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$92M total possible payment to Surmodics

Abbott enters agreement with Surmodics to market its Surveil drug coated balloon

By Katie Pfaff, Staff Writer

Abbott Laboratories has inked a deal with Surmodics Inc. to collaboratively develop, trial and seek EU and U.S. approval for the Surveil drug coated balloon (DCB) in treatment of superficial femoral artery. Abbott will obtain exclusive global commercialization rights for Surveil under the agreement, which includes a $25 million initial payment to Surmodics and $67 million in potential milestone payments. Surveil is being assessed in a U.S. pivotal, randomized trial, TRANSCEND.

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Inside

Shuren says 'regulatory sprints' key to moving breakthrough devices

By Mark McCarty, Regulatory Editor

The breakthrough devices program now includes 510(k) devices as well as PMA devices, but the FDA's Jeff Shuren said recently that the agency's review staff now engages with device makers in "regulatory sprints" in an effort to break logjams in the development and evaluation process for these novel and often complicated devices.

Shuren, who has led the Center for Devices and Radiological Health since 2009, was speaking in a webinar by Wells Fargo Securities LLC of San Francisco, and he noted that the breakthrough

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Researchers create open-source AI to diagnose retinal health, other diseases

By Stacy Lawrence, Staff Writer

Artificial intelligence and machine learning efforts have often taken up retinal imaging as an early application within health care. But, these projects have required massive training and reside largely within major technology players, such as IBM Watson and Google parent Alphabet Inc., who thus far have failed to advance them into practice.

In addition, another critique of AI applications in health care is their common lack of an ability to explain the specific basis upon which it has made a particular diagnosis. Now, researchers at the Shiley Eye Institute at UC San Diego Health have

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The number of CE marked medical devices in Europe continues to decline

By Bernard Banga, Staff Writer

PARIS – For the seventh year running, the European Association Medical Devices – Notified Bodies (Team-NB) has released the results of its annual survey on CE marks, the certification needed to market medical devices in the European Union.

According to the latest survey by Team-NB – a Brussels-based trade group for notified bodies – its members issued 19,763 CE mark certifications in 2016. This is a 6 percent drop compared to the previous year and means the number of CE marks

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Dreamed receives CE mark for smart decision software

By David Ho, Staff Writer

HONG KONG – Dreamed Diabetes Ltd. has received the CE mark for its Advisor Pro decision-support platform for assisting health care professionals in the management of type 1 diabetes.

The Petah Tikva, Israel-based company's cloud-based software helps physicians to come up with personalized insulin treatment plans for diabetic

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BioWorld MedTech's Oncology Extra

Regulatory Editor Mark McCarty and Senior Science Editor Anette Breindl on one of med-tech's key sectors

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CE mark

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has fallen for the third consecutive year. New certificates related to introducing new medical devices into the European Union have also fallen. Their number (4,098) fell by 8.5 percent in 2016, with the cumulative decline since 2010 standing at 41.34 percent.

"The CE mark landscape is currently being reshaped, with tougher requirements for manufacturers and notified bodies," Françoise Schlemmer, Team-NB's director, told *BioWorld MedTech*. Team-NB brings together 24 notified bodies undertaking 80 percent of CE marking in Europe. Notified bodies (NBs) are independent third parties with a key role in accessing the European medical technology market. This is worth an estimated $135.6 billion and is the second biggest medical device market after the U.S.

"Ever since the June 2012 scandal involving silicone breast implants produced by the French company PIP, the entire medical technology sector has had to cope with regulatory requirements becoming gradually tougher on the European market," said Schlemmer. To such an extent that almost 2,000 CE marks were nullified in 2016, i.e., an increase of more than 45 percent compared to the previous year. The reasons for this mentioned by NBs include fewer CE marks for own brand labelers, unfulfilled requirements, non-conformities not closed, payment defaults, medical device manufacturers considering the cost of CE marks to be too high, and transfers to other notified bodies.

In total, 28,248 med-tech companies – 32 percent EU companies and 68 percent outside the European Union – received a CE mark issued by one of around 20 notified bodies. According to Team-NB's 2016 survey, six large notified bodies awarded well in excess of 1,000 CE marks, five medium-sized notified bodies dealt with 350-1,000 certificates and a dozen small notified bodies issued 350 CE mark certificates.

A new landscape for a new medical device regulation

"There has been a sharp decline in medium-sized notified bodies, which are bearing the brunt of an increasingly difficult market," said Schlemmer. The number of notified bodies has fallen considerably over the past six years. Whereas there were more than 85 companies throughout the European Union's 28 member countries in 2012, there are only 53 today. Dozens of small and medium-sized organizations in Austria, Italy, Hungary, Lithuania, Luxembourg, Poland, the Czech Republic, Romania, Slovakia and Portugal have had to close.

"We're seeing notified bodies consolidate to cope with the European Commission's tighter requirements," said Schlemmer. In Denmark, a joint venture between DNV GL and Nemko AS resulted in Presafe Denmark A/S. Cross-border consolidations are also on the increase. For example, the German notified body Dekra SE has taken over the Dutch body NV Kema, and the British BSI Group has acquired the German EUROCAT Institute for Certification and Testing GmbH.

Brexit has completely changed the situation in the United Kingdom. Unless a suitable deal is made, all certificates issued by British notified bodies under EU regulations will become void from March 30, 2019, onwards. Notified bodies are already anticipating this scenario. The Swedish notified body Intertek Semko AB will close in the following months its U.K. subsidiary AMTAC Certification Services Ltd. to bring this business back to Sweden. Some British notified bodies are moving their head offices outside the U.K. For example, BSI Group has applied for designation in the Netherlands, SGS SA in Belgium and Lloyd's Register Quality Assurance Ltd. in Ireland.

> *"Notified bodies are anticipating the requirements so as not to be a bottleneck in the new regulatory process for CE marks.*
>
> Françoise Schlemmer
> Director, Team-NB

The new medical device regulation

The EU's new medical device regulation was published in May 2017 and will be mandatory from May 2020 onwards. The difficulty for Europe's med-tech ecosystem lies in its ability to anticipate the new requirements of this EU medical device regulation (2017/745). Med-tech companies will henceforth have to provide more stringent clinical evidence to get products onto the market, with premarket and postmarket approval processes for high-risk implantable devices. Notified bodies will undergo stricter inspection by the relevant authorities and will require more human resources for unannounced audits. They will also need auditors with greater skills and more technical reviewers for their re-notifications.

"Back in 2013, we anticipated this movement by complying with a code of conduct for notified bodies whose requirements are in advance of the current medical device directive and in-vitro diagnostic regulation," said Schlemmer. Beginning in 2016, Team-NB's working groups have been reviewing the new regulatory texts to help its members identify and interpret the impact of these new requirements on notified bodies' procedures and processes. "We're aiming to provide guidelines that will support our members to submit their applications as quickly as possible and be ready to take their designation audit under new regulations," said Schlemmer. According to a survey – published in February 2018 – of notified bodies' applications for designation under the new regulation, all Team-NB members surveyed have decided to apply for designation under the new medical device regulation. In addition, 55 percent of these members have applied for designation under the in-vitro devices regulation, with most of them applying before Feb. 12, 2018.

Team-NB's latest annual survey reveals the marked progress made by notified bodies on human resources. They now employ 1,816 people – an average of 86 people per NB – which represents a 12 percent annual increase in their workforce. According to Schlemmer, "this hasn't yet peaked since notified bodies have embarked on a policy of active recruitment." They plan to double or even triple their staff over the next three to five years so that CE mark audits can be done within three to six months. For the time being, med-tech firms still have to wait nine months to obtain a CE mark. In this tense period, notified bodies have raised their prices by more than 33 percent over the past four years. Daily rates for audits are now between $1,850 and $1,940. ♦