INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE



## Health Canada Announces New Medical Device Directorate

Health Canada is creating a stand-alone Medical Devices Directorate (MDD) within its Health Products and Food Branch that will take a "lifecycle approach" and also take on postmarket functions currently within the Marketed Health Products Directorate

"The landscape for medical devices is changing rapidly and innovation is challenging Health Canada and all its partners to increase our focus on medical devices," said Pierre Sabourin, assistant deputy minister for the Health Products and Food Branch, in announcing the news to stakeholders.

The directorate will add capacity and focus on expanding Quality Management System and implementation of ISO 9001. It will also strengthen postmarket surveillance and will build on Health Canada's newly created digital health unit.

Among other device-related changes, Health Canada says it is being challenged to:

*(See* **Canada***, Page 2)*

## FDA Clarifies Guidance On Export Certificate Denials

The FDA released final guidance for devicemakers laying out the information it provides when it denies export certificate requests and the steps firms should take to appeal rejections.

The agency issues a Certificates to foreign governments (CFGs) to demonstrate that a device is approved or cleared in the U.S. and meets all regulatory requirements. The final guidance clarifies the agency's August 2018 draft and explains in greater detail what would lead it to deny a CFG request.

Companies with recalled devices, seized devices, injunction proceedings or out-of-compliance establishments could all warrant a denial, the agency said. If the agency denies a CFG request, it will send a detailed explanation, including major violations of any

*(See* **Guidance***, Page 2)*

## Australian Court Finds J&J Liable for Mesh Injuries

The Federal Court of Australia has found Johnson & Johnson responsible in a lawsuit by more than 1,350 women over injuries linked to failures of its pelvic mesh.

The class action suit against the company and its subsidiary Ethicon seven years ago alleged that the meshes — implanted after childbirth to repair pelvic organ prelapse — were defective and came with inadequate warnings. The women alleged serious and permanent injuries such as erosion of the mesh into surrounding organs, incontinence and chronic pain.

The court found that Ethicon sold the devices without properly warning women about the risks, and was negligent for rushing the products to market before proper testing.

"The post-market evaluation of all the Ethicon devices was deficient," said Justice Anna Katzmann. "It fell well below the level of care required of a reasonably prudent manufacturer."

Katzmann also called out the Therapeutic Goods Administration, saying that the evaluation of the products before and after they were marketed were inadequate

In a statement, Ethicon said that it "believes that the company acted ethically and responsibly in the research, development and supply of these products." Ethicon plans on appealing the ruling.

Katzmann said that she would rule on damages in February 2020.

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**Guidance,** *from Page 1*

noncompliant facilities with references to quality system regulations.

Establishments with No Action Indicated or Voluntary Action Indicated classifications for their most recent quality system inspections won't be denied CFGs, the agency said, adding that the level of detail in any communication will depend on the individual case.

"For open recalls, the agency intends to base its decision to issue a CFG on the current status of the recalled products," the guidance notes. "For a product line with an open lot-specific recall, lots not under recall may be included on a CFG, provided the firm signs a statement indicating that it will not ship the lots of the product that are subject to the recall."

Noncompliant firms may submit a plan of correction after receiving the agency's summary of violations, the guidance said adds, setting a 90-day timeline for an agency response. The plan should be sent to the agency contact named by the investigator.

Firms with other issues should submit a request for review within 60 calendar days of their denial date by contacting CDRH's Exports Team within the Office of Regulatory Programs via email. The reviews can take 30 days or longer to complete, the agency said.

Read the final guidance here: www.fdanews.com/11-15-19-ExportCertificates.pdf.
— James Miessler

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**Canada**, *from Page 1*

- Shift how it regulates investigational trials;
- Re-examine risk-based approaches;
- Find ways to regulate software that allow for rapid innovation cycles; and
- Create new pathways for innovative technologies.

The MDD will have a staff of 165 and a budget of almost Can$16 million ($12 million).

The new directorate "will position Health Canada to be more focused on this evolving product line and more agile and adaptable to its rapid growth and change," Sabourin said.

"Although Canada has one of the best regulatory systems in the world for medical devices with some of the most stringent requirements, the pace of change is challenging us to do better. Creating the MDD is a significant step in response to this challenge and set up the medical device program for a successful future," the agency said.

## GSK Accuses Boehringer Ingelheim Of Lying About Its COPD Inhalers

GlaxoSmithKline (GSK) hit Boehringer Ingelheim with a lawsuit in a Pennsylvania federal court accusing it of false advertising over its dry powder inhalers Ellipta and Diskus for chronic obstructive pulmonary disease (COPD).

GSK accused BI of running a promotional campaign to healthcare providers for its competing product Respimat that "falsely and misleadingly downplays the efficacy of the drug delivery" achieved by GSK's inhalers.

The lawsuit in the U.S. District Court for the Eastern District of Pennsylvania alleges that, in September 2018, GSK reached out to its competitor demanding that it cease using a brochure which claimed that a majority of COPD patients would be unable to fully benefit from Ellipta and Diskus. Over the next nine months, the competitors exchanged eight letters outlining the claims made in the brochure, the suit alleges.

However, BI began using a revised brochure in 2019 that addressed GSK's previous concerns but still conveyed the message that certain COPD patients cannot obtain adequate benefit from the inhalers, according to the complaint.

BI also made the claims on at the American Academy of Family Physicians' conference on Sept. 27, and its sales representatives were making the claims in visits to healthcare providers, the suit alleges.

GSK asked the court to put an injunction on the brochures and marketing materials that convey the false messages and urged the court to make BI retrain its staff to no longer convey the messages.

"We will actively pursue all options necessary to stop competitors from communicating misleading information about our medicines," GSK told *FDAnews*.

BI maintains its materials are "accurate, truthful and supported by science."

Read the complaint here: www.fdanews.com/11-14-19-GSKInhalerSuit.pdf.

## FDA Issues Guidance on Transdermal And Topical Drug Delivery Systems

The FDA outlined its current thinking on the information sponsors of transdermal and topical delivery systems (TDS) should include in their NDAs and ANDAs in draft guidance released Wednesday.

Transdermal and topical delivery systems "present similar manufacturing and quality control concerns and similar risks to patients," the agency noted.

Sponsors should include a summary of the quality characteristics of the drug — known as the quality target product profile (QTPP) — and a list of critical quality attributes (CQAs) for the product. They should also flag important product quality components for the drug substance, excipients, container closure system, and manufacturing processes, the agency said.

The guidance offers a list of typical manufacturing steps and operations for TDS, including mixing, coating, drying and lamination, and describes their potential impacts on quality. For example, mixing can have an effect on attributes such as assay, drug substance and/or excipient stability, content uniformity, microscopic appearance, and physical properties of the adhesive.

Read the draft guidance here: www.fdanews.com/11-20-19-TDSdraftguidance.pdf.
— James Miessler

## Petition to FDA Questions Trial Of Naltrexone Implant in Prisoners

BioCorRX's use of a naltrexone implant for addiction treatment in state prisoners and the homeless was brought into ethical question by a consumer advocacy group in a citizen petition urging the FDA to launch an investigation.

The company only managed to implant one prisoner with the combination product at the Louisiana Department of Corrections facilities in a trial that was discontinued this spring. The trial had aimed to experiment on nine more inmates as part of an addiction recovery program.

*(See* **Implant***, Page 4)*

## BRIEFS

### Singapore Warns of Trace Compounds in Glaucoma Implants

Singapore's Health Services Agency issued an alert on a recall of all lots of Allergan XEN glaucoma treatment system due to the presence of residual compounds from the manufacturing process.

The system is comprised of the XEN 45 gel stent preloaded into a XEN injector that is permanently implanted into the eye. The implant is designed to lower eye pressure in patients with refractory glaucoma where previous surgical treatment failed or medications alone were not sufficient.

During an in-process inspection, four units in an unreleased XEN 45 lot were observed to have trace amounts of residual polishing compounds used in the needle sleeve manufacturing process, Allergan said.

Allergan later recalled 15 lots of the implants, and healthcare professionals were advised to stop using the devices as foreign particles on the needle assembly could be transferred to the patient's eye during the procedure.

Allergan said that foreign particles in the eye could result in irritation, inflammation, local allergic reaction, hypersensitivity, iritis/iridocyclitis or uveitis/sterile endophthalmitis.

It warned that removal of an implanted XEN device is not recommended, and physicians should continue the standard of care post-operative follow up regime for XEN surgery.

### Switzerland to Mirror EU MDR For Combination Products

The Swiss agency for therapeutic products said it will follow the EU's Medical Device Regulation for combination products.

Applications for an integral device combination product that lacks certification from a conformity assessment body must demonstrate that the device component satisfies requirements under Annex 1 of the EU MDR 93/42/EEC, the agency said.

Swissmedic said it will follow the revised provisions under the new EU MDR once the regulations become effective in May 2020. Under the new regulation, a notified body opinion must be submitted with applications for integral device components.

### TGA Flags Risks for Accu-Chek Blood Glucose Meters

Australia's Therapeutic Goods Administration announced product defects in the Accu-Chek Guide and Accu-Chek Performa blood glucose meters that could cause a delay in therapy.

Accu-Chek Guides with serial numbers lower than 92911000001 and Performa meters with serial numbers between 68920000000 and 68925525056 may display battery replacement indications, unexpectedly show the low battery icon, have short battery life and fail to turn on, the agency warned.

The errors could lead to serious medical issues for diabetic patients if therapy decisions are hindered by the device defects, the agency said.

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### Implant, *from Page 3*

"BioCorRX and the [Louisiana Department of Public Safety and Corrections] conducted what clearly amounts to a clinical investigation testing a sustained-release naltrexone implant in prison inmates," according to the Public Citizen petition signed by experts in consumer protection, bioethics and human rights.

The prisoners were unaware that the implant was not approved by the FDA for use, and also that they were part of an experiment.

The company was also planning on testing the addiction device implant in the homeless in Philadelphia, but did not get that far as it lacked state approvals.

In announcing the first implant in its pilot medication-assisted treatment program in May, BioCoRx noted that naltrexone implants have been used worldwide for about 20 years. "We are proud to partner with the Louisiana Department of Corrections to showcase the effectiveness of sustained release naltrexone combined with structured behavioral therapy and peer support," said BioCorRx CEO Brady Granier.

Read the citizen petition here: www.fdanews.com/11-20-19-Letter.pdf.

## 483 Roundup: FDA Flags Three Devicemakers for GMP Lapses

**Environmental Tectonics:** A litany of good manufacturing practices lapses related to documentation and validation resulted in a seven-item Form 483 for Environmental Tectonics following an inspection of its Southampton, Pennsylvania facility.

The company manufactures industrial sterilizers as well as test chambers.

FDA inspectors observed service reports that represented medical device reportable events that were not considered complaints and processed as such. For example, one service report documented a broken handle on a hyperbaric chamber in which a patient was locked for about 20 minutes. A user facility adverse event was filed with the FDA, but no information was available in the service report concerning the medical impact on the patient, the agency said.

In addition, a review of the service report log noted that a previous complaint describing a patient locked inside a hyperbaric chamber was documented about six months earlier.

In a separate observation, a field steam sterilizer, which was designed and labeled for sterilizing porous and nonporous heat and moisture stable surgical instruments, was not properly validated, and there were no performance data available to ensure the device met its intended purpose. No verification specifications were documented in the firm's acceptance activities.

Other records were missing for the steam sterilization device, including device history records and test checklists.

A device history record for another instrument, the bara-med monoplace hyperbaric chamber, didn't refer to the location of a unique device identifier or universal product code. Other devices were also lacking information on UDIs and UPCs, the investigators said.

*(See* **483s**, *Page 6)*

### Tips for Managing Complaint Investigations

Once a complaint is deemed potentially reportable as a medical device report (MDR), a designated individual within the complaint handling unit must promptly begin an investigation.

The skill set for an MDR investigation is specialized and different from skills required for other investigations, so it is important that devicemakers carefully select and train employees to conduct MDR investigations, according to quality expert Dan O'Leary, president of Ombu Enterprises.

The investigation must determine whether the device failed to meet a specification. If so, it must ferret out the root cause of the inadequacy. It also must examine the relationship of the device to the reported incident or adverse event.

The investigation should conclude with a determination of whether or not a CAPA is needed. The complete results of the investigation must be included in the MDR event file and the regulations require an individual MDR record for each event. The information is collected in the MDR event file, which is linked to at least one individual complaint record.

If there are multiple complaints about the same issue, the MDR event file for that issue or event could be linked to multiple individual complaint records. These files need to include all information about the adverse event, such as documentation, deliberations, reportability decision-making, information submitted to the FDA and acknowledgements that the MDR was successfully uploaded to the FDA database.

FDA employees must be allowed to access, copy and verify these records. It is acceptable for the MDR event file to be part of a complaint file. In such cases, the devicemaker must clearly identify the complaint file as having an associated or included MDR event file.

**Excerpted from the FDAnews management report: *Complaint Management for Devicemakers: From Receiving and Investigating to Analyzing Trends*.**

**483s**, *from Page 5*

**Xodus Medical:** Numerous complaints for unsealed cautery tip cleaning surgical devices were not documented as complaints, and validation procedures were found to be lacking at Xodus Medical during an inspection of its New Kensington, Pennsylvania plant.

The maker of surgical equipment failed to review, evaluate and revalidate its production process for sealing when changes and process deviations occurred. When products were returned due to failure to meet their specifications, these complaints were not reviewed, evaluated or investigated, the FDA said.

The agency investigators said the firm's production processes were "not conducted, controlled and monitored to ensure that a device conforms to its specifications." Equipment used in production was causing unsealed packaging of sterile products, and lots were not inspected before being shipped and released.

Between Nov. 1, 2016 and July 25, 2019, the company received 453 Returned Goods Authorizations (RGA) for products, but the RGAs were "not all shared or provided to the department responsible for evaluating complaints," and they were not reviewed and evaluated to determine if the reported failures required documenting a complaint, the 483 said.

In addition, corrective and preventive action activities were not documented, and procedures for rework of nonconforming product were not established, the FDA said.

**Bellaire Aesthetics:** Bellaire Aesthetics didn't establish procedures for receiving, reviewing and evaluating complaints, an FDA inspection of the firm's Middle Island, New York facility revealed.

The company makes skincare devices, such as microneedle devices for aesthetic purposes.

The three-item 483 cited the firm for not establishing written procedures that describe how it stores products to prevent potential mix ups.

During the inspection, investigators observed that the storage area "did not appear to be organized," and there were no specific product placement or quarantine areas. The 483 noted that the device-maker discontinued selling certain medical devices that were still being stored in its inventory alongside products that were currently offered for sale.

Investigators also observed that the company had not established any complaint procedures to specify how the firm receives, reviews, evaluates and maintains complaints.

The manufacturer also failed to establish medical device reporting procures for evaluating and investigating complaints or for reporting adverse events to the FDA.

Read the Environmental Tectonics Form 483 here: www.fdanews.com/11-21-19-environmental-tectonicscorp483.pdf.

Read the Xodus Medical Form 483 here: www.fdanews.com/11-21-19-xodusmedicalinc483.pdf.

Read the Bellaire Aesthetics Form 483 here: www.fdanews.com/11-21-19-bellaireaestheticsinc483.pdf.

## Industry Urges Australia to Follow International SaMD Classifications

The proposal by Australia's Therapeutic Goods Administration to align its regulation of software as a medical device with the EU's approach drew general support from stakeholders, with some also urging the agency to look at approaches by the International Medical Device Regulators Forum, the FDA and Health Canada.

The agency proposes to classify software according to its potential to cause harm and to ensure that software products that are downloaded from overseas suppliers have an Australian sponsor who is responsible for the product in the Australian market.

Most comments supported aligning the classification levels with either the EU Medical Device Regulation or the classification principles of the International Medical Device Regulators Forum.

Public comments on the proposal generally supported a requirement for downloaded software to have an Australian sponsor, but devicemakers said it would be challenging to enforce.

Some stakeholders questioned the TGA's proposed changes to the framework for regulating medical devices software, citing concerns about the cost of compliance for products that may have a new classification based on the safety risk.

Johnson & Johnson said it supported the TGA's proposal to develop a risk-based pathway for SaMD and global harmonization of these requirements. It urged the TGA to align its regulations with the IMDRF risk classification system.

J&J also proposed that the TGA exempt low-risk devices from the regulations and take an approach similar to the FDA and Health Canada that focuses on higher-risk products.

Roche noted that the number of Class I software products would be minimal, and that only one type of software functionality results in a Class I determination.

Read the J&J and Roche comments here: www.fdanews.com/11-22-19-Submission.pdf.

# APPROVALS

### Avatera Nabs CE Mark For Robotic Laparoscopy Device

Avatera has received the CE Mark for its Avatera system, a robotic device used to perform minimally invasive laparoscopy procedures.

The device consists of two components: a surgical robot with four arms used to control an endoscope and Avatera instruments, and a control unit containing manual input devices, foot switches and an eyepiece.

The system employs a single-use concept for instruments and sterile accessories, removing the risk of cross-contamination.

### Axonics Earns FDA Premarket Approval For Sacral Neuromodulation Device

Axonics has obtained the FDA's premarket approval for its sacral neuromodulation system for treating overactive bladder and urinary retention.

The implantable, rechargeable device is the first of its kind to be approved by the FDA, and the only sacral neuromodulation device greenlit for full-body MRI scans without removal.

With the agency's decision, patients receiving an MRI scan anywhere below the head can avoid additional surgery, as they no longer need to have their neurostimulator removed before they undergo the scan.

### FDA Clears Ultromics' AI-Powered EchoGo

Ultromics has received 510(k) clearance from the FDA for its AI-powered technology, EchoGo, which assists in the measurement of heart functions, including automated cardiac strain.

The technology automatically analyzes ultrasound-based heart scans to calculate cardiac

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

**Approvals**, *from Page 7*

strain. It is the first AI application cleared for that use. EchoGo also measures left ventricular ejection fraction and left ventricular volumes.

## Hologic's Breast Cancer Imaging Technology Cleared

Hologic's 3DQuorum Imaging Technology received 510(k) clearance from the FDA. The technology lowers the number of 3D images needed in reviews of breast cancer.

The technology, powered by Hologic's artificial intelligence analytics system, reconstructs high resolution 3D data to make six millimeter "SmartSlice" images, helping physicians to more quickly identify areas of interest in breast cancer patients.

Using Hologic's 3DQuorum, radiologists require only one third of the 3D images they normally require during review, the company said.

## Sky Medical's Geco Device Cleared for Marketing

UK-based Sky Medical Technology received 510(k) clearance from the FDA for its geko device for stimulation of the calf muscles to prevent venous thrombosis in non-surgical patients at risk for venous thromboembolism (VTE).

The device was previously cleared for immediate post-surgical stimulation of calf muscles to prevent VTE, increasing blood circulation and edema reduction.

The geko is a battery powered, wearable device the size of a wristwatch and worn at the knee. It stimulates the common peroneal nerve activating the calf and foot muscle pumps, resulting in increased blood flow in the deep veins of the calf.

## Paige Earns CE Mark for Prostate Cancer Detection Solution

Paige has earned the CE Mark for the Paige Prostate, a first-in-class prostate cancer detection solution, along with the Paige Insight, its AI-based digital pathology viewer.

The vendor neutral products allow pathologists to view and collaborate on digitized slides from different sites and scanners. The Paige Prostate provides clinical grade accuracy, with equivalent performance in images taken with multiple scanners and on slides prepared at hundreds of institutions.

Pathology practices around the world have begun to embrace digital pathology to "realize the potential of the technology with real-time quality assurance, gains in productivity, and improved collaboration across sites," said Paige CEO Leo Grady.

## Biocept's Sample Collection Kit Earns CE Mark

Biocept has received the CE Mark for its CEE-Sure blood collection tube and sample collection shipping kit.

The collection tube is designed to keep blood samples from coagulating and to protect cells, allowing samples to be transported without refrigeration or special shipping conditions.

The product offers the ability to preserve and ship specimens containing circulating tumor cells, circulating tumor DNA, and circulating tumor RNA for use in oncology and prenatal diagnostics, as well as other molecular testing.

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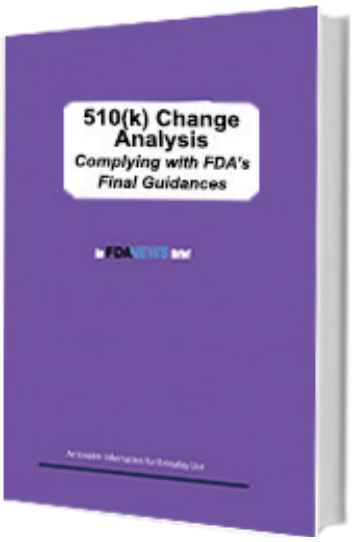


# 510(k) Change Analysis: *Complying with FDA's Final Guidances*

**510(k) Change Analysis: *Complying with FDA's Final Guidances*** breaks down the guidances finalized in October, 2017 — *Deciding When to Submit a 510(k) for a Change to an Existing Device* and *Deciding When to Submit a 510(k) for a Software Change to an Existing Device* — and provides a step-by-step method for making the right call for submitting a new 510(k) application. Expert-developed spreadsheets walk you through the questions you must ask and lead you to the proper conclusion.

After reading this book, you'll understand:

- What kinds of changes trigger the need for a new 510(k) application and which don't
- How to evaluate the effect of the change on the device's safety and effectiveness
- How to assess the risk the change may introduce
- The components of risk as described in ISO 14971
- How to follow the complex flowcharts the guidances present
- How to develop a risk matrix
- How to document the decision-making process, including justifying a decision not to file a new 510(k)

In addition to the decision-making spreadsheets that all but do the work for you, the report includes copies of both guidances and an example of a change analysis effort.

Order your copy of the **510(k) Change Analysis** brief for step-by-step instruction on deciding whether you need to submit a new 510(k) if you change an existing device.

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# The EU-MDR Transition: *Meeting the CE Mark Deadline*

If you plan to continue putting devices on the European market, you'll need to implement the EU-MDR.

Due to the slow progress in the EU companies are being guided through a soft transition plan.

**Dan O'Leary** — industry expert with more than 30 years of experience in quality, operations and program management — explains the hybrid system, where you maintain a device certificate under the MDD and a QMS under the MDR.

**The EU-MDR Transition: *Meeting the CE Mark Deadline*** explains how to take advantage of the soft transition to the new regulation. The soft transition allows companies to retain certain aspects of the current CE Mark applications while following new registration requirements, if their notified bodies approve.

But, what does that really mean?

This report breaks down all the rules and explains all the implications of a soft transition, providing a path to follow to full compliance:

- **Transition Timeline:** All the dates and deadlines on the transition timeline
- **SOPs:** How to develop an SOP for the post market surveillance you will have to conduct under EU-MDR
- **Adverse Events:** How to report adverse events
- **Forms:** What new forms will be required
- **Technical documentation:** How to structure technical documentation for your hybrid system

Start implementing the hybrid MDD/MDR system to keep your products on the European market until the full EU-MDR comes into effect.

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