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IN THIS ISSUE

FDA Aims to Encourage Consumer Access to Genetic Tests

The FDA has classified genetic health risk assessment systems as Class II with special controls, and is proposing to exempt the devices from premarket reviews.

Consumers are increasingly embracing genetic health risk (GHR) testing to learn their individual risk for developing certain diseases, prompting some to make more informed lifestyle choices, noted FDA Commissioner Scott Gottlieb.

The saliva-based tests require special controls to ensure that they can provide reasonable assurance of safety and effectiveness. By combining special controls with a premarket review exemption, the agency "seeks to strike a balance that provides for an efficient pathway to bring these tests to consumers, without sacrificing the assurances offered by FDA oversight," Gottlieb said.

The requirement for the FDA to publicly disclose its proposed list of device types that could be potentially be exempt from a

(See **Tests**, *Page 2)*

TGA Updates Regulatory Framework For 3D-Printed, Personalized Medical Devices

Australia's Therapeutic Goods Administration is proposing five changes to its regulatory approach for 3D-printed and personalized medical devices to reflect the rapid technological advancements over the past two decades.

"The idea that a hospital would be able to use a 'printer' to manufacture an implant for a particular patient's anatomy would have been considered impossible in the not too distant past; but it is a reality today," the TGA said, in a consultation paper.

The agency is inviting comments on the following proposed changes:

- Changing the definition of custom-made medical devices to be inclusive of 3D-printed patient-specific devices, and adding new definitions for customized medical device; patient-specific medical device, personalized medical device, mass produced medical devices and medical device production system;

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premarket review, if and when finalized, was created by the 21st Century Cures Act. Testing systems for evaluating vitamin D levels and endoscopic maintenance systems are among the other listed device types for potential exemption.

Under the limited exemption, GHR systems would be subject to a one-time FDA review, to mitigate the risk of false negatives and false positives by ensuring that certain information be submitted to FDA to allow the agency to assess the safety and effectiveness of the device and the regulatory controls necessary to address those issues as well as to ensure the devices perform to acceptable standards, the agency said.

The tests present risks of misleading or inaccurate results that could be used by patients to make decisions without consulting their care providers. To address this issue, the agency is requiring that manufacturers of the tests abide by the special controls in the GHR final order. They include:

- A statement in device labeling explaining that the test" provides genetic risk information based on assessment of specific genetic variants but does not report on a user's entire genetic profile";
- The genetic test must use a sample collection device that is FDA-cleared, -approved, or –classified as 510(k) exempt, with an indication for in vitro diagnostic use in over-the-counter DNA testing; and
- A hyperlink in device labeling that directs consumers to a web page on the manufacturer's website with information about the device, such as any changes to the device that could significantly affect its safety or effectiveness.

Manufacturers may provide direct-to-consumer access to new GHR tests only after they have demonstrated conformance to the special controls, and have received a one-time FDA review.

The agency's new regulatory approach for GHR tests "builds on the important lessons we learned from the FDA's authorization of the first GHR and carrier screening tests sold directly to consumers," Gottlieb said. The genetic testing company 23andMe prompted the new regulatory approach when it submitted a De Novo classification request to the FDA for its personal genome service test in June 2016.

In April, the FDA granted the company marketing approval for the first direct-to-consumer genetic tests that could identify risks for 10 diseases, including Parkinson's disease and late-onset Alzheimer's disease. It also announced its intention to exempt these and other GHR testing systems from premarket reviews (*IDDM*, April 10).

Read the final order on GHR tests here: www.fdanews.com/11-08-17-MDClassification.pdf.

Read the notice on exemptions from premarket notification here: www.fdanews.com/11-08-17-MDPremarketNotification.pdf. — Ana Mulero

TGA, *from Page 1*

- Adding new requirements for manufacturers to the conformity assessment procedure for custom-made devices, such as providing a statement about a device to the patient receiving it; and allow TGA to inspect facilities that produce custom-made devices;
- Changing the definition of a manufacturer to clarify that producers of customized devices, such as healthcare providers, are not required to meet the same regulatory requirements of manufacturers because they are not defined as such;
- Redefining diagnostic imaging recording devices to add "software and anatomical models intended for diagnosis or investigation of the anatomy" to the classification; and
- Reclassifying devices with human material as Class III medical devices, rather than biologicals, to be better aligned with other jurisdictions like Europe and Canada.

TGA called on stakerholders for feedback on the proposed regulatory changes to address any potential unintended consequence.

Read the consultation paper here: www.fdanews.com/11-10-17-Consultation.pdf.

Japan and Poland Sign Confidentiality Agreement in Move Toward MDSAP

Japan and Poland signed a confidentiality agreement to share regulatory information in a move that will make it easier for Poland to participate in the Medical Device Single-Audit Program.

The agreement will facilitate the flow of information and documentation between Japan's Ministry of Health Labor and Welfare (MHLW) and Pharmaceutical and Medical Devices Agency (PMDA) and Poland's Office for Registration of Medicinal Products, Medical Devices and Biological Products (URPLWMiPB).

Japan, which joined the MDSAP Consortium in June 2015, has been reaching out to global regulators to get them involved in the program. PMDA has been ramping up training activities with overseas regulators, and it invited international regulators to a medical device seminar in Tokyo, Nov. 6-10.

The MDSAP initiative aims to allow a single audit to verify compliance with regulatory requirements of all program participants.

If successful, the program will make better use of human and material resources, and will have a long-term impact on global regulatory harmonization, the Polish regulatory authority said.

Poland is an EU member, but the EU has not yet signed on to MDSAP, although it currently has observer status at MDSAP Consortium meetings (*IDDM*, May 15).

The MDSAP program will not become fully operational until Jan. 1, 2019, but participating manufacturers and auditing organizations have begun to prepare for how MDSAP regulatory authorities will use program outcomes.

For example, Health Canada will use MDSAP certificates to decide on whether to issue device licenses, and program audit reports submitted to the CDRH will be accepted as substitutes for routine FDA inspections (*IDDM*, Sept. 25).

Devicemakers selling products in Canada must comply with the single audit requirement by March 2019. Health Canada will expect all device licenses to be supported by MDSAP audits by that time, and if a manufacturer doesn't have a MDSAP certificate, its license will be suspended.

Companies selling their devices in other regions covered by the MDSAP Consortium — which currently includes Australia, Brazil, Canada, Japan and the U.S. — should be aware that information from the Canadian audit will be shared with the regulators in the other regions.

Poland has also signed bilateral cooperation agreements with the FDA, South Korea's Ministry of Food and Drugs Safety, Mexico's Federal Committee for the Safeguarding of Health (COFEPRIS) and the Chinese Food and Drug Administration.

India Aims to Ease Import Process for Medical Devices

Medical device and IVD imports to India should not be held up at ports because of "slight confusions" over product names, pending applications during mergers and acquisitions, or shelf-life issues if the importers have valid registration certificates and import licenses, according to the Central Drugs Standard Control Organization.

The CDSCO issued an Oct. 31 notice to port offices in response to complaints that products were being inappropriately withheld for those reasons.

U.S. devicemakers, meanwhile, continue to push back against India's new price controls on certain devices that resulted in sharp decreases in their average prices, and say some may pull their products from the Indian market.

India set price caps on coronary stents and knee implants but is considering extending the caps to other medical devices such as orthopedic implants and catheters (*IDDM*, Oct. 23).

Device Tax Repeal Letters To Congress Keep Piling up

The push for a permanent repeal of the Affordable Care Act's medical device tax has gained significant momentum with two more letters to Congress — one from 13 patient advocacy, disability, research, and community healthcare organizations; and another from Research!America.

Devicemakers across the U.S. have been pushing for the repeal of the 2.3 percent excise tax, which went into effect in 2013, but is currently suspended through Jan. 1, 2018.

Earlier this year, representatives of 36 conservative groups sent a letter to Congress urging lawmakers to block the return of the device tax on Jan. 1, following the two-year suspension under the Consolidated Appropriations Act of 2016 (*IDDM*, Aug. 21).

Opponents of the tax cite concerns that it will hinder innovation efforts and job creation in the industry. AdvaMed reported in February that the latest data from the U.S. Department of Commerce showed the medical technology industry lost nearly 29,000 jobs while the device tax was in effect (*IDDM*, March 13).

Research!America President and CEO Mary Woolley wrote in a Nov. 2 letter that the nonprofit alliance — with members that include patient advocacy groups, universities, and academic health centers — believes that the 115th Congress has been laying the groundwork for "a new era of unprecedented advancement" against chronic health conditions, but that "the nation would be blocking its own path by sustaining the medical device excise tax."

Reinstatement would stifle R&D investment in devices, which in turn would have a larger adverse effect on the patients with the certain health conditions such as cardiovascular disease for which technological advancements are more important, Woolley said. It would also negatively impact the development of new diagnostic tools, she said.

Her concerns were echoed in a Nov. 8 letter by the 13 advocacy groups, which include the AIDS Institute, the Congress of Neurological Surgeons, and the U.S. Pain Association.

They argued that the uncertainty around the future of the tax is "preventing manufacturers from maximizing investments in the research and development needed to continue to improve patient care in the U.S. and around the world" and pointed to the multiple advancements in medical device innovations that millions of Americans have benefitted from in recent years as well as the potential that these hold for the future that would be affected if the tax were to be reinstated.

The advancements, such as implantable technologies, advanced imaging systems, and patient monitoring solutions, have resulted in an increased life expectancy in the U.S. of more than five years, and significant reductions in mortality rates for major diseases, including stroke and heart disease with a reduction of nearly 60 percent, the patient advocacy groups said.

The repeal has bipartisan support. It was included in the GOP's proposed bill to repeal and replace the Affordable Care Act, which was withdrawn earlier this year.

Read the patient advocacy groups' full letter here: www.fdanews.com/11-09-17-medicaldevicetax.pdf.

Read Research!America's full letter here: www.fdanews.com/11-09-17-MDtax.pdf. — Ana Mulero

FDA Flags GMP Problems At Indiana Devicemaker

Production workers at ATS Manufacturing threw out all of the nonconforming products they found and failed to document any follow-up activities over the course of nearly four years, an FDA investigator discovered in an August 14-18 inspection.

In a Form 483 report, the FDA official listed inadequate procedures for controlling nonconforming products among 10 inspection observations at the medical device manufacturer's facility in Elkhart, Indiana.

Between October 2014 and August 2017, production workers said they had been scrapping all nonconforming products they identified but documentation of this activity could not be found during the inspection.

The facility also lacked documentation for inspection of raw materials since January 2015, and many required device history records.

The investigator also identified problems in calibrating and maintaining equipment. The firm's calibration log revealed that the last calibration was performed on Feb. 5, 2014 and the due date for the next calibration was listed as Feb. 5, 2015. The firm failed to document that maintenance had been done on any equipment since January 2015.

In addition, there was no evidence of any internal quality audit being performed at the facility since July 11, 2014, and management had yet to conduct a single review of the firm's quality system.

Other nonconformities noted in the Form 483 report relate to process validation, CAPA procedures, as well as monitoring and controlling process parameters.

For example, the firm failed to provide evidence that the quality data sources in a CAPA procedure had been documented between Jan. 1, 2015 and Aug. 14, 2017, or analyzed to determine whether a correction action was needed.

Read the ATS Manufacturing Form 483 here: www.fdanews.com/11-09-17-atsmanufacturingllc483.pdf.

How to Build a Better Internal Audit

The annual internal audit can be considered the devicemaker's front-line defense against 483 observations, warning letters and other enforcement actions. As such, it needs to be carefully designed, targeted to specific goals and fully supported by management.

Four common mistakes keep showing up on 483s and warning letters. One of the most common citations is companies using internal auditors who have direct responsibility over the area they are reviewing. For instance, if complaint handling falls under the purview of the quality systems manager, that individual should not audit the complaint handling process. Independence of the auditors is a requirement under 21 CFR Part 820, the Quality System Regulation (QSR).

Another common citation is for companies that don't do internal audits at all, or don't do them with sufficient frequency, which for the FDA means at least once a year.

Failure to establish procedures for internal audits, along with the related citations of failing to establish adequate procedures or failing to follow written audit procedures, are a third common citation in 483s and warning letters. Devicemakers need to have a document that states what they will do regarding internal audits and then follow those procedures.

The fourth top citation is failure to adequately document audit findings. It doesn't matter how well a company may have conducted an audit or followed its audit procedures if there is no documentation of that fact. Documentation procedures should be included in the overall audit procedures and followed scrupulously.

Excerpted from the FDAnews report: ***Effective Internal Audits and Quality Control Units for Devicemakers*****.**

Pfizer EpiPen Manufacturer Draws Lengthy FDA Inspection Report

A Pfizer company was hit with a lengthy Form 483 from the FDA for 14 nonconformities.

A team of FDA investigators and officials inspected Meridian Medical Technologies' EpiPen manufacturing plant in Brentwood, Missouri from February through March and found major issues with validating and verifying product designs.

The combination drug/device manufacturer had not established adequate input and output design procedures at the time of the inspection.

Design requirements for its products, including the EpiPen and EpiPen Jr., were inappropriate for ensuring their delivery system was reliable, the agency said. The company had not completed any design validation testing.

The agency also flagged problems with complaint handling and investigations that identified manufacturing defects, and visual inspections that failed to remove all of the defective units.

Read the Meridian Medical Form 483 here: www.fdanews.com/11-09-17-meridianmedicaltechinc483.pdf.

FDA Finalizes De Novo Evaluation Guidance, Proposes Acceptance Criteria

The FDA finalized guidance on the evaluation process for De Novo classification requests and issued draft guidance on the acceptance criteria.

The final guidance, first drafted in August 2014 to update the agency's 1998 policy, provides a pathway for Class I or Class II classifications. It includes updated recommendations on two interactions between industry and agency staff during the De Novo classification process — the optional pre-submission interaction for obtaining feedback on a request prior to submission, and the De Novo request.

The agency issued a separate summary document on the two options for De Novo classification of devices with low or moderate risk, one for devices that have received a Not Substantially Equivalent determination in response to a 510(k) submission, and another for devices for which there is no existing device to assess substantial equivalence.

The guidance includes the criteria agency staff will use when evaluating a De Novo request, and it describes when the review clock will stop while a request is placed on hold. For example, De Novo requests that lack sufficient information to determine whether there could potentially be existing predicate devices may be placed on hold.

The draft guidance outlines preliminary questions for the FDA's initial review of a request, and the criteria agency staff will use in the acceptance review process It also includes a checklist for De Novo classification requests.

Read the final guidance here: www.fdanews.com/11-01-17-DeNovoClassificationProcess.pdf.

Read the draft guidance here: www.fdanews.com/11-01-17-AcceptanceReview.pdf.
— Ana Mulero

3D Printing Set to Transform Device Industry, Experts Say

3D printing is poised to transform the medical device industry, according to several players in the space who participated in a recent FDAnews webinar.

Simulation and modeling using 3D printing are "really at the forefront of the precision medicine revolution," said Daniel Matlis, founder and president of Axendia.

To date FDA has cleared more than 85 applications for 3D-printed medical devices which span product lines such as prosthetics and implants, said Matlis, who moderated the webinar, titled When it Comes to 3D Printing, the Future is Already Here: *Are You Ready for the Precision Medicine Revolution?*

Though 3D printing was born in the 1980s, recent years have seen significant advances. The dental industry embraced it first, using it to make printed braces, sometimes onsite — think Invisalign.

Now companies are using it to design and custom make medical devices, and making 3D models of a patient's anatomy to enable surgeons to perform practice runs of a surgery before opening the patient up, thus reducing time in the operating room and improving outcomes, said Matlis. The emerging area is called patient-specific preoperative planning.

This use of 3D printing is already helping the medical device industry speed up the product development lifecycle, said Thomas Marchand, co-founder and CEO of BIOMODEX, a tech startup that develops 3D printed surgical simulators from CT scans for surgery planning.

It's "de-risking the operation," choosing the best medical device for every patient, and training the physician to position the device the right way every time, he said.

The process also assists with training for a new device, and provides clinical study support.

"We can simulate. We can provide synthetic organs for the physicians to train on the day before the operation," said Marchand, whose company is part of the 3D Experience Lab, a startup accelerator driven by Dassault Systems. — Suz Redfern

APPROVALS

Butterfly Network Receives 510(K) Clearance for Chip-Based Imaging System

Butterfly Network received FDA 510(k) clearance for its ultrasound-on-a-chip based imaging system, the Butterfly iQ for iPhone.

The clearance covers 13 clinical applications for a single ultrasound transducer. The technology combines the capabilities of the typical three probes into a single ultra wide-band, 2D matrix array comprised of thousands of microelectromechanical systems.

The artificial intelligence applications are tightly coupled to the hardware to assist clinicians with image acquisition and interpretation.

Abbott Wins CE Mark For XIENCE Sierra Stent

Abbott earned a CE Mark for its XIENCE Sierra coronary stent system.

The device helps cardiologists to access and unblock difficult-to-reach lesions. It features a thin profile, increased flexibility, longer lengths, and small-diameters.

Abbott has submitted an application to the FDA for approval of the device in the United States.

IRadimed Wins 510(k) Clearance of MRI-Compatible Patient Vital Signs Monitor

IRadimed received marketing clearance from the FDA for its 3880 magnetic resonance imaging-compatible patient vital signs monitoring system.

The non-magnetic monitor can be used to transport patients from critical care departments of hospitals to the MRI scanner room and back to critical care without an interruption in vital signs monitoring.

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The device has a wireless tablet remote control that allows for the transfer of vital signs information to clinicians.

FDA Clears Atlas Spine's Expandable Implant

The FDA cleared Atlas Spine' Ortus implant indicated for restoring patients' anatomic alignment.

The expandable posterior lumbar interbody system's starting height (6.5mm) is one of the smallest in the expandable device market.

Surgeons pack graft material after the device is deployed. The Ortus PL is the first implant in a "deep pipeline" of expandable technology it plans on launching, the company said.

Luminex Strep Assay Wins FDA Clearance

Texas-based Luminex received 510(k) marketing clearance for its ARIES Group A strep assay.

The assay detects Steptococcus pyogenes using throat swab specimens. The strep assay is the sixth to receive FDA clearance for use in the ARIES system over the last 24 months.

Medtronic Receives CE Mark For Implantable Spinal Cord Stimulator

Medtronic received the CE Mark for the Intellis platform for both spinal cord stimulation and peripheral nerve stimulation as an aid in the management of certain types of chronic pain.

The device can improve patient-physician communication by tracking and sharing daily activities, body positions and therapy usage and giving physicians an objective view of mobility and progress.

The device is managed on the Samsung Galaxy Tab S2 tablet interface and can record and track patient activity 24/7. It is now available in Europe and the United States.

Abbott's Mitraclip Approved In Japan as Transcatheter Mitral Valve Repair Device

Abbott received approval from Japan's Ministry of Health, Labor and Welfare for the company's MitraClip device for treatment of people with mitral regurgitation, a progressive heart disease in which the mitral valve does not close properly, allowing blood to flow backward into the heart.

The MitraClip system is a catheter-based, minimally-invasive therapy delivered to the heart through a blood vessel in the leg. By securing a portion of the leaflets of the mitral valve with a clip, the heart can pump blood more efficiently throughout the body, relieving symptoms and improving patient quality of life.

MitraClip was approved by the FDA in 2013, after obtaining CE Mark approval in Europe in 2008.

Medacta Wins FDA Clearance for 3DMetal Tibial Cones for Knee Surgery

Medacta received FDA clearance for 3DMetal Tibial Cones for knee revision surgery. The device can be used for structural support in areas of bone deficiencies that may compromise revision implant fixation.

The cones recreate a structural foundation for the intended revision implant by achieving proximal fixation and force transmission in the remaining host bone.

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Customer Service
(888) 838-5578 • +1 (703) 538-7600
customerservice@fdanews.com

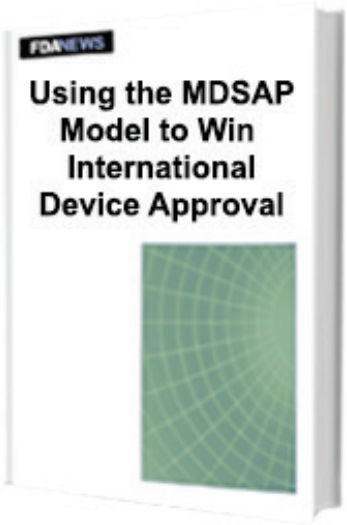
Editor: Ana Mulero
+1 (703) 538-7634
amulero@fdanews.com

Ad Sales: Jim Desborough
+1 (703) 538-7647
jdesborough@fdanews.com

Multi-User Sales: Jeff Grizzel
+1 (703) 538-7669
jgrizzel@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • www.fdanews.com

Reporters: Conor Hale, Zack Budryk, Gregory Roberts, Josephine Hill **Managing Editor:** Declan Conroy **President:** Cynthia Carter



Using the MDSAP Model to Win International Device Approval

Are you one of the 75% of device manufacturers who conduct internal audits solely "because you have to — because the FDA and ISO regs say so?"

Instead of cringing at the idea of conducting an internal audit, consider implementing the Medical Device Single Audit Program (MDSAP) model. It's a single audit of your quality management system and satisfies medical device regulatory authorities.

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

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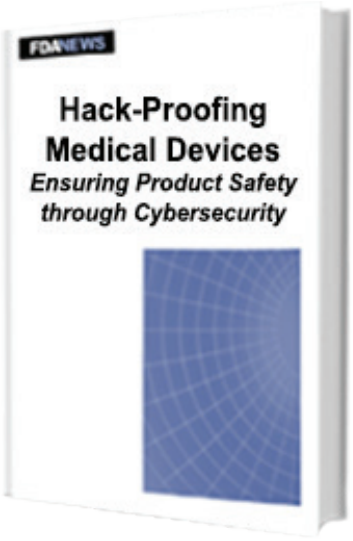

Hack-Proofing Medical Devices: *Ensuring Product Safety through Cybersecurity*

How does the FDA expect you to fight cyber incursions?

With the recent release of the final guidance on postmarket management of cybersecurity, you now have advice from the agency.

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