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IN THIS ISSUE

FDA Approach to Cybersecurity Leaves Open Questions

Recent FDA guidance on medical device cybersecurity leaves some unanswered questions for manufacturers, especially on how best to identify and communicate risks.

The agency's final guidance deals with post-market cybersecurity management and calls for manufacturers to monitor for vulnerabilities and report any cyber intrusions. But it is not explicit about how companies can find and deal with weaknesses before they are exploited by hackers and about the risks involved in disclosing any vulnerabilities.

The agency said risk management programs should include procedures for monitoring cybersecurity information sources for vulnerabilities, as well as robust software lifecycle processes, threat modeling, a coordinated vulnerability disclosure policy, and mitigations that address risks before they are exploited.

The final guidance (*IDDM*, Dec. 30, 2016) clarified some elements in the draft but left others vague, according to Steven Boranian,

(See **Cybersecurity**, *Page 4)*

Devices are Facing Tougher Marketing Hurdles in EU

New EU requirements for CE marks are making it harder for manufacturers to get new marks when registering or re-registering products.

Medical device manufacturers are facing more significant hurdles in the EU because of tougher clinical data requirements and the steep drop in the number of Notified Bodies available to approve medical devices for sale in the EU.

Higher standards under the EU's Medical Device Regulations (MDR) have cut the number of Notified Bodies from 87 to 57 since last year and up to 15 more are expected to drop out this year. Waiting lists for product approvals are now longer, and some CE marks have been suspended without warning or have not been renewed in

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time, according to Gert Bos, executive director and partner at Qserve Group in the Netherlands.

Bos discussed the changes with *IDDM* following his presentation this week at the 9th Annual EU Medical Device Clinical Research Conference in Berlin, Germany.

The remaining Notified Bodies are becoming more strict in granting CE marks, he said. This is in part because guidelines published last year (MEDDEV 2.7.1) which are meant align with provisions in the MDR and provide general principles for clinical evaluations, have introduced more thorough pre- and post-market data collection requirements (*IDDM*, Oct. 28, 2016).

High-risk products under the new MDR must be supported by the manufacturer's own premarket data for the device under review. The data also must be gathered from real-world use instead of focus groups. According to Bos, more than 90 percent of devices currently marketed in the EU might not currently meet these requirements. "The gap is huge, and it is hard to imagine that all these products will move into clinical trials," he said.

Low-risk products have a somewhat easier path by claiming substantial equivalence to existing products. However, the definition of substantial equivalence is much narrower under the MDR, and devices must be nearly identical in terms of intended use, target population, other factors. The studies used to support substantial equivalence also must be very similar.

The MDR requires post-market clinical data for currently marketed devices, as well as a plan to generate such data for any new product being launched. This requires manufacturers to implement new procedures for lifecycle management and traceability.

In addition to manufactures, other companies in the medical device supply chain are under pressure. For example, the MDR imposes greater responsibilities and more potential liability on importers, authorized representatives, and distributors.

Bos said manufactures should select a Notified Body that can meet the new MDR requirements and that has the resources to conduct proper conformity assessments. At the same time, it is important to find a Notified Body sooner rather than later. "The window of opportunity is closing" as the MDR is being implemented, and Notified Bodies are getting more and more selective in terms of which manufacturers they choose to work with, he said.

MTI Precision Products Gets Form 483 for Design Change

MTI Precision Products received a Form 483 with 8 observations including inadequate design change procedures, maintenance of complaint files, and other issues.

The FDA inspectors reported during a visit to the firm's Coatesville, Penn., facility in late August and early September 2016 that procedures for design change were inadequate. Specifically, an engineering change for the Sonic Scaler device was not approved by management or evaluated to determine if it required verification or validation. In addition, a design change for the company's Low Speed Dental Motor was not properly documented.

MTI also failed to properly maintain complaint files when a small screw came off a device and was swallowed by a patient. No evaluation was documented to determine if the complaint was reportable under Medical Device Reporting requirements.

The agency inspectors also found a device master record was not reviewed before manufacturing began at the facility, and approved specifications for components, finished products, packaging, and labeling were not established. The company also failed to complete an inspection for several dental devices placed in interstate commerce.

Read the Form 483 here: www.fdanews.com/01-19-17-MTI.pdf.

Device Companies Urge Trump To Support Value-Based Care

Dozens of healthcare organizations, including several device makers, wrote an open letter to President Donald Trump urging him and Congress to continue the pursuit of value-based care.

The organizations — representing various sectors of the industry, and including Merck, Pfizer, Sanofi, Amgen and Johnson & Johnson — said they have made significant investments in building alternative payment models, and have been seeing improvements in healthcare quality and lower costs.

The organizations committed to working with the administration and Congress to build new policy, specifically calling for an expansion of waivers from fee-for-service regulatory requirements, and for more public and private investment in the testing and scaling of new payment models.

"Now is not the time for policymakers to signal a shift away from value-based care, either through action or inaction," they wrote, as Republicans in Congress and the White House gear up to repeal the Affordable Care Act over the coming months.

The ACA instituted several payment reforms, such as encouraging the development of accountable care organizations under Medicare. The letter also cited the "two decades of bipartisan leadership" resulting in the 2015 Medicare Access and CHIP Reauthorization Act, known as MACRA or the Doc Fix, which consolidated performance incentive programs into the Merit-based Incentive Payment system.

Through private and public sector alignment, the move toward value-based care "is succeeding, measurably improving healthcare quality and contributing to historically low costs," the letter states. "As you take up the mantle of addressing the challenge of improving quality while safely reducing costs, we strongly urge you to continue focusing on driving value-based, patient-centered payment models that incent healthcare innovation."

The letter, with the full list of 116 organizations, is available here: www.fdanews.com/01-26-17-HealthLettertoTrump.pdf. — Conor Hale

Covidien Gets Form 483 For Complaint Procedures

FDA inspectors hit Covidien with a Form 483 for inadequate complaint evaluation and process control procedures, as well as failure to ensure appropriate design and installation of manufacturing equipment.

Following a September 2016 of the company's Sunnyvale, Calif., facility, inspectors reported that procedures for receiving, reviewing, and evaluating complaints by a formally designated unit were not adequate. For example, a service technician filled out a Physician Feedback form without getting answers from the complainant. This resulted in several errors, including questions on the form being based on assumptions made by the service technician and not confirmed by any of the complainant's clinical personnel; a complaint form containing incorrect information; a 14-day delay in issuing a complaint; and the complaint being closed without a determination of whether a Medical Device Reporting investigation was required.

The Form 483 also said procedures describing process controls necessary to ensure conformance to specifications were not adequately established. Covidien manufactured certain lots of product in its clean environment rooms when a Comparative Effectiveness Research certification was expired, without noting the deviation in the device history record as the company's written procedures required.

Finally, the inspectors said the appropriate design, construction, placement, and installation of manufacturing equipment was not ensured. Specifically, the Covidien did not perform an installation qualification of a piece of equipment to ensure it was installed according to the manufacturer's specifications.

Read the Form 483 here: www.fdanews.com/01-18-17-Covidien.pdf.

Advanced Breath Diagnostics Hit With 11-Count Form 483

Advanced Breath Diagnostics was hit with a Form 483 citing 11 observations related to corrective and preventive actions (CAPA), rework and reevaluation activities, acceptance procedures, and other areas.

FDA inspectors visited the company's Brentwood, Tenn., facility in late August and early September of 2016 and found that procedures for corrective and preventive action were not adequately established. For example, three of seven completed CAPA records reviewed contained no documentation of verification or validation activities used to determine the effectiveness of the actions, investigation requirements were not completed in some cases, and there were no requirements for analyzing quality data from analytical instrumentation to identify causes of nonconforming products. In addition, Advanced Breath failed to document certain corrective and preventive actions.

The Form 483 said rework and reevaluation activities were not documented in a device history record and the company did not implement certain procedures for product acceptance, including in-process leak testing.

Inspectors also cited Advanced Breath for not establishing procedures to ensure that equipment was routinely inspected, checked, and maintained.

Additional observations included failure to document the modification of broken equipment and to verify that it still functioned correctly, maintain records of a correction action, adequately define procedures for the control of nonconforming products, document changes to approved vendor lists, document supplier audits, and adequately establish procedures for controlling labeling activities.

Read the Form 483 here: www.fdanews.com/01-19-17-AdvancedBreath.pdf.

Cybersecurity, *from Page 1*

a partner at Reed Smith. In one change from the draft, the final guidance calls on companies to participate in Information Sharing Analysis Organizations (ISAOs) as a way to monitor cybersecurity information. The FDA has a memorandum of understanding with one ISAO — the National Health Information Sharing & Analysis Center — to help foster communication among manufacturers and other stakeholders about cybersecurity issues.

Other elements of a risk management program remain unclear. For example, the recommendations for maintaining robust software lifecycle processes and for using threat modeling do not explain what these activities would look like in practice, Boranian said.

In addition, it is unclear to whom a company's cyber vulnerability disclosure policy should be directed. It makes the most sense to disclose vulnerabilities to physicians, who are best equipped to understand and react to the information, he said. But disclosing vulnerabilities to patients may cause them to overreact and ask their physicians to disable important medical device functions unnecessarily.

The biggest challenge for manufacturers will probably be identifying and communicating risks, according to Jay Crowley, vice president of unique device identification services at USDM Life Sciences. Participating in ISAOs will help manufacturers stay on top of emerging threats, but it will be difficult to communicate those risks in a way that does not expose a company to further attacks, Crowley said. The final guidance does not address this issue.

Manufacturers also will have to assess whether the benefits of connecting a particular device — such as better monitoring and faster diagnostics — outweigh the added costs of implementing the robust cybersecurity risk management program called for by the guidance. The cost of compliance is unlikely to be prohibitive, but "we're not going to connect every device just because we can," he said.

Read the final guidance here: www.fdanews.com/12-28-16-CybersecurityGuidance.pdf.

Cell Marque Cited for Device Acceptance Procedures

Cell Marque Corp. was hit with a Form 483 for not adequately establishing procedures for device acceptance and for reviewing complaints.

After visiting Cell Marque's Rocklin, Calif., facility in late September and early October, inspectors reported that the company had not defined acceptance criteria for its S1OOA1 in vitro diagnostic device to ensure that it performed as intended.

S1OOA1 is an antibody used to help identify renal neoplasms. Cell Marque initiated a Class II recall of several lots of S1OOA1 in May 2016 because of lots showing no staining, which indicated potential false negative results.

In addition, the Form 483 said the company did not establish adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Specifically, the firm did not implement its official complaint handling practices. Nine of the eleven troubleshooting incident reports the inspectors reviewed were of customers alleging deficiencies with a product. But the incidents were not captured as complaints.

Read the Form 483 here: www.fdanews.com/01-06-17-CellMarque.pdf.

Sontec Instruments Cited For Design History, Other Violations

Sontec Instruments was cited in a Form 483 for failing to establish unique design history files, failing to adequately document design verification results, and other violations.

During an October 2016 visit to the firm's Contennial, Colo., facility, the FDA inspectors found that the design history file did not demonstrate that the design was developed following regulatory requirements. Specifically, Sontec holds a 51O(K) for Class II medical devices in seven general categories, including clamps, forceps, knot tiers, needle holders, knot pushers, scissors and suction tips. But the company failed to establish unique design history files for each type of device.

Inspectors also reported that design verification results, including the identification of the design, the methods, the date and the individuals performing the verification, were not adequately documented in the design history file. There was no documentation for the design verification of certain specifications for several types of needle holders as required by Sontec's standard operating procedures.

The Form 483 also said that procedures for acceptance of incoming products were not adequately established. These products included several types of needle holders and a type of forceps.

Finally, complaints involving the possible failure of a device to meet any of its specifications were not evaluated and investigated where necessary, and the evaluation of potential suppliers was not documented.

Read the Form 483 here: www.fdanews.com/01-19-17-Sontec.pdf.

Malaysia Offers Expedited Reviews For Devices Approved Elsewhere

Malaysia's Medical Device Authority (MDA) has established an expedited review process for medical devices already approved in other jurisdictions including the U.S., Canada, Australia, the EU, and Japan.

In a new circular, the authority sets out criteria for quality management systems, post-market surveillance, and technical documentation for various classes of medical devices. The process for approving devices that are already sold in other countries is simpler and less costly than the standard medical device registration process, the circular says.

For example, for Class A (low-risk) devices, regulators will look at the device's intended use and classification, the scope of the manufacturer's quality management system, labeling, and certain aspects of the manufacturing process, the authority said.

Read the circular here: www.fdanews.com/01-23-17-recognizeddevices.pdf.

UK's NICE Recommends Use of SecureAcath

The UK's National Institute for Health and Care Excellence is recommending the use of the SecureAcath device in the UK to secure peripherally inserted central catheters (PICCs).

The device is used to affix PICCs to the skin, is well-tolerated and can lead to cost savings because it is less expensive than alternatives, NICE said.

In a new guidance, NICE summarizes studies of its use and recommends that it be considered for any PICC inserted for 15 days or longer.

SecurAcath is easy to use, does not need to be replaced, and is associated with few catheter-related complications such as migration, occlusion, thrombosis, and infection, the institute said.

The device received a CE mark in December 2009.

Read the NICE guidance here: www.fdanews.com/01-23-17-percutaneouscatheters.pdf.

Australia Streamlines Medical Product Advisory Committees

Australia's Therapeutic Goods Administration streamlined its advisory committees for medical products following a review of the country's regulatory framework for medical devices and drugs.

The authority has reduced the number of advisory committees — which provide independent advice used in making regulatory decisions — from 11 to seven.

Those committees are:

- The Advisory Committee on Medical Devices;
- The Advisory Committee on Medicines;
- The Advisory Committee on Vaccines;
- The Advisory Committee on Biologicals;
- The Advisory Committee on Complementary Medicines; and
- The Advisory Committees on Medicines Scheduling and Chemicals Scheduling.

BRIEFS

Bone Index Receives FDA Clearance For the Second Generation Bindex

Finland–based, Bone Index has gained FDA marketing clearance for its second generation Bindex device to help in osteoporosis diagnosis.

The device measures the cortical bone thickness of the tibia and the algorithm calculates the density index.

Roche's Next Generation Roponin T Test Cleared for Marketing

The FDA has granted marketing clearance to Roche's Troponin T test as an aid in the diagnosis of myocardial infarction.

The device reports the troponin biomarker within nine minutes.

FDA Awards Biolase Marketing Clearance For Epic Pro Diode Laser System

Irvine, California–based, Biolase received the FDA's clearance to market its dental diode laser system.

This device is the newest addition to the company's portfolio of soft-tissue diode lasers.

FDA, Health Canada Clear 7D Surgical's Image Guidance System

Toronto–based, 7D Surgical has won FDA and Health Canada marketing clearance for its Machine-vision Image Guided Surgery (MIGS) system for spine surgery.

The MIGS technology is embedded in an overhead surgical light, which eliminates line of sight barriers in the operating room. The unit is controlled by the surgeon using a foot pedal.

Camber Gains FDA Marketing Clearance For its Joint Fixation System

Wayne, Pennsylvania–based, Camber Spine Technologies has received FDA clearance for its Siconus SI joint fixation system.

The system is designed for use in adult patients as an adjunct to sacroiliac joint fusion in the treatment of the degenerative sacroilitis, or sacroiliac joint disruptions.

FDA Approves BD's PleurX Catheter System for Pleural Effusions

Franklin Lakes, New Jersey–based BD (Becton, Dickinson and Company) has won FDA marketing clearance for its PleurX catheter system.

The device system was initially approved in 1997 for managing malignant and recurrent fluid buildup.

With the new indication, the system is now cleared for patients suffering from certain non-malignant recurrent pleural effusion factors, including congestive heart failure and fluid buildup around the lungs.

Prescient Surgical Achieves FDA De Novo Clearance for CleanCision System

FDA's CDRH has granted de novo clearance to Prescient Surgical's CleanCision wound retraction and protection system.

The device is designed for surgical wound edge protection, retraction, and continuous cleansing with a sterile irrigant solution.

Prescient plans to launch the CleanCision device in 2017.

Fujifilm Gains FDA Approval For Mammography System Software

Stamford, Connecticut–based, Fujifilm Medical Systems U.S.A has achieved FDA approval for its Digital Breast Tomosynthesis (DBT), an optional software upgrade for its Aspire Cristalle digital mammography system.

With the DBT software option acquiring a series of low-dose image slices at different angles, producing a three-dimensional image. The acquired images are reconstructed into a series of 1 millimeter slices, making it easier to identify lesions that might be difficult to see in traditional 2D mammography images due to overlapping breast structures.

Grassley Presses CMS For Records, Answers on Mylan

Sen. Charles Grassley (R-Iowa) put pressure on the Centers for Medicare and Medicaid Service to release records on Mylan's classification of the epinephrine auto-injector the EpiPen for Medicaid.

The Republican senator requested that CMS hand over records that show the steps the agency took to notify Mylan that it misclassified its EpiPen as a generic for the Medicaid Drug Rebate Program (MDRP). This is second time Grassley has asked for documents regarding the misclassification, which allowed Mylan to pay lower rebates to states for several years.

CMS has stated that "on multiple occasions" it provided guidance to Mylan on the classification of drugs for the rebate program, and explicitly told the company that the EpiPen was misclassified, but has not provided evidence to substantiate these claims, Grassley said.

Handwritten at the bottom of the letter is a note from Grassley that says: "I think you know what we want [and] you didn't provide. We need 'records.'" He added that, if the handwritten note is not "plain" enough, CMS can contact his staff for "very specific" details on what he is requesting.

In a letter sent earlier this month, CMS told Grassley that Mylan had not yet reached a settlement with the Justice Department to resolve claims that it misclassified the allergy therapy and underpaid state rebates — evading the senator's questions on how it attempted to correct the company's error.

Read the letter here: www.fdanews.com/01-26-17-GrassleyLetter.pdf.

Manufacturers Seek Clarification Over Surgical Aspirator Labeling

Two manufacturers have asked the FDA to clarify the types of devices covered in the agency's draft guidance on ultrasound surgical aspirator devices.

The draft, issued in November 2016, recommended that manufacturers of the devices, with an indication for use in general surgery, laparoscopy, or gynecologic surgery, should prominently include the following contraindication in their product labeling:

> CONTRAINDICATION: This ultrasonic surgical aspirator device is not indicated for and should not be used for the removal of uterine fibroids.

The agency also recommended that manufacturers update other portions of their labeling to make it consistent with this contraindication. For example, a manufacturer may revise the list of procedures in the labeling for which the aspirator can be used (*IDDM*, Nov. 11, 2016).

Integra LifeSciences Corporation said the final guidance should clarify that it applies to general and specific indications for use within general, laparoscopic, and gynecologic surgery. Integra also noted that the draft guidance asks manufacturers with existing 510(k) clearances for ultrasonic surgical aspirators to provide updated labeling to purchasers of devices that have already been distributed. Integra said the final guidance should confirm that the updated labeling would not be considered a correction or require a correction report. The company also sought a clarification that manufacturers may post updated labeling on the web and provide paper copies upon request.

In a separate comment, Medtronic said the final guidance should specify which of two types of ultrasonic surgical instruments it applies to and how to differentiate between them. The two types, aspirators and dissectors, can be differentiated through their indications for use, the company said. The indications for use of ultrasonic dissectors typically refer to soft tissue incisions, vessel coagulation or a similar technology. Dissectors are intended as adjuncts to or substitutes for other surgical instruments such as scalpels or electrosurgical instruments. — Jeff Kinney

Trump Freezes FDA Hiring, Suspends New FDA Regulations

On the administration's first full workday Monday, President Donald Trump froze federal hiring for most agencies, leaving the FDA with hundreds of job vacancies out of its workforce of approximately 15,000.

A common move in the first days of any new administration, the freeze puts the agency at odds with the 21st Century Cures Act provision to accelerate hiring and authorizing the FDA to spend up to $20 million in fiscal 2017. The length of Trump's hiring freeze is uncertain.

On Friday, the White House ordered the FDA and other federal agencies to halt any new regulations or guidances until they can be reviewed by Trump administration appointees. It also temporarily postponed regulations that were published before Jan. 20 but did not take effect immediately.

The FDA released more than 25 final and draft guidances in the last two weeks of the Obama administration — including four related to devices.

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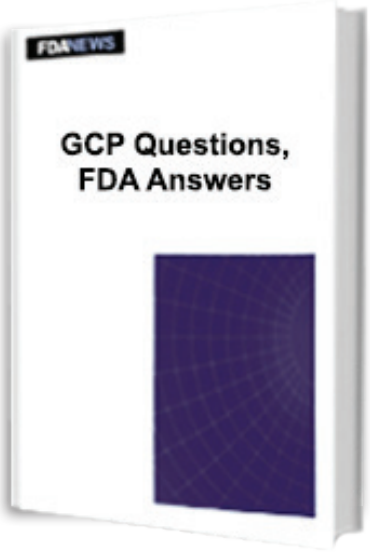

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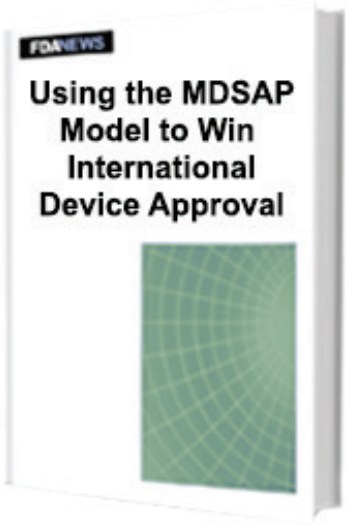

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