MEDTECH INSIGHT
CITELINE COMMERCIAL

23 Aug 2024 | **News**

News We're Watching: AMP Sues FDA To Block Lab-Developed Test Rule; FDA Guidances; ICU Medical Infusion Pump Correction

by Brian Bossetta

This week, a medical group sued the FDA to block a lab-developed test rule; the FDA published guidance on device classifications; Defibtec issued a recall of its chest compression device and ICU Medical updated instructions for its infusion pump batteries; Maui Imaging raised a $4m DOD grant to put imaging tech into military-based trauma units.

FDA Faces Second Lawsuit On LDT Rule

The Association for Molecular Pathology (AMP) has filed a lawsuit to block the US Food and Drug Administration from implementing a policy change that would apply agency oversight to lab-developed tests.

The *suit*, which was filed on 19 August in a Texas federal court, argues that "LDTs are not manufactured, packaged, nor commercially distributed as medical devices." Additionally, AMP points out that Congress delegated LDT oversight not to the FDA, but to the Centers for Medicare and Medicaid Services.

AMP also says that FDA regulation would be significantly more expensive and time-consuming for LDT developers and would create regulatory requirements duplicative of those already imposed by CMS.

This is the second lawsuit the agency is facing on the LDT final rule. The American Clinical Laboratory Association (ACLA) filed a similar suit in May. (Also see "*Could SCOTUS Chevron Reversal Reverse FDA's Final Rule On LDTs?*" - Medtech Insight, 30 Jul, 2024.)

One Death Linked To Recall Of Defibtech Chest Compression Device

Defibtech has issued a *recall* of its RMU-2000 ARM XR Chest Compression Device due to a problem with the motor that may cause the device to stop compressions.

The device administers chest compressions on adults whose hearts suddenly stop and are not circulating blood throughout the body.

Using the affected device, according to the FDA, may cause serious adverse health consequences, including death.

The FDA reports one death, and one injury, associated with the recall.

In an urgent device correction letter, the company provided customers with a list of *serial numbers* of the affected devices that should not be used.

Defibtech said it will contact customers to arrange for the return of the devices with refunds, repairs, or replacements at no cost.

FDA Publishes Guidance For Receiving Information On Device Classifications

The FDA is providing *guidance* to establish procedures for submitting, reviewing, and responding to requests for information regarding the class in which a device has been classified or the requirements applicable to a device under the Federal Food, Drug, and Cosmetic Act.

Specifically, the guidance addresses section 513(g) of the FD&C Act, which provides a means for obtaining the agency's views about the classification and the regulatory requirements that may be applicable to a particular device.

The FDA notes that its response to a 513(g) request for information will not address “the specific types of nonclinical, animal, or clinical testing appropriate to support clearance or approval of a marketing application” and that a response to a 513(g) does not constitute final agency action, but “provides responsive information based on the information provided by the requestor.”

FDA Issues Final Guidance For Manufacturers User Manuals

The US FDA has published *final guidance* for manufacturers to provide user manuals accompanying electronic products in either paper or electronic form. The agency says it issued the guidance in recognition that electronic media are widely used now to provide instruction, while at the same time reducing paper consumption, increasing accessibility, and providing rapid means for editing and updating content.

With the availability of electronic information storage and display technology, many commercial

product manuals are provided electronically. Electronic documentation, according to the FDA, saves storage space, reduces paper consumption, increases accessibility, and provides rapid means for editing and updating of content.

The guidance also notes that manuals in any form should be in English.

ICU Medical Issues Correction For Infusion Pump Batteries

ICU Medical, Inc. is *updating* its instructions for use for replacement batteries that power the Plum 360 Infusion System — large volume infusion pumps that administer fluids. The system delivers blood or blood products, drugs, and other fluid mixtures through subcutaneous, intramuscular, intravenous, and intrathecal administration.

The batteries and replacement batteries power the pump when not plugged into an AC source, such as during patient transport.

The company says the update stems from a manufacturing defect of the batteries, which can result in the substantial diminishment of battery life. The FDA says use of the affected batteries can cause serious injury or death to patients due to interruption, under-infusion, or delays in the delivery of critical fluids, blood products, and medications.

Maui Imaging Wins $4M US DOD Grant To Put Imaging Tech In Trauma Units

Maui Imaging won a $4m US Department of Defense (US Army Medical Research and Development Command) contract to support trauma medicine across four branches of the military with its FDA-cleared imaging technology, the company says.

Maui's imaging technology, Maui K3900, which received FDA clearance in October 2023, differs from existing imaging ultrasound technologies in that it provides scans that look like a cross between ultrasound and computed echo tomography, without the need for dangerous ionizing radiation, X-rays, the company says. The firm describes its CET as pinging the designated part of the human body, seeing anatomy beyond what the ultrasound can see and the uses algorithms to accommodate the reflected energy from various flight paths and sums up the data to create a reliable image of all structures below the probe. Barriers, such as bone, fat, instruments and implants are intended to become part of the image instead of obstacles to image formation, it says. The company says it is performing clinical studies with the military and elsewhere to demonstrate these capabilities.

Sibel Health's Wearable Monitor Platform FDA Cleared For Use With Third Party Software

Sibel Health, maker of clinical-grade vital sign monitoring devices Anne Chest and Anne Limb, on 22 August announced two additional FDA clearances that allow third-party developers to design apps for its wearable sensors.

The two wearable sensors, Anne Chest and Anne Limb, (part of the Anne One platform), are

FDA-cleared to measure a wide range of physiological parameters for patients 12 years and older in the home or hospital setting. Last May, the Anne One platform also received FDA 510(k) to include continuous neonate and vital sign monitoring of infants at any gestational age up to 2 years old.

"We know we can't make software for every application - and with these FDA-clearances, we won't have to," says Steve Xu, co-founder and CEO of Sibel Health. " We want to enable other creators to have access to continuous vital signs from our FDA-cleared sensors wherever they see a clinical need."

In April, Sibel Health was awarded a $17.5m grant from the Bill & Melinda Gates Foundation to advance the use of the Anne One platform for labor triage and continuous maternal health monitoring in low- and middle-income countries to reduce obstetrical morbidity and mortality. Partnering with the University of Edinburgh and the National Institute for Health and Care Research Global Health Research Unit on Global Surgery (Global Surgery Unit) Sibel Health will first target institutes in India, Pakistan, and Nigeria.