EU finalizes more stringent CE mark rules with explosive ‘supernova’ of regulation

By John Brosky, Contributing Writer

PARIS – The CE mark is dead, long live the new CE mark.

Five years after launching a reform of regulations for commercializing medical devices and in vitro diagnostics (IVDs), the European Council released the final text for the Medical Device Regulations (MDR) and IVD Regulations (IVDR), setting in motion a countdown to enforcement.

“The future is in this version and like it or not, this is what we will work with, what we need to make a success, because the alternative that it does not work is so much worse,” said Ronald Boumans, the Senior Global Regulatory Consultant in The Hague, The Netherlands for the Emergo Group Inc., based in Austin, Texas.

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Siemens’ Digital Ecosystem combines imaging, diagnostic and medical data

By Stacy Lawrence, Staff Writer

Med-tech giants increasingly are turning to sophisticated analytics in an attempt to intensify their customer relationships. The move is part-and-parcel of a broader strategy to secure large, multi-year deals with hospital systems that encompass

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Intersect Ent picks up FDA nod for sinus treatment implant

By Omar Ford, Staff Writer

Intersect Ent Inc., has received FDA approval for the Propel Contour steroid releasing sinus implant. The Menlo Park, Calif.-based company’s device treats patients with chronic sinusitis, a common condition affecting on in seven U.S. adults and frequently requires a combination of surgical and medical

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U.S. Supreme Court reverses Federal Circuit in Promega patent spat with Life Technologies

By Mark McCarty, Regulatory Editor

The U.S. Supreme Court has overturned a ruling by the Court of Appeals for the Federal Circuit in the case of Life Technologies v. Promega, but by some accounts, the outcome may do much more than declare that more than

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Embolic protection for TAVR

Advisory panel sees a place for Claret’s Sentinel in cath lab

By Mark McCarty, Regulatory Editor

The FDA advisory committee had no formal vote regarding the de novo petition for the Sentinel device by Claret Medical Inc., but the panelists were assured by the safety data, and thus advised the agency that the device ought to be available to interventional cardiologists for embolic protection in patients undergoing transcatheter aortic

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multiple product offerings by appealing to the institutions’ need to both improve value-based care efforts, as well as to better manage individual care.

Siemens Healthineers, a major imaging player and the health care business of Munich, Germany-based Siemens AG, recently debuted its latest efforts on the integrated analytics front. It presented an initial prototype of its Digital Ecosystem at the Health Information and Management Systems Society (HIMSS) annual conference. The platform is expected to be available commercially this fall. Also at HIMSS, the conglomerate offered a new FDA clearance for novel MRI compression technology to improve ease of image acquisition.

THE APP-IFICATION OF HEALTH CARE

“Our goal is very simple. We want to create an open, relevant digital ecosystem covering all the aspects of the health care system including laboratory diagnostics, point of care and imaging,” Siemens Healthineers VP of Marketing in Digital Health Services Marc Lauterbach told Medical Device Daily. Data, connectivity and predictive analytics applied both at the individual and population-level is the unifying vision.

The Digital Ecosystem is intended to offer Siemens customers ease-of-use and an environment that will support a wide variety of digital programs and tools. In fact, the conglomerate likens the new Digital Ecosystem to successful consumer platforms such as an App Store for a mobile device.

“When it comes to the actual ecosystem, I like to use the example of comparing it to the App Store or Itunes,” said Lauterbach. “The Iphone is not just about a technical device, it makes it easy to use and download apps in a simple and easy-to-approach way.”

He continued, “There have been a lot of discussions about digitalization, however if you ask customers how much it affects daily clinical operations, there is no conception that they have control over all their data. If it works over their own clinic networks, that’s great, not to mention outside networks.”

The expectation is that the system will provide a single login to enable access to a host of potential operational and clinical tools. The prototype is already populated with some tools from partners, including imaging analytics platform Arterys, storage infrastructure provider Dell EMC, online physician consultation service Secondopinions.com, integrated referral management startup Stroll Health, MRI decision support and workflow specialist SyntheticMR AB, open source software platform for medical image informatics 3D Slicer, European teleradiology- and telepathology service provider TMC, American radiology service provider USARAD and disparate data source connector Viewics.

Lauterbach acknowledged that its imaging competitors, like the Boston-based General Electric Corp. and Amsterdam,

Digital Ecosystem, from Siemens Medical Solutions USA Inc.

Netherlands-based Koninklijke Philips N.V., are working on their own approach to integrated health care data analytics.

“In the end, I think it’s not only about how accommodating it is for customers, health care providers and all the various different players. I think that’s where we have a big advantage, we are covering the broadest base not only with imaging but also with point of care and now we are going into genomics,” he said.

Concluded Lauterbach, “At some point, I can imagine a few players that are really big, so people might not be willing to join another platform. It’s an interesting time in that regard because everyone is trying to position themselves.”

POPULATING THE ECOSYSTEM

Siemens is in the midst of reaching out to additional potential partners to populate the ecosystem, and said it’s getting a strong reception. “The reaction from potential partners was amazing at HIMSS,” said Lauterbach. “The number who wanted to join us was quite a positive surprise.”

The Digital Ecosystem builds upon Teamplay, which Siemens launched two-and-a-half years ago. That cloud-based platform is already in use by hundreds of its customer sites.

It is intended to encompass imaging, in-vitro diagnostic and medical documentation data from its customers who have agreed to participate. It will allow the participants to exchange data and information with experts, including seeking another opinion on a particular patient.

The Digital Ecosystem is slated to integrate cancer genomics data via cancer genome diagnostic platform NEO, which Siemens acquired last May when it bought Neo New Oncology AG of Cologne, Germany. The technology offers molecular profiling assays based on tissue specimens and body liquids, including liquid biopsy capabilities.

“We are incorporating the new technology we acquired through Neo New Oncology. We are doing genomics for certain areas of the genome that are linked to certain treatment pathways to make recommendations with lab diagnostics, imaging,” said Lauterbach.

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Siemens also expects to integrate more machine learning analyses, such as the arterial blood flow tool from start-up Arterys. “Machine learning is an area we are very interested in providing to our customers. It is a natural extension of the ecosystem,” he added.

BREATHE EASIER WITH IMAGE COMPRESSION

Also at HIMSS, Siemens Healthineers disclosed an FDA clearance for its Compressed Sensing technology, which enables faster magnetic resonance imaging (MRI). The process for acquiring an MRI image is reduced to 16 seconds – from about four minutes – due to an algorithm that reduces the required data.

The technology is said to offer high quality images that don’t have any relevant diagnostic information loss. The first application of the technology is the Compressed Sensing Cardiac Cine, which is specifically for arrhythmia and respiratory problems. It’s available on the Magnetom Aera 1.5 Telsa (1.5) and Magnetom Skyra 3T MRI scanners from Siemens.

These patients typically had to hold their breath for 10 to 14 seconds at a time over a four-minute period to obtain adequate MR images. But now, patients will be able to breathe freely during the 16 second image acquisition time.

Any image artifacts created by breathing and heartbeats are eliminated by the algorithm. This is a plus for all patients, but particularly for the elderly and very ill, who may have difficulty holding their breath. Arrhythmia patients were typically unable to get high-quality MRIs, but this technology will likely change that.

Intersect

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The CMS ruling could also impact, sinus treatment specialist Entellus Medical Inc. The Plymouth, Minn.-based company has developed balloon sinus dilation products to treat patients. “While the reimbursement change should benefit Entellus’ office use, we wonder if it might slow down procedures in the hospital and if it may create significant pricing pressure in the operating room,” Lavin said.