone-growth stimulators.

The work plan further calls for determining the extent of improper Medicare payments for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) used during long-term stays in skilled nursing facilities. The OIG also plans to see whether the Centers for Medicare and Medicaid Services have established a way to identify and recoup inappropriate payments for DMEPOS. This review is prompted in part by a July 2009 OIG report that found that Medicare Part B allowed $30 million worth of inappropriate DMEPOS payments in 2006.

Finally, the OIG will determine how much Medicare paid for DMEPOS ordered by physicians who had financial relationships with manufacturers and group purchasing organizations. It will use 2015 data from the Open Payments database, which was established by the Physician Payment Sunshine Act.

Read the Work Plan here: www.fdanews.com/11-28-16-WorkPlan.pdf. — Jeff Kinney

UK Recalls Infant Ventilators and Tests, Orthopedic Surgical Tools

The UK's Medicines and Healthcare products Regulatory Agency released urgent recall notices for a range of medical devices, including Smith & Nephew's Reflection dead blow mallet, Roche's neonatal cobas test, Acutronic's neonatal ventilator and Zimmer Biomet's bone cement.

Hirzel, Switzerland-based Acutronic issued an urgent field safety notice for its fabian neonatal ventilators that could stop working.

The recall affects the fabian high frequency oscillation (HFO) and oxygen therapy device for neonatal and pediatric patients and its fabian Therapy evolution devices used in NICU units.

The company reported that it received a complaint related to the oxygen saturation by pulse oximetry (SpO2) option that could cause the ventilator to unexpectedly stop.

The problem was associated with a software issue that could lead the digital surgical pleth index monitor to freeze.

It said the short-term preventive action is to disable the SpO2 option and restart the device.

The company said it would issue a software bug fix shortly.

Read the Acutronic notice here: www.fdanews.com/12-01-16-Acutronic.pdf.

Neonatal Bilirubin Test Discrepancies

Roche issued an urgent field safety notice for neonatal bilirubin results measured on its cobas b 123 POC systems.

Following a complaint about discrepancies in neonatal test results, the company traced the problem to a software issue with the test running on software version 4.5.

Although the problem would likely not result in a medical issue with the overall population, Roche warns that for the population most at risk (newborns under 28 days and premature neonates), incorrect medical decisions could be made based on the inaccurate results.

Roche issued notices to its customers to update its software to version 4.8. If an update is not possible, the company released a work-around solution to reconfigure the software.

View the Roche notice here: www.fdanews.com/12-01-16-Roche.pdf.

Hip Replacement Mallet Malfunction

Following a number of complaints about its Reflection dead blow mallet used in hip replacement surgery, Smith & Nephew issued an urgent field safety recall.

Customers complained about cracks on welds located near the head of the mallet, which is filled with lead beads. In some cases, the lead beads escaped from the mallet into the surgical wound.

The company said it was recalling the mallets "as the risk of lead escaping from the mallet and the potential adverse effects associated with lead exposure were previously unidentified risks." The mallet was first placed on the market in 1995.

Smith & Nephew asked customers to quarantine the devices immediately and return them to the company.

Read the Smith & Nephew notice here: www.fdanews.com/12-01-16-SmithNephew.pdf.

Opitpac Bone Cement

Biomet Orthopedics Switzerland announced it was removing Optipac bone cement manufactured since January 2014 because it couldn't guarantee that the sterilization process is compliant.

Although it said there were no immediate health risks, Biomet said that long-range worst case health risks could include infection around the prosthesis that could require revision surgery. Moreover, undetected long-term infection could lead to sepsis and potential death.

It identified long-term most probable risks of inflammation, pain, early infection and potential swelling around the joint.

The recall and removal affects 22 products. Read the notice here: www.fdanews.com/12-01-16-Biomet.pdf. — Tamra Sami

FDA Strikes Certain Data Requirements For Imported Products in Final Rule

Taking into account industry criticism, the FDA has loosened the data requirements that manufacturers of combination products will have to meet to determine the admissibility of imports entering the U.S.

For combination products consisting of at least one medical device and one investigational new drug, the final rule removes the requirement to submit the investigational new drug application number.

In a little more than a decade, the volume of FDA-regulated imports entering the country rose from 6 million to 35 million, said Howard Sklamberg, FDA's Deputy Commissioner for Global Regulatory Operations and Policy.

That prompted the FDA to seek ways to automate the preliminary review of imports. The final rule, which takes effect Dec. 29, would specifically allow low-risk imports to receive a "may proceed" designation based on a review of the data submitted. This is intended to allow the FDA to focus on high-risk imported devices, according to the final rule.

Technical revisions have been made to certain sections of the proposed rule, which was published in July, to provide clarification on FDA oversight, including:

1. The owner of an FDA-regulated product is now defined as the importer of record, or the one responsible for submitting the data.
2. The FDA will now directly provide a notice that an FDA-regulated product is to be sampled, rather than the U.S. Customs and Border Protection agency providing notice.
3. The FDA may now provide written notices electronically to the importer of record about the FDA's decision to refuse FDA-regulated products or subject the product to administrative destruction; and
4. The FDA can reject an entry for failure to provide through ACE the complete and accurate information required by the rule.

Read the final rule here: www.fdanews.com/12-01-16-ACE.pdf. — Jeff Kinney

BRIEFS

Medtronic Issues Recall For Neurovascular Products

Medtronic is recalling of certain lots of its embolization device, Alligator retrieval device, X-Celerator hydrophilic guidewire, and Ultra-Flow and Marathon flow-directed micro catheters due to the potential separation and detachment of the polytetrafluoroethylene (PTFE) coating on parts of these devices.

The devices are designed to be used together for treatment of cerebral aneurysms.

The distribution dates are between Nov. 10, 2014 to Aug. 5, 2015.

FDA Approves Rodo Abutment System

Rodo Medical has received FDA clearance for the Rodo abutment dental system which has the shape-memory Smileloc retentive sleeve.

The sleeve combined with proprietary Rodo abutment and coping, uses Nitinol to create an attachment between a restoration and a dental implant, eliminating the need for cement or screws.

The system is used in tandem with compatible dental implant systems in the upper and lower jaw to retain crowns, bridges and over-dentures.

Quidel's Solana(R) Molecular Assay Achieves FDA Clearance

Quidel has received clearance from the FDA to market its Solana herpes assay for the detection and identification of different types of herpes and varicella from lesion samples obtained from patients showing symptoms.

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Solana can process up to 12 patient samples in each run.

The assay is not intended for use with cerebrospinal fluid or to aid in the diagnosis of herpes or varicella infections of the central nervous system nor in prenatal screening.

ConvertX Nabs FDA Clearance For Kidney Stent System

The FDA has cleared BrightWater Medical's ConvertX kidney tube stent system for treatment of obstructions.

The device is implanted and converts from a catheter to a stent without the need for radiation or sedation. It then remains implanted in the patient like a standard internal kidney tube stent.

BrightWater Medical is will submit an application for the ConvertX system to the EU for CE marking.

QView Medical Get FDA PMA Approval for QVCAD

QView Medical has received FDA approval for QVCAD, which is a CAD system for automated breast ultrasound (ABUS).

QVCAD presents the CAD results, which include a C-thru navigator image and CAD marks indicating regions of interest, in tandem with the original ABUS image.

The QVCAD pivotal reader study submitted in the PMA application demonstrated that QVCAD reduces reader review time while preserving the accuracy of diagnosis.

Abbott Gains CE Mark For i-STAT Alinity System

Abbot has received CE marking for the i-STAT Alinity system, which is a portable blood testing platform available for sale in Europe.

The all-in-one device performs and analyzes a range of blood tests using only two to three drops of a patient's blood. Results are delivered in two to 10 minutes.

The device is currently not available in the U.S.

Exact Imaging Receives CE Mark Approval For its ExactVu Micro-Ultrasound System

Exact Imaging has received CE Mark approval for its ExactVu micro-ultrasound system for prostate imaging and biopsy guidance.

The system's high resolution is derived from its operating frequency of 29 MHz, which is more than double the operating frequencies of conventional ultrasound systems.

Due to the increase in resolution, the device system enables the urologist to view abnormalities clearer in the regions and perform biopsies.

Skyline Medical Wins Health Canada Approval for Streamway

Skyline Medical has won Health Canada approval for its Streamway medical fluid disposal device.

The device is an automated direct-to-drain medical fluid disposal system.

The company expects to reach a deal in the coming weeks to distribute the product across 1,500 hospitals in all 13 Canadian provinces.

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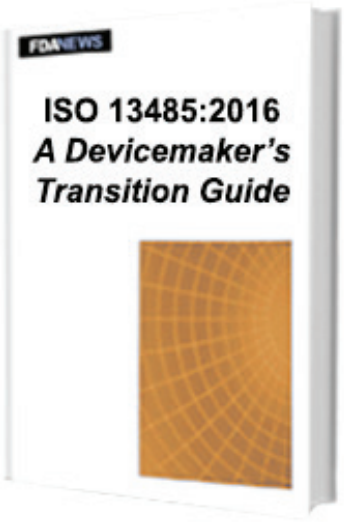

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