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News We're Watching: Neuralink's Blindsight Gets FDA Breakthrough Device Tag; FDA Pump Recalls, Guidances; Discure, DeepLook Bolster Coffers

by Marion Webb

This week, Neuralink announced it received US FDA breakthrough device designation for a device to restore sight; medtechs Discure and DeepLook secured new funding; FDA pump recalls from B. Braun Medical and Fresenius Kabi; Axonics prevails in patent infringement lawsuit with Medtronic; Merit Medical buys Cook Medical for $210m.

Elon Musk's Neuralink Received FDA Breakthrough Device Designation For Device To Restore Vision

Elon Musk's brain-computer interface company *Neuralink Corp.* announced on 17 September its experimental implant Blindsight aimed at restoring vision received FDA breakthrough device designation. The breakthrough devices program at the US Food and Drug Administration is a voluntary program for certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases. It is intended to speed up development, assessment and review for premarket approval and de novo clearance.

Musk wrote in a simple post on his X social media platform that Blindsight "will enable even those who have not lost both eyes and their optic nerve to see."

"Provided the visual cortex is intact, it will even enable those who have been blind from birth to see for the first time," Musk wrote on X. He explained that vision will at first be low resolution, and eventually be better than natural vision. (Also see "*'Mental Health, Beyond Medication': Motif*

Targets Depression With Minimally Invasive DOT" - Medtech Insight, 16 May, 2024.)

The visual cortex is the part of the brain responsible for processing visual information. The company added a call for interested participants to apply to their Patient Registry, which indicates that the company hopes to progress into human clinical trials.

Israel-Based Discure Secured $11M In Series A Funding

Bioelectronic implantable device maker Discure Technologies announced on 10 September it secured $11m in an oversubscribed series A financing round, following a simple agreement for future equity raised of $5m, bringing its total funding raised to $16m. (Also see "*How Two Medtech CEOs Are (And Aren't) Using ChatGPT In Their Businesses*" - Medtech Insight, 20 Apr, 2023.)

The latest round was led by BOLD Capital Partners, Supernova Invest and Sanara Capital, with participation from unnamed US hospital systems, surgeons and other investors.

Discure's CEO Yuval Mandelbaum said while the SAFE round funded the complete development of the Discure System, the latest investment will accelerate growth, facilitate key hires and fund the first-in-human clinical study in Canada and Italy. Discure developed a minimally invasive bioelectornic device to treat and reverse degenerative disc disease by actively controlling the reintroduction of fluid, oxygen and nutrients into the degenerative disc, the company says. Low back pain is the leading cause of disability globally and accounts for economic losses over $100bn in the US alone, it says.

The company received FDA device breakthrough designation for its device in 2021.

DeepLook Medical Announces Performance Data, Funding Series Close

DeepLook Medical says its flagship product significantly enhances breast imaging performance and reduces recall rates. The start-up, which developed the first FDA-cleared AI technology to detect cancer in dense breasts, has released *data* showing its DL Precise tool greatly improved patient outcomes at a major hospital in New York while cutting down on costs.
The hospital, according to DeepLook, saw a 12% improvement in recall rates, enabling better adherence to the American College of Radiology (ACR) guidelines while DL Precise was instrumental in detecting previously undiagnosed cancers.

As DeepLook notes, 37% of mammography centers are currently noncompliant with ACR guidelines, which means they face up to a 2% reimbursement reduction from Medicare as well as private insurers. Non-compliance, according to the company, could lead to annual profit losses

of $50,000 to $200,000 per institution based on patient volume.

Breast density is an essential factor in screenings as women with dense tissue are at higher risk for developing cancer. Dense tissue can also hide tumors making diagnosis more difficult. Unfortunately, many women are unaware of the significance of density or whether they have it.

The FDA recently issued a final rule that now requires mammograms provide information regarding density to patients. (Also see "*Mammograms Should Inform Women About Breast Density, FDA Says*" - Medtech Insight, 13 Sep, 2024.)

DeepLook also announced a "successful" first close of series A funding the company says positions it for continued growth and innovation.

DeepLook plans to use the capital to forward commercialization of its technology "with existing and new commercial partners, expand the technology into other modalities, and expand its reach globally."

FDA Announces Pair Of Infusion Pump Recalls

The US FDA has designated two recalls of infusion pumps class I, the agency's most serious. The first *recall* from *B. Braun Medical Inc.* adds the lnfusomat Space Infusion System/Large Volume Pump to a *previous recall* the company issued last year of the Infusomat Space Large Volume Pump Wireless and lnfusomat Space Large Volume Pump Non-Wireless BATTERY PACK.

The company initiated the recalls due to the risk that a false alarm could indicate a blockage where there was none resulting in the pump stopping and not delivering needed medications or fluids.

Use of the affected pumps may cause serious adverse health consequences, including abnormal or unstable blood pressure, and death.

The FDA reports one injury and one death associated with the affected Braun devices.

In the second recall, *Fresenius Kabi AG* initiated a *recall* of certain lots of the Ivenix LVP Primary Administration Sets after identifying a manufacturing defect that may cause uncontrolled medication flow.

The recalled devices can result in medication overdose and death.

The FDA reports two injuries associated with the recall, but no deaths.

The Ivenix Large Volume Pump, which is one of three primary components of the Ivenix Infusion System, uses air pressure to precisely control the flow of fluids to the patient.

November Meeting Planned On Total Product Life Cycle Issues For Generative AI Devices

The FDA's Digital Health Advisory Committee will meet on 20-21 November to discuss total product life cycle (TPLC) issues raised by devices using generative AI, the agency *announced* on 17 September. The agency has also opened a *public docket* to collect comments on the topic in advance of the meeting.

The public meeting will be held at the Holiday Inn Gaithersburg in Gaithersburg, MD, and will be webcast live on YouTube.

This is the debut meeting of the Digital Health Advisory Committee, for which the FDA announced voting members in August. (Also see "*Digital Health Advisory Committee Announces Voting Members, Pool Of Industry Representatives*" - Medtech Insight, 9 Aug, 2024.)

FDA Releases Draft Guidance On Biocompatibility Assessment

A new FDA *draft guidance document* details the specific approaches regulators would like researchers to use in evaluating the biocompatibility of medical devices for use in device premarket submissions.

The 45-page draft, issued on 20 September, is intended to help manufacturers use what regulators have learned from past device submissions to improve the consistency and reliability of chemical composition studies. It makes recommendations around both specific and unspecific screening, the evaluation of biocompatibility endpoints such as system toxicity or carcinogenicity and proving chemical equivalency to a predicate device as part of a biological equivalency evaluation.

Topics addressed include preferred ways to gather information, test article extraction, chemical analysis and data reporting. The document also includes appendices that go into greater detail on solvent use, reporting and other issues.

The FDA is accepting *comments* on the draft through 19 November.

Merit Medical Buys Cook Medical Lead Management Portfolio For $210M

Merit Medical Systems Inc. has agreed to buy *Cook Medical LLC*'s end-to-end lead management portfolio for $210m, including medical devices and accessories used to manage leads in patients who need a pacemaker or an implantable cardioverter-defibrillator lead.

Merit plans to fund the transaction through a combination of cash on hand and borrowings. The transaction is expected to close in the fourth quarter of 2024.

Merit estimates that Cook Medical generated about $37m in 2023 revenues. The company predicts that its acquisition of Cook Medical will add about $40m in revenue on an annual basis, beginning in fiscal year 2025.

The cardiac intervention market represents around $900m annually in the US, EMEA, and APAC regions, said Fred Lampropoulos, Merit's chairman and CEO.

"The addition of Cook's lead management business positions Merit to represent more than $100m in combined annualized electrophysiology and cardiac rhythm management revenue serving the global cardiac intervention market" from the 2025 financial year, he said.

Axonics Did Not Violate Medtronic's Neuromodulation Technology Patents, Jury Rules

Irvine, CA-based medical device company *Axonics Modulation Technologies, Inc.* announced on 18 September it has won a patent infringement lawsuit brought against the company by *Medtronic plc* in US District Court for the Central District of California.

Medtronic first brought the lawsuit to the Central California district court in 2019 after Axonics received FDA approval for its rechargeable sacral neuromodulation (r-SNM) system to treat incontinence. In the complaint, Medtronic claimed that Axonics r-SNM system infringed three technical elements individually patented within Medtronic’s InterStim device. A full jury trial found that Axonics' r-SNM neurostimulation system did not infringe on any of Medtronic's patents.

"A jury of our peers recognized that Axonics' proprietary tined lead design and temperature sensor technology is differentiated from our competitor's intellectual property," said Raymond Cohen, CEO of Axonics. "As we have said since this case was first filed in late 2019, our view is that Medtronic's lawsuit was initiated to stifle competition, limit patient and physician choice, and protect the incumbent's monopoly in sacral neuromodulation.”

Medtronic said it "respectfully disagrees with the jury's verdict and will file post-trial motions, and an appeal, if necessary, to overturn this verdict," as reported by Law360.

GE HealthCare Received FDA Clearance For Imaging Tool To Assess Alzheimer's

GE HealthCare Technologies, Inc. announced on 17 September its MIM Software received FDA 510(k) clearance to perform Centiloid scaling for positron emission tomography or PET-based amyloid imaging analysis and quantification. Available with MIMneuro, a vendor-neutral solution, the Centiloid scale helps clinicians more confidently determine the density of amyloid plaque in a patient's brain. Amyloid plaque density is one component of Alzheimer's disease, which affects more than 6 million in the US today, and is expected to more than double to nearly 13 million by 2050.

The accumulation of beta-amyloid protein in the brain is linked to cell death and tissue loss. In recent years, clinical results for amyloid-targeting treatments have showed the potential to delay cognitive decline in some patients with Alzheimer's.

Germitec Launches US Operations

French medtech company Germitec, which recently received FDA de novo clearance for its Chronos automated disinfection device, announced its entrance into the US market as part of its international growth strategy.

The company hopes to capture market share in the US high-level disinfection for ultrasound probes, which represents an opportunity of 60,000 units, driven by the rapid expansion of imaging exams including ultrasounds, Germetic said. Keith Koby, who is the newly appointed president of North America for Germetic, will lead that expansion effort, the company said.

Chronos is indicated for use in health care environments to disinfect in about 90 seconds such surfaces as external, transvaginal, and transrectal ultrasound probes that do not contain lumen and identations or channels that are deeper than their widths. The company says the device uses ultraviolet-C light to disinfect probes with a button click. According to Germitec, ultrasound probes can lead to cross-contamination and health care-associated infections (HAI). HAIs result in 99,000 deaths annually in the US, according to the Centers for Disease Control and Prevention.