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IN THIS ISSUE

Editor's Note: Due to the holidays, *International Devices & Diagnostics Monitor* will not be published Dec. 25. The next issue will be published Jan. 1, 2018.

Patient Engagement Continues To Grow, Despite Difficulties

The shift to increased patient input for device development and clinical trials in recent years has been more challenging than expected, according to participants at the FDA/CMS Summit.

As part of a shift by the FDA to patient-centered care that began in 2011, the agency set a goal of increasing its engagement with patients and it is now 96 percent patient-engaged, according to CDRH Director Jeff Shuren.

The percentage of FDA-approved clinical trials that include patient-reported health outcomes has now reached 80 percent, Shuren said

Patient data that can be collected and analyzed for reducing inefficiencies or driving policy goals relate not only to the attributes of the devices, but also the tradeoffs the patients can accept. For example, the FDA approved the first portable hemodialysis device, NxStage's System One, this summer after study results showed

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Q&A: CDRH Director Jeff Shuren On Leapfrog Guidances

CDRH has been leading the way at the FDA with agency-wide policy advances, Commissioner Scott Gottlieb said at the AdvaMed MedTech Conference.

The center created a new model framework aimed at enhancing the review of total product lifecycles, and shifted its focus to quality product manufacturing. Director Jeff Shuren has spearheaded a lot of these changes, including a shift toward patient engagement. CDRH is now 96 percent patient-engaged, he noted at the recent FDA/CMS Summit.

The center issued "leapfrog" guidance earlier this month on considerations for additive manufacturing, or 3D-printing, of medical technologies and other products (*IDDM*, Dec. 11). The FDA uses

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this type of guidance to share its initial thoughts on emerging technologies that are likely to be of public health importance.

The final version of the guidance includes new information on 3D-printing of patient-matched devices, and Shuren said the agency is considering adding more details. He noted that these kinds of devices are an aspect of precision medicine, where medical care is tailored to a patient.

Shuren spoke to FDAnews about CDRH's use of leapfrog guidances.

Q: What does CDRH hope to accomplish with leapfrog guidances?

CDRH Director Jeff Shuren: I think what you're going to see in the future is our now systematically identifying what are the areas where we're anticipating to see novel technologies and there is insufficient guidance out there on what our recommendations would be on bringing the product to the market, so we can provide more predictability on some of those novel technologies.

A lot of times in our guidances, we try to cover a lot of ground. And in some cases, where we're pushing folks more and more is: "If we can't work everything out, that's fine. Let's just put pen to paper on what we have worked out and maybe enter part of the puzzle." That's a lot better than not saying anything. Let's not wait until we think we have all the answers.

There's certainly some that we've already put out like in the ophthalmological space for retinal implants — minimally invasive treatments on glaucoma. There are more things that we're looking at.

Q: How does CDRH determine what areas are in need of the agency's clarification in the form of leapfrog guidance?

Shuren: I think that you can anticipate us now using our horizon scanning capabilities to identify those places where we could have a big impact if we provided more clarity.

It might be that we don't have all the answers, which means that we have to be collaborating in the community to figure those out in advance of the technology coming out before us.

We did this for the artificial pancreas. We put out guidance in 2012 on these closed loop systems and that was years in advance of the first-generation artificial pancreas coming out. That's another example of leapfrog guidance.

Q: Did this guidance involve any special challenges?

Shuren: Because you're layering the material one on top of the other, depending on the material, how you layer it, the angles …it could change the properties of the device. We're trying to figure out what are the aspects of additive manufacturing that impact the characteristics and ultimately the final product, to then feed that information to product developers so that they can take it into account when they're making products. — Ana Mulero

Summit, *from Page 1*

patients were willing to take on the risk of using a dialysis machine by themselves, Shuren said.

The cost of patient studies can be an obstacle. Jamie Sullivan, vice present of public policy and outcomes at the COPD Foundation, pointed out that an IRB approval for a patient study can sometimes cost $1,000 or more and the process can take weeks to complete.

This may not be an issue for larger firms, but it may make conducting studies aimed at understanding a patient population nearly impossible for smaller firms, said Barry Liden, vice president of patient engagement at Edwards LifeSciences.

Another major challenge for patient groups and device firms has been getting health insurance companies more involved in patient data collection. Panelists said it has been very difficult to get payers involved unless there is a discussion around what's in it for them — reducing hospital readmissions, for example. — Ana Mulero

CDRH to Design New 510(k) Pathway, Outline 'Acceptable Uncertainty' Factors

A new 510(k) pathway for demonstrating substantial equivalence to an existing medical device can be expected to come out of CDRH as early as Q1 2018.

As part of developing the new voluntary and alternative 510(k) pathway, the FDA is also drafting new guidance on "acceptable levels of uncertainty" to establish a balance between the collection of pre-market and post-market data for approving premarket submissions of devices.

The FDA's regulatory process for manufacturers of new moderate-risk devices has "remained largely unchanged since it was first implemented 40 years ago," Commissioner Scott Gottlieb said in a blog post announcing the agency's intent to issue the draft guidances.

The existing framework for 510(k) submissions is failing to reflect the innovation that the agency is seeing today with certain medical technologies, and to "realize the full potential of the FDA's consensus standards program," Gottlieb said.

New 510(k) Pathway

The consensus standards program, which was established by the FDA Modernization Act of 1997, allows CDRH to use guidance documents to incorporate recognized standards intended to aid industry in demonstrating the safety and effectiveness of new technologies. According to Gottlieb, CDRH has issued guidance documents recognizing more than 1,200 national and international standards, entirely or partly, under the consensus standards program.

However, manufacturers are still required to demonstrate substantial equivalence through the 510(k) pathway regardless of whether they meet the consensus standards. This is also despite the fact that new products must sometimes be compared to 40-year-old predicate devices.

"It's sometimes hard to identify sufficient, appropriate predicate devices in order to conduct testing," Gottlieb said. "This can create an obstacle to certain kinds of innovation and lead to inefficiency in the review process with few, if any, benefits to patient safety," he added. "In fact, at times, it can make it less efficient for FDA to assure the safety of the device."

In its attempt to address these issues, the agency set a goal of releasing draft guidance outlining a 510(k) pathway by Q1 2018. It will be used for well-understood devices in pre-specified categories and is intended to provide additional flexibility in the submission process.

Devicemakers will be allowed to demonstrate substantial equivalence by meeting safety and performance criteria, including FDA-recognized standards, FDA guidance, or both.

Factors of Acceptable Uncertainty

In a separate draft guidance document, the FDA also intends to set forth its policy on "acceptable uncertainty" factors, such as public health need and the likelihood that uncertainty can be resolved in a post-market setting as opposed to pre-market, Gottlieb noted.

For example, the agency "might accept greater uncertainty for a device where gathering extensive clinical evidence pre-market would not be feasible given the small patient population that the device is intended to treat," according to Gottlieb.

In his blog post, Gottlieb only provided details on these two draft guidances set to be released in early 2018. But they are among numerous guidances CDRH has listed as priorities for the fiscal year.

CDRH divided the guidance topics into lists of high-priority (A-list), those that will be addressed if "resources permit" (B-list), and final guidances dating back as far as 1978 that are in need of a retrospective review. The two Gottlieb noted are on the A-list of draft guidances.
— Ana Mulero

CDRH Unveils Guidance Development List for FY 2018

Industry can get a glimpse of CDRH guidances set to be finalized, drafted or revised during fiscal year 2018 on a newly posted list on the FDA website.

Commissioner Scott Gottlieb offered some details on two of the listed draft guidances in a related FDA Voice blog.

One guidance, the Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria, will establish a new voluntary and alternative 510(k) pathway intended to provide additional flexibility.

Another guidance, the Application of Acceptable Uncertainty to Support Marketing Authorization Decisions for Medical Devices, will outline how the FDA intends to determine acceptable levels of uncertainty with submissions.

The two draft guidances will be given more priority for development during FY 2018 than some others included in the list, which is divided into guidance documents that the agency "fully intends" to issue (A-list), those that will be published "as resources permit" (B-list), and those that date back as far as 1978 and are "subject to focused retrospective review," the FDA said.

The lists are not meant to be comprehensive, and resource constraints or other issues may prevent CDRH from being able to go down the lists in their entirety, the agency said.

There are five final guidances on the A-list compared to a total of 10 that were listed for FY 2017. However, the number of A-list draft guidances to be published in FY 2018 is significantly greater than the previous year, 10 vs. 4 draft guidance topics (*IDDM*, Jan. 2)

The first final guidance on the A-list — Medical Device Accessories: Describing Accessories and Classification Pathway for New Accessory Types — will only receive revisions. It was issued in December 2016, defining accessory as "a finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices" (*IDDM*, Jan. 2).

Other final guidances on the FY 2018 A-list include:

- Unique Device Identification: Policy Regarding Compliance Dates of Class I and Unclassified Devices;
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices; and
- Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases.

Other draft guidances on the A-list include:

- Export Certificates;
- Multifunctional Device Products: Policy and Considerations;
- Humanitarian Devices Exemption (HDE) Program;
- 510(k) Third Party Review Program; and
- Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.

Final guidance topics on the B-list include Human Factors List of High Priority Devices, and Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics.

The two draft guidances on the B-list are Premarket Submissions for Patient Matched Guides to Orthopedic Implants, and Replacement Reagents Policy for Technologically Similar Instruments for In Vitro Diagnostic Devices. The list is significantly shorter than the B-list draft guidances for FY 2017 with eight different topics.

A total of 24 guidances from 1978, 1988, 1998 or 2008 were also selected for retrospective review, down from 53 in FY 2017.

Read the full announcement here: www.fdanews.com/12-14-17-CDRHFY2018.pdf. — Ana Mulero

TGA Logs More Adverse Event Reports for Devices

Australia's Therapeutic Goods Administration saw a significant increase in adverse event reports for medical devices in 2016 — logging 3,841 AERs compared with 3,359 the previous year.

Most of the reports (81 percent) were made by medical device sponsors, but the number of reports by doctors also spiked, increasing to 88 reports in 2016 from 54 in 2015.

During 2016, the agency conducted post-market reviews on heater-cooler devices, insulin pumps, prosthetic aortic heart valves, urogynecological meshes, self-test/point-of-care urine hCG pregnancy tests, chest drains, breast implants, gloves and chlorhexidine-based disinfectants.

Post-market reviews are usually triggered by adverse event reports, repeated recalls, recurrent breaches of the Advertising Code and TGA laboratory findings. Outcomes from postmarket reviews include changes to labeling or suspension or removal from the Australian Register of Therapeutic Goods (ARTG).

Earlier this year, the agency conducted a product safety review of heater-cooler devices after five confirmed reports of *Mycobacterium chimaera* infections following heart surgery. The regulator reported that all the patient infections in Australia were associated with Sorin Group's Stockert 3T heater cooler devices, and the agency withdrew that device as well as several others from the market (*IDDM*, May 22).

Most recently, the TGA removed transvaginal mesh products indicated for treating pelvic organ prolapse via transvaginal implantation. The agency had conducted a post-market review of the devices and determined that the risks outweighed the benefits. The agency removed 43 surgical mesh devices from the market and limited use of two mesh products for non-urogynecological purposes.

The TGA has received more than 40,441 adverse events reports involving medical devices since the agency's Incident Report and Investigation Scheme (IRIS) began collecting data in 1986. The IRIS program works closely with health facilities to improve awareness among health professionals about medical device adverse event reporting.

The TGA's Database of Adverse Event Notifications (DAEN) includes reports made to the TGA from sponsors, health professionals and the public. Reports in the database start from July 2012 when the database was launched.

Read the TGA report here: www.fdanews.com/12-12-17-TGApostmarket.pdf.

New Zealand Removes Surgical Mesh Products From Market

New Zealand's Medsafe is removing surgical mesh products from the market that are used for urogynecological indications.

The move follows a similar action by Australia's Therapeutic Goods Administration last month. Medsafe said it relied on Australia's safety report in making its decision.

"As is also the case in Australia, Medsafe's response is effectively a limit on the supply of mesh for the repair of pelvic organ prolapse and stress urinary incontinence rather than a limit on use of surgical mesh for other types of surgery," the New Zealand agency said.

Medsafe also will require suppliers to provide safety information about their devices.

"Most suppliers have indicated, in light of Australia's announcement on limiting the supply of these devices for this use, that they intend to voluntarily do the same here from Jan. 4 next year," said Julie Anne-Genter, associate administrator for health.

Medsafe's limitation means suppliers cannot market the devices for the surgery. There are two types of products used in New Zealand — one

(See **Mesh**, *Page 6)*

IDEs Submitted Under Early Feasibility Program Have More Than Doubled

The number of investigational device exemptions submitted under CDRH's Early Feasibility Study Program has more than doubled, with 57 submitted in FY 2017 up from 26 when the agency issued EFS guidance in 2013.

Agency officials said 75 percent of IDEs submitted over the last two years have received timely FDA approval within the 30-day review cycle.

Approximately half of EFS IDEs are submitted by small medical device manufacturers as the program is intended for agency staff to aid study sponsors, especially those with limited financial resources, during early clinical evaluations of new medical technologies.

"An important lesson learned from the EFS Program so far is that the enhanced opportunities for collaboration between the sponsor and FDA's review team are crucial for success," said Owen Faris and Andrew Farb at CDRH's the Office of Device Evaluation, and Maureen Dreher at CDRH's Office of Science & Engineering Laboratories in a blog post. — Ana Mulero

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is solely for transvaginal use, and the other for a range of surgeries.

Medsafe requires suppliers to either confirm that they will comply with the requirements of the TGA in Australia, or to supply information supporting continued use for these indications within the next 45 days. The deadline for this information is Jan. 24.

In June, Medsafe released an updated action plan to boost the safety of surgical mesh, prompted by adverse events linked to the device in recent years. Other changes the New Zealand government is supporting include a review of best practices around informed consent for mesh procedures (*IDDM,* June 12*).*

Australia Withdraws 45 Mesh Devices

Australia's TGA withdrew 45 devices from the market for urogynecological use following an extensive review that found that the risks outweighed the benefits of these products for treating pelvic organ prolapse.

In August, the TGA re-classified transvaginal mesh devices as "high risk," bumping them from Class IIb (medium to high risk) up to Class III (high risk), requiring manufacturers to seek additional regulatory approval (*IDDM*, Aug. 7).

Meanwhile, the FDA issued a final order in January reclassifying specialized surgical instrumentation for use with urogynecologic surgical mesh from Class I to Class II with special controls based on new information regarding adverse events (*IDDM*, Jan. 9).

In May 2014, the FDA published a proposed order to reclassify the devices from Class I to Class II. In the order, the agency said it would convene a panel to discuss the reclassification before finalizing it. The panel found that the devices are associated with various complications, including damage to blood vessels, nerves, and connective tissue, as well as irritation and infection.

AHA Urges FDA Cybersecurity Oversight of Devicemakers

The recent ransomware attacks in the U.S. healthcare industry have highlighted the need for increased product security for medical devices, the American Hospital Association said in a letter to the FDA.

Representing nearly 5,000 healthcare organizations, the association called on the FDA to increase its oversight of the medical device industry and to ease the "substantial and unsustainable" regulatory burden on hospitals and health systems.

More FDA oversight is especially needed with regard to updating and patching devices as new threats emerge, as well as efforts to improve transparency and the dissemination of key information regarding device software during cyberattacks, AHA said.

The association pointed to the upwards 200,000 computers across more than 150 countries that were victims of the WannaCry ransomware attack earlier this year.

Ransom payments were demanded to restore the attacked systems, the AHA noted, and the healthcare sector was a prime target because of the nature of the services provided. "Medical devices with embedded, outdated software likely were the vector," it said.

Some of its members reported that many devicemakers were slow to provide needed information about the products they use, such as the existence of cyber vulnerabilities, and the availability of device patches, during the WannaCry attack. The steps the devicemakers recommended to mitigate the impact of the attack, including taking a device off-line, were expensive, operational or affected patient care, according to the AHA.

In addition to recommending more FDA oversight of manufactures' device security efforts, the AHA recommended that the agency "proactively set clear measurable expectations" for devicemakers before cyberattacks occur as well as play a more active role during cybersecurity attacks. The role could include issuing FDA guidance to devicemakers on the "expectations for supporting their customers to secure their products."

As the healthcare system continues to be plagued by cyberattacks, new legislative efforts are underway to tackle the issue. Reps. Dave Trott (R-Mich.) and Susan Brooks (R-Ind.) introduced a bill mid-October targeting the country's cybersecurity vulnerabilities in connected medical devices.

The Internet of Medical Things Resilience Partnership Act calls for the FDA and the National Institute of Standards and Technology to form a public-private partnership that would be charged with developing standards, guidelines, frameworks and best practices to enhance the country's healthcare cybersecurity (*IDDM*, Oct. 16).

Last month, the House Energy and Commerce Committee set a Dec. 15 deadline for the Department of Health and Human Services to develop an action plan for creating "bills of materials" aimed at curtailing cybercrime. Each component of a medical technology would need to have its own BOM, as first recommended in a 2017 report from the HHS' cybersecurity task force (*IDDM*, Nov. 27). — Ana Mulero

House Proposes 5-Year Extension of Medical Device Excise Tax Suspension

The House Committee on Ways and Means has introduced a bill that would extend the temporary suspension on the Affordable Care Act's medical device tax by five more years.

If adopted, Rep. Erik Paulsen's (R-Mo.) legislation, H.R. 4617, would amend the Internal Revenue Code of 1986 section regarding the temporary moratorium on the 2.3 percent medical device excise tax by replacing "2017" with "2022" and become effective after Dec. 31, 2017.

The tax went into effect in 2013, but in the 114th Congress Paulsen helped pass a two-year suspension through Jan. 1, 2018 under the Consolidate Appropriations Act of 2016,

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FDA to Harmonize Adverse Event Codes with IMDRF Terminology

FDA Adverse Event Codes will be updated with a spring 2018 deployment of CDRH's electronic medical device reporting system and its eSubmitter software, the agency announced.

The changes to the codes used in eMDR reports for a Device Problem, Manufacturer Evaluation Method, Manufacturer Evaluation Result, and Manufacturer Evaluation Conclusion will be harmonized with adverse event reporting terminologies used by IMDRF — the global initiative involving regulatory bodies in the U.S., Australia, Brazil, Canada, China, Europe, Japan, Russia, and Singapore aimed at harmonizing medical device regulations.

eMDR deployment is currently set for Apr. 6, 2018. Earlier this year, the agency posted a notice about its plans to release version 3.0 of its eSubmitter software, which transmits the submitted files to the FDA gateway, this November but later changed the release date to December (*IDDM*, Nov. 6).

In June, eSubmitter received an update to generate R2 XML for all submissions, among other changes outlined in the new announcement. The new scheme allows for multiple devices and patients within a single submission. But the eMDR system will continue to only accept a single device and a single patient per report, the agency said.

The FDA encouraged stakeholders to "begin preparing to update the codes used in their HL7 ICSR XML applications…as soon as possible" because the codes being retired "will be rejected by eMDR once this update is deployed."

Code hierarchies posted on FDA.gov are linked to IMDRF codes as the agency ultimately plans to harmonize all other adverse event codes with IMDRF terminologies in a future update. — Ana Mulero

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Industry trade association AvadMed was quick to put out a statement after the 5-year extension was proposed in the House as it has been adamantly urging a full repeal of the tax, citing hindered innovation, deterred job creation, among other issues.

AvadMed's President and CEO Scott Whitaker applauded the proposed extension as "an important first step to provide medical technology innovators with confidence that this tax will not go back into effect" and urged Congress to adopt it "immediately."

The Medical Device Manufacturers Association and the Medical Alley Association issued similar statements, echoing the belief that the bill signals interest in a full repeal.

Medical Alley President and CEO Shaye Mandle said, "With bipartisan support and over 260 cosponsors, this proposal signals to health consumers and innovators that Congress is committed to helping people get the care and technology they need."

"While we know that Congressman Paulsen and others will continue to seek full repeal, this extension would allow current investments and plans to move forward, giving health consumers additional confidence in treatment options and improved outcomes," Mandle added.

The excise tax has been very unpopular not just in the medical device industry, but also among patient advocacy groups, healthcare organizations, and many others. Last month, two separate letters, including one from Research!America, were sent to Congress to urge a permanent repeal, arguing that reinstating the excise tax would stifle R&D investments in medical devices (*IDDM*, Nov. 13).

"If we want to protect and create more high-paying jobs and if we want to ensure more life-improving and life-saving technologies are available to help patients, we cannot allow the medical device tax to start up again," said Paulsen said in a statement. — Ana Mulero

Medtronic Pays $2M to Settle Unlawful Marketing Suit

Devicemaker giant Medtronic has agreed to a $2.4 million settlement in a case at Massachusetts' Suffolk Superior Court over claims about deceptively marketing its Infuse Bone Graft.

The payment amount may just be pocket change for the largest global medical device company, which has historically focused on products for the diabetic population. Yet Attorney General Maura Healey said it led to the conclusion of a multistate investigation, alongside attorneys general from Oregon, California, Illinois and Washington state, totaling a $12 million settlement.

The complaint claimed that Medtronic "used deceptive company-sponsored scientific literature to convey false and misleading claims about Infuse's safety, comparative efficacy, and superiority in order to expand the market" for the device, including offering millions in consulting fees to physician authors who published studies that "omitted discussion of adverse results, downplayed side-effects," among other allegedly deceptive information.

As part of the settlement, Medtronic also agreed to imposed requirements to have Infuse-related clinical trial data made available on ClinicalTrials.gov.

The Ireland-based company received FDA approval for Infuse in 2002, which is intended to help stimulate bone growth, for lumbar spine procedures. — Ana Mulero

APPROVALS

FDA Approves Monthly Buprenorphine MAT for Opioid Use Disorder

The FDA approved Invidior's Sublocade, the first once-monthly buprenorphine injectable as a medication-assisted treatment for opioid use disorder.

Buprenorphine, a partial opioid agonist, is one of three drugs approved as an opioid MAT. First approved in 1981, it is currently available as a generic tablet, dissolvable film or implant.

Last month, two FDA advisory committees overwhelmingly recommended approval of the pre-filled syringe; it will be distributed only to healthcare professionals for injection, to reduce the chances of diversion.

FDA Clears Flushable Lia Diagnostic Pregnancy Test

Lia Diagnostics achieved 510(k) clearance for a flushable, biodegradable pregnancy test for over the counter use.

The Lia Diagnostic Pregnancy Test features proprietary coating technology. The device is made from the natural, plant fibers used in most toilet papers and weighs less than six squares of the lading three-ply toilet paper.

FDA Approves EluNIR Drug-Eluting Stent System

Cardinal Health's interventional cardiovascular business, Cordis, and Medinol have scored FDA approval for their EluNIR drug-eluting stent system.

The EluNIR DES, which previously obtained CE Marking, is indicated for treating narrowing or blockages in patients with coronary artery disease — a common type of cardiovascular disease.

The stent was designed to have the "narrowest strut width of any stent in the U.S. market" to make it easy to use for clinicians, the companies said.

FDA Clears Camber Spine 3D-Printed Interbody Fusion Implant

The FDA issued 510(k) clearance to Camber Spine for its SPIRA –C Open Matrix Cervical Interbody device.

The 3D-printed implant features a roughed titanium surface designed to promote bone cell proliferation, and a pore size optimized for bone ingrowth.

It is indicated for use at one or two contiguous intervertebral levels in patients who have

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received at least six week of nonsurgical treatment for degenerative disk diseases. This is the second clearance the firm has obtained over the last four months for an implant in its SPIRA family.

VitalConnect Extends Wear Duration of Wearable Biosensor

VitalConnect has secured its fifth 510(k) clearance for a 25 percent extension in the wear duration of its wearable sensor — the VitalPatch — from 96 hours to 120, or five days.

The disposable biosensor is indicated for single patient use. It is the "smallest and lightest wearable biosensor" for the continuous, real-time monitoring of eight biometric measurements, including single-lead electrocardiography, heart rate, and activity, the company said.

Varian Secures ANVISA Registration For Halcyon Treatment System

California devicemaker Varian Medical Systems received registration from Brazil's ANVISA for its Halcyon treatment system.

The system is designed to enhance image-guided radiotherapy treatment for cancer. Halcyon can provide volumetric imaging in 15 seconds and the treatment workflow can be completed with nine steps.

Varian obtained Shonin Approval to introduce the device for commercial distribution in Japan last month.

Hologic's 3rd Respiratory Assay Snags FDA Clearance

The FDA cleared the third Hologic respiratory assay for use in its Panther Fusion system.

The AdV/hMPV/RV assay is indicated for the detection of adenovirus, human metapneumovirus, and rhinovirus. The other two respiratory assays that run in the Panther Fusion system — the Flu A/B/RSV assay and the Paraflu assay — received FDA clearance in October. The assays can perform multiple tests using a single sample.

FDA Approves Boston Scientific's Deep Brain Stimulation System

Boston Scientific won FDA approval for its Vercise deep brain stimulation system.

The system is indicated for treating symptoms of Parkinson's disease by delivering adaptable stimulation of a region in a patient's brain through implanted leads, powered by an implantable pulse generator device.

The battery-powered device was developed using cochlear implant technology. The battery is rechargeable and the battery can last up to 15 years or more.

Intersect ENT Snags FDA Approval For In-Office Sinus Implant Treatment

The FDA approved the SINUVA Sinus Implant, manufactured by Intersect ENT.

SINUVA is designed using bioabsorbale polymers to treat recurrent nasal polyps in patients who have previously undergone sinus surgery.

It can be inserted by physicians trained in otolaryngology during a routine office visit. It works by expanding the sinus cavity to deliver an anti-inflammatory steroid to the polyp disease site.

The implant softens and polyps decrease over time so patients have the ability to remove it by simply sneezing or blowing their nose after 90 days or earlier.

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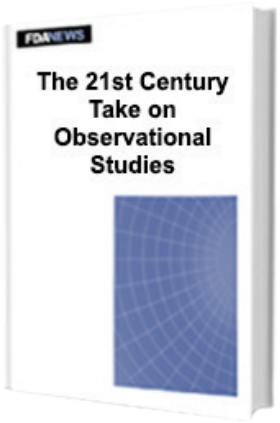

The 21st Century Take on Observational Studies: *Using Real-World Evidence in the New Millennium*

Passage of the 21st Century Cures Act reaffirmed Congress's and the FDA's commitment to using real-world evidence to supplement or even replace traditional clinical trials.

More flexible, faster and cheaper research methods, including observational studies, are now acceptable in the FDA's approval process.

Observational research requires an entirely different set of procedures and careful planning to ensure the real-world evidence collected is valid and reliable.

The 21st Century Take on Observational Studies walks you through everything you need to know about the opportunities and pitfalls observational studies can offer. The report looks at the growing trend toward observational research and how provisions in the 21st Century Cures Act create even more incentives to rely on real-world evidence in the development of medical products. The report covers:

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- The evolution of patient-focused research
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- How drug- and devicemakers view observational research and how they are using it

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