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House Votes to Repeal Medical Device Tax

The House voted July 24 to fully repeal a 2.3 percent excise tax on medical devices, with 57 Democrats joining 226 Republicans in supporting the measure.

The Protect Medical Innovation Act of 2018 (H.R. 184) had 279 cosponsors from both sides of the aisle and was approved with a vote of 283 to 132. The permanent repeal follows two temporary suspensions of the tax since it was first enacted in 2013 to help pay for the Affordable Care Act.

The tax received its first temporary moratorium, also with bipartisan support, under the Consolidated Appropriations Act of 2016 and it came back into effect Jan. 1, 2018. A two-year suspension was enacted Jan. 22 — just a week before the first payments on the tax were going to be due (*IDDM*, Jan. 29).

(See **Tax**, *Page 2)*

Least Burdensome Medical Device Regulation Is Producing Results, Gottlieb Says

FDA Commissioner Scott Gottlieb updated the House Energy and Commerce Committee on the agency's progress in implementing the 21st Century Cures Act in regards to medical devices, noting the agency continues to apply the act's concept of least burdensome regulation towards medical devices and has seen positive results.

CDRH has taken the Cures Act's expansion of least burdensome device regulation and used it as a focal point for medical device regulation, resulting in speedier review times and better quality applications from sponsors in the last few years, Gottlieb said, in testimony at the July 25 hearing.

For example, he said, the center used the Cures Act's provisions for streamlined authority to exempt more than 70 Class I device types and over one thousand Class II two device types from the requirement to submit a 510(k) after a premarket review

(See **Cures**, *Page 4)*

FDA Warns Against Marketing OTC Hearing Aids

CDRH's Office of Device Evaluation issued a letter reminding manufacturers not to market hearing aid devices as OTC products until regulations are finalized.

Provisions for regulations in the FDA Reauthorization Act of 2017 that create a category of OTC hearing aids and define their requirements have not yet been instated, so OTC hearing aids remain restricted devices, and their sales must adhere to federal and state requirements, said ODE's Director William Maisel.

The agency has a deadline of August 18, 2020 to publish the proposed regulations. It will then consider public comments and publish final regulations within 180 days of the end of the comment period.

Tax, *from Page 1*

The measure now moves on to the Senate where its path remains uncertain.

"Our strategy is clear: get to 60 votes so the Majority Leader can put this bill on the floor and pass it," said AdvaMed President and CEO Scott Whitaker. "We have eight Democrats now. If we can get two-to-four more, I'm confident the bill will pass. We've never been closer. So we'll spend the coming weeks making our case, both here in Washington and back in key states."

One Congresswoman who initially cosponsored the bill, Rep. Dina Titus (D-Nev.), ultimately rescinded her support and voted against repeal.

"I originally cosponsored H.R. 184 as part of a package of bipartisan ideas to move forward on health care reform and address issues with the implementation of the Affordable Care Act (ACA)," said Congresswoman Titus. She said changes that have occurred in the last 16 months caused her to reconsider. She is concerned the bill's passage will add $20 billion to the deficit.

Other lawmakers have long argued that the medical device excise tax could lead to higher prices for consumers as well as the loss of manufacturing jobs. AdvaMed cites U.S. Department of Commerce indicating that the medical device industry employs roughly 400,000 people, but nearly 29,000 jobs were lost while the medical device excise tax was in effect.

Some but not all of those jobs were recovered by the temporary suspension, according to Rep. Erik Paulsen (R-Minn.), the bill's leading sponsor.

"Companies responded [to the temporary suspension] by hiring more engineers and more technicians and putting more money in research and development projects for these new life-saving technologies," said Paulsen before the vote on the House floor.

After the measure passed the House, Rep. Paulsen issued a statement reiterating his belief that a permanent repeal will lead to job creation: "I'm more optimistic than ever we'll be successful in giving these job creators the certainty and predictability they need to thrive." — Tiffany Winters

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AngioDynamics to Pay $12.5 Million Over False Claims Allegations

Devicemaker AngioDynamics agreed to pay the U.S. government $12.5 million to resolve false claims allegations for two of its medical devices, the LC Bead and the Perforator Vein Ablation Kit.

The Department of Justice alleged that the company caused healthcare providers to submit false claims to Medicare, Medicaid and other federal healthcare programs for the two devices.

The New York-based company will pay $11.5 million to resolve allegations that the company caused false claims to be submitted to government healthcare programs for procedures involving an unapproved drug-delivery device that was marketed with false and misleading promotional claims.

From May 2006 through December 2011, AngioDynamics served as the U.S. distributor for Biocompatibles, the manufacturer of LC Bead, and it marketed LC Bead for use as a drug delivery device in combination with chemotherapy drugs. Although the FDA had twice declined to approve this use of LC Bead, AngioDynamics personnel routinely claimed that it was "better", "superior", "safer" and "less toxic" than alternative treatments, even though there was insufficient clinical evidence to support the truthfulness of these claims, the government alleged.

Inaccurate Codes

The government alleged that AngioDynamics was aware that many insurers declined to provide coverage for certain LC Bead procedures and, as a result, instructed healthcare providers to use inaccurate billing codes when submitting claims for such uses.

The federal share of the civil settlement is roughly $10.9 million, and the state Medicaid share of the civil settlement is about $600,000. The government previously resolved related criminal and civil claims against Biocompatibles in November 2016.

AngioDynamics also will pay $1 million to resolve allegations that the company caused false claims to be submitted to federal healthcare programs in connection with the use of the PVAK, later renamed the 400 micron kit.

In 2008, AngioDynamics acquired the kit as part of a product suite that uses a laser to close or collapse malfunctioning veins. The FDA had cleared the PVAK only for use in treating superficial veins. In 2011, AngioDynamics requested that the FDA clearance include the treatment of perforator veins, but the agency said that would constitute a new indication for which safety and efficacy were unknown.

Subsequently, AngioDynamics voluntarily recalled the PVAK and re-issued the product under a new name, the 400 micron kit that did not refer to the unapproved use of treating perforator veins.

FDA Releases Device User Fees for FY 2019

The FDA announced MDUFA IV user fees for fiscal 2019 with modest increases that will go into effect on Oct.1.

For pre-market applications, product development protocols or biologics license applications, the standard fee will be $322,147, up from $310,764 for fiscal 2018. Small businesses will pay $80,537 compared with $77,691 in fiscal 2018. The same fees apply for premarket reports and efficacy supplements.

The standard and small business fees for 510(k) premarket notification submissions will be $10,953 and $2,738, respectively, while de novo classification requests will be $96,644, with a $24,161 fee for small businesses.

Fees for 180-day supplements for standard and small business fees will be $48,322 and $12,081, respectively, and real-time supplement standard and small business fees are $22,550 and $5,638, respectively.

Businesses may qualify for the small business fees if their gross receipts or sales do not exceed $100 million for the most recent tax year. They may also qualify for a waiver of the fee for their first premarket application or premarket report if their gross sales or receipts don't exceed $30 million.

FDA Issues Untitled Letter To South Korea's Ycellbio

South Korean devicemaker Ycellbio got into hot water with the FDA for marketing its Y-PRP kit in the United States without FDA clearance and the agency issued the company an untitled letter.

The firm was advertising its Y-PRP system on its website for facilitating separating and harvesting "pure sources of concentrated platelets from a small sample of blood at the patient's point of care," the FDA said.

The agency said the claims on the website indicate the kit is a device because it is part of "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, or is intended to affect the structure or function of the body of man or other animals (21 U.S.C. 321(h))."

For example, the company made claims that the Y-PRP kit was a regenerative therapy that could be used for dermatology, general surgery, chronic wounds and ophthalmology applications.

The FDA said the company had not submitted a premarket review application as requested for the device and was in violation of the FD&C Act.

Ycellbio had submitted a device listing information in 2016, indicating that the Ycellbio PRP kit was a Class I mixer/blood tube device and that general controls were sufficient to provide reasonable assurance of safety and effectiveness for Class I devices.

However, the FDA informed the company in a March 23, 2016 letter that its Ycellbio PRP kit was not a Class I device and it would actually be classified as Class III device for which a PMA would be required before it could be legally marketed in the U.S. The firm was marketing the device globally.

Ycellbio released an August 2017 media release that said the Ycellbio PRP kit had approvals from KFDA, EU CE Mark, TFDA and Russia. "We are planning to work on FDA 510(k) approval, which will accelerate penetration into the U.S. market," the company said, adding that the "unique and convenient system will attract many potential customers in various medical fields including anti-aging regenerative medicine, cosmetic therapy, orthopedic surgery, or sports medicine."

The Ycellbio PRP kit brochure also included the FDA logo, and unauthorized use of the logo "may violate federal law and subject those responsible to civil and/or criminal liability," the FDA said.

The firm did not response to a request for comment.

Read the FDA letter here: www.fdanews.com/07-26-18-Letter.pdf.

Cures, *from Page 1*

is deemed unnecessary to provide assurance of safety and efficacy.

"Eliminating the 510(k) requirement for these products saves time and resources for industry and allows FDA to focus its oversight on higher risk products while still ensuring that patients have access to safe and effective medical devices," he said.

In addition, Gottlieb announced that the voluntary Expedited Access Pathway (EAP) program, which was expanded by the Cures Act, has been used to designate 72 devices as breakthrough products so far, including a brain implant for blind patients.

"The Breakthrough designation facilitated early interactions between FDA and the sponsor and brought together intra-agency specialists to pose questions, solve problems, and evaluate the benefits and risks of the device for which no standard existed," he said.

The agency is also running a digital health software precertification (Pre-Cert) pilot program to explore a potential voluntary pathway for examining the safety and efficacy of certain device software. The program focuses primarily on the software developer or manufacturer as opposed to the product and is examining the use of real-world evidence to support safety and efficacy evaluations.

Read Gottlieb's full testimony here: www.fdanews.com/07-25-18-Gottlieb.pdf. — James Miessler

FDA Hits Dynaflex on CAPAs, Device History Records

DynaFlex failed to follow proper procedures for CAPA and design control, the FDA said in a Form 483.

The agency issued the form following an April inspection of the company's St. Ann, Missouri facility. Investigators found the company's CAPA procedures did not include an analysis of quality data to identify the causes of nonconformances and that the firm failed to validate corrective and preventive actions.

The facility also lacked design controls for its class 2 medical devices, including design history files, design inputs or outputs, verifications, transfers or design changes.

Investigators also found the validation of machines used for manufacturing did not include documentation of the approval of process changes or the acceptance criteria for review and approval of the validation.

The FDA also found the device master record for the company's sleep apnea device did not include components such as production methods or procedures, packaging and labeling specifications, quality assurance and acceptance procedures, or drawings, compositions and specifications of the appliance.

Read the DynaFlex Form 483 here: www.fdanews.com/07-26-18-Dynaflex.pdf. — Zack Budryk

Iowa Firm Cited for Quality, Complaint Handling Issues

The FDA flagged TJN Manufacturing in a Form 483 for problems with quality, CAPAs and production processes.

In an April inspection of the device manufacturer's Davenport, Iowa facility, the agency found the firm lacked the required quality system procedures for producing medical devices. Moreover, the company had not properly established procedures to ensure design changes were properly documented and reviewed.

The company has also failed to create a device history record showing its class two device met critical specifications and user requirements, and the facility did not maintain documentation relating to each unit's manufacturing and release. Moreover, the company had not developed work instruction and final production check lists to ensure that all devices were manufactured according to specifications.

In addition, the company failed to develop and implement a CAPA procedure and it did not document and review complaints relating to its devices. The firm had no written complaint handling procedures that defined the requirements for documenting medical device complaints.

Read the TJN Manufacturing Form 483 here: www.fdanews.com/07-26-18-TJN.pdf.
— Zack Budryk

Advanced Monitoring Cited For Vendor Acceptance Procedures

The FDA cited Advanced Monitored Caregiving after a March inspection of the devicemaker's New York facility turned up problems with procedures for device acceptance and evaluation of potential suppliers.

The agency investigator found the acceptance procedures for several devices did not include instructions for device pairing and data transmission testing. The final testing acceptance records presented during the inspection did not indicate if the devices transmitted accurate readings and they did not document the equipment used to conduct the testing.

The company also failed to properly document its evaluation of potential suppliers and it did not produce documentation that demonstrated proper assessment of vendors as detailed in its written procedures. In addition, the facility did not obtain approval signatures for software change testing documentation ahead of the updates.

Read the Advanced Monitored Caregiving Form 483 here: www.fdanews.com/07-26-18-Advanced.pdf. — Zack Budryk

BRIEFS

FDA Cautions Bayer Over Postmarket Requirements for Essure

Bayer announced it would stop selling its Essure permanent birth control device after Dec. 31 and the FDA said it expects the company to meet its postmarket obligations.

"For women who have received an Essure implant, the postmarket safety of Essure will continue to be a top priority for the FDA," said FDA Commissioner Scott Gottlieb said.

The device is estimated to have been used by more than 750,000 patients worldwide and it has been associated with serious risks including persistent pain, perforation of the uterus and fallopian tubes, and migration of the coils into the pelvis or abdomen.

When adverse events first surfaced in 2015, the FDA convened an expert panel to investigate complaints. In February 2016, the agency ordered Bayer to conduct a post-market study to better evaluate the device's safety profile, and in November 2016, the agency updated the labeling of the device, adding a boxed warning and a patient decision checklist to help women considering Essure be fully informed about potential risks.

In April, when the FDA became aware that many patients were not being adequately counseled, it limited sale and distribution of the device to health care providers and facilities that provide information to patients about the risks and benefits of the device to give patients the opportunity to sign an acknowledgement that they fully understood the potential risks before having the device implanted (*IDDM*, April 16).

"This method of permanent birth control, where coils are inserted into the fallopian tubes creating a blockage that prevents the passage of an egg from the ovary, has been associated with numerous adverse events that were reported to the FDA including a significant collection of recent reports that have mentioned issues involving surgery to remove the device," Gottlieb noted.

UK Limits Use of Vaginal Surgical Mesh

The UK's Medicines and Healthcare products Regulatory Agency is "pausing" the use of vaginal surgical mesh for stress urinary incontinence and pelvic organ prolapse. MHRA said the procedure has not been banned, but it will be implemented through a "high vigilance program of restricted practice."

Surgical mesh is used to provide temporary or permanent support for weakened structures and muscles in surgery. Other common uses include the repair of hernias, pelvic organ prolapse and stress urinary incontinence.

NHS England said that vaginally inserted meshes will only be used when there is no alternative "and after close and comprehensive consultation between patient and clinician, with rigorous oversight and governance at all times."

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The FDA will always — **always** — do inspections, and Commissioner Scott Gottlieb and the FDA have certainly not provided any hint that they are going to stop doing them any time soon. You can't afford to be caught off guard. Warning letters, 483 citations, and hits to your reputation can cost you time, energy and money!

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FDA Approves Magnetic Lymph Node Biopsy Device

The FDA approved an innovative magnetic device for guiding lymph node biopsies in mastectomy patients that doesn't require an injection of radioactive materials.

The Magtrace and Sentimag Magnetic Localization System can identify specific "sentinel" lymph nodes for surgical removal. Sentinel nodes are the first to which cancer cells are likely to spread from a primary tumor, so lymph node testing indication of whether cancer has spread from the breast.

The device uses magnetized particles to guide the biopsy procedure, with the magnetic particles traveling to lymph nodes and becoming trapped there, allowing magnetic detection of the nodes.

The FDA based its approval on data from a trial of 147 patients with breast cancer, which indicated the detection rate for the system was 94.3 percent compared to 93.5 percent for the control method detection rate.

"Currently, a sentinel lymph node biopsy is performed after injection of radioactive materials and/or blue dye. This magnetic system we're approving today will offer patients undergoing mastectomy an option for their sentinel lymph biopsy procedure that does not require the injection of radioactive materials," said Binita Ashar, director of CDRH's Division of Surgical Devices. — Zack Budryk

APPROVALS

Quidel's Bordetella Assay Receives FDA Clearance

The FDA granted 510(k) clearance to Quidel's Solana Bordetella assay, a molecular diagnostic assay used with its Solana molecular diagnostic instrument for detection of pertussis bacteria.

Together, the assay and diagnostic instrument can differentiate between Bordetella pertussis and Bordetella parapertussis nucleic acids obtained from patients suspected of having a respiratory tract infection caused by the bacteria.

Pertussis, also known as whooping cough, is highly contagious and it has become more common in recent years.

FDA Grants Expanded Clearance For Nova Biomedical's Glucose Meter

Nova Biomedical received 510(k) clearance for its StatStrip glucose hospital meter system, the first finger-stick capillary testing meter for critically ill patients with and without diabetes.

The device can now be used with capillary, venous and arterial specimens from all patients. It can be used for point-of-care testing to measure and correct for abnormal hematocrit, the percentage of blood by volume that is made up of red blood cells.

The new clearance eliminates the need for hospitals using StatStrip to define "critically ill" patients for testing purposes.

Zavation Receives FDA Clearance For Expandable Corpectomy Cage

The FDA granted 510(k) clearance to Zavation's Normandy vertebral body replacement system.

The device is placed in the vertebral body space to provide structural stability in skeletally mature patients. It is made up of spacers that come in various sizes and types to accommodate the patient's anatomy.

The device is indicated for use in the cervical and thoracolumbar spine for replacement of vertebral body due to tumor, trauma or osteomyelitis, or for reconstruction following the removal of vertebral body and discs.

Vallum Gets 510(k) Clearance For Spinal Interbody Fusion Device

Vallum received 510(k) clearance for its polyetheretherketone PEEKplus nanotextured spinal interbody fusion device, which uses nanotexturing to improve bone fusion and growth.

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

Approvals, *from Page 7*

The surface promotes osteoblast functions needed to grow bone and encourages fusion by generating osteogenic responses.

The nanotexturing can be applied to any PEEK device without impacting its design or size.

Nanotexturing has the potential to set "a new standard in the performance of spinal fusion interbody implants," according to Eric J. Woodard, chairman of Vallum's medical advisory board.

Adaptiiv Cleared to Market 3D Bolus Software

The FDA granted 510(k) clearance for Adaptiiv's 3D bolus software, allowing the company to market the 3D printing software in the U.S.

The software is used to create 3D customized personal medical devices, primarily for the treatment of cancer.

The patient-specific devices can be used during radiation treatment to address issues practitioners face, such as air gaps in bolus and sparing healthy tissues during electron treatments.

Lumendi Receives CE Mark For Endoscope Accessory

Lumendi gained a CE Mark for its DiLumen endolumenal interventional platform for use as an endoscope accessory in endolumenal weight loss procedures.

The device, a non-sterile, single-use sleeve, is meant to allow complete positioning of a conventional endoscope in the large intestine.

The accessory gives users increased visualization, and its endolumenal approach is expected to avoid incisions and minimize the need for general anesthetics.

Companion Medical's InPen System Gains Approval

Companion Medical received a CE Mark for its InPen system, an insulin pen that is also cleared by the FDA.

The insulin pen features an accompanying integrated diabetes management app. The app is currently available for iPhones, and a launch for Android is planned for later this year.

The device gives information on aggregated glucose, insulin and meal data. It offers daily views that let providers monitor the patient's patterns related to glucose adherence and control.

Mirada's AI Software Cleared by FDA

The FDA granted 510(k) clearance for imaging software developer Mirada's artificial intelligence DLC Expert software, approving it to be used for planning radiation oncology treatment.

The software helps users spot tumors and important structures on patient CT scans, reducing the time it typically takes to perform an analysis.

The software is part of Mirada's Workflow Box 2.0 Zero-Click platform, which provides data routing and support for custom applications.

Candela Cleared for Pulsed Dye Laser

Candela received FDA's 510(k) clearance for its Vbeam Prima device, a pulsed dye laser used to treat a range of skin conditions.

The 595 nm pulsed dye laser device is cleared for treating conditions like rosacea, acne, spider veins, port-wine stains, wrinkles, warts and stretch marks, as well as photo aging and benign pigmented lesions.

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FDA and ISO Devicemaker Training Requirements

Device manufacture is a complicated business, but few areas are more rulebound than QMS. Many a devicemaker has come up short trying to stay abreast of the FDA's QSR, ISO 13485:2016, and other ISOs while trying to comply with competence, training and awareness rules.

It takes more than teaching simple skills to achieve the state of job readiness and performance required of devicemakers' workforces. Regulators agree that a comprehensive training program should consider employee education, experience, background and skills. What they don't agree on is what those concepts mean and how to incorporate them into training.

FDA and ISO Devicemaker Training Requirements breaks down training requirements in both the FDA's QSR and international standards ISO 13485, 9001 and 10018 — among others — shows where they overlap and where they differ and provides a plan for developing a training program that fills in all the gaps. You will learn:

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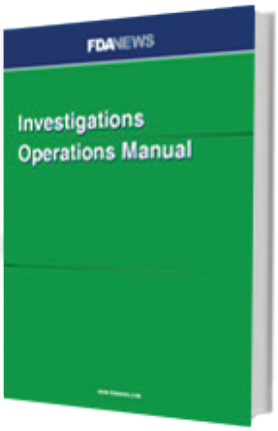

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