MEDTECH INSIGHT
CITELINE COMMERCIAL

09 Aug 2024 | **News**

News We're Watching: Medtronic Recall; FDA Approves Injector For Opioid Overdose; EKO Teams Up With LSU Tigers For Heart Monitoring

by Brian Bossetta

This week, Medtronic recalled a nerve monitoring system due to reports of false responses. The US FDA approved the first auto-injector for opioid-overdose, made by Purdue Pharma. The agency granted de novo authorization for Labcorp's PGDx elio plasma focus Dx used by labs for genetic profiling. As of 7 August, 950 AI/ML devices have been approved by the FDA. EKO Health teamed up with LSU to help detect arrhythmias and murmurs in student-athletes.

Potential Nerve Damage Prompts Medtronic Recall

Medtronic plc has issued a *recall* of a nerve monitoring system used to locate, monitor, and stimulate nerves of the skull, spine, and those that connect the brain and spinal cord to muscles and sensory cells.

The FDA has designated the recall class I, its most serious.

The company recalled the NIM Vital Nerve Monitoring System due to reports of false negative responses in which the system fails to issue an electromyography (EMG) tone when the NIM probe is placed on a nerve during procedures.

This failure could result in serious adverse health consequences, including nerve damage, facial nerve damage, nerve weakening and paralysis.

The FDA reports 10 injuries associated with the recall, but no deaths.

The FDA further notes that the recall is a correction, not a product removal, and that Medtronic is deploying a software update to fix the problem.

In the meantime, Medtronic advises surgeons to rely on “alternate monitoring, surgical skills, experience and anatomical knowledge” to prevent damage to nerves if monitoring is compromised.

EKO Health Teams Up With LSU Tigers To Beat Heart Disease

Eko Health has joined forces with the Louisiana State University athletics department to prevent heart disease.

The San Francisco-based company that specializes in AI technology for the early detection of heart and lung disease, has equipped LSU’s athletic department with CORE 500 digital stethoscopes and AI algorithms for the “enhanced detection of cardiac conditions” during physical exams of the school’s athletes.

In April, the FDA cleared the company’s AI tool, which was developed with the Mayo Clinic and allows physicians using the Eko digital stethoscope to detect signs of heart failure during routine exams that often go undiagnosed. (Also see "*AI Tool Could Be ‘Groundbreaking’ In Early Detection Of Heart Failure*" - Medtech Insight, 2 Apr, 2024.)

The donation of the devices to LSU makes the university the first college sports program to implement Eko Health's technology to care for student-athletes.

"Early detection of arrhythmias and murmurs is incredibly important for everyone — but especially LSU student-athletes who are constantly pushing their bodies to perform at a high level," said Kelechi Akamiro, a sports medicine physician at Our Lady of the Lake Health, LSU’s Baton Rouge-based health partner. “These new digital technologies have the propensity to assist us in detecting irregularities or problems with even greater precision."

FDA Approves First Nalmefene Hydrochloride Auto-Injector to Reverse Opioid Overdose

The FDA has *approved* Zurnai, the first nalmefene hydrochloride auto-injector for the emergency treatment of opioid overdose for patients 12 years and older. The device was developed by *Purdue Pharma L.P.*, which played a major role in the US opioid epidemic.

When administered quickly, the FDA says nalmefene, an opioid receptor antagonist, can reverse the effects of overdose, including respiratory depression, sedation, and low blood pressure.

Zurnai is a single-dose, pre-filled auto-injector available only by prescription.

The approval of Zurnai, according to the FDA, is supported by safety and pharmacokinetic studies, as well as a study in healthy individuals who use opioids recreationally, to assess how quickly the product works.

The FDA lists drug overdose as a major public health issue in the US with more than 107,000 reported fatal overdoses occurring in 2023.

The agency approved the first nasal spray formulation of nalmefene in May 2023.

61 New AI/ML Devices Added To FDA Approved List

As of 7 August, 950 artificial intelligence/machine learning devices have been *approved by the FDA.* 61 of these were approved within the last five months, from the period of 1 April to 25 June.

The majority of these new devices are in radiology, which is also a trend in approved AI/ML devices. Radiology makes up the largest category of AI/ML enabled devices currently on the market. (Also see "*Radiology Reigns Supreme: 151 New AI/ML Devices Added In Last 9 Months*" - Medtech Insight, 14 May, 2024.)

The other devices approved during the time period were in the specialties of neurology, gastroenterology-urology, ophthalmic, hematology, general hospital and dental.

There was only one de novo AI/ML device, the Rho from 16 Bit Inc, which is a radiological device that utilizes AI to identify problems with bone density. The rest of the devices were approved through the 501(k) pathway.

Labcorp Receives FDA De Novo Marketing Authorization For PGDx Liquid Biopsy Test

Labcorp says its PGDx elio plasma focus DX, recently *approved* by the FDA, is the industry's "first and only" knitted, pan-solid tumor liquid biopsy test that enables tumor mutation profiling "all from a simple blood draw.

The qualitative next-generation sequencing–based in vitro diagnostic, according to Labcorp, uses a targeted high-throughput hybridization-based approach to capture single-nucleotide variants (SNVs), insertions, and deletions in 33 genes.

Labcorp says the testing kit provides results in 4 to 5 days with a clinical success rate of over 96% and can profile a wide range of solid-tumor types — "particularly when tumor tissue is limited or unavailable."