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News We're Watching: First OTC Blood Glucose Monitor, Recalls For Ventec and Medtronic, Guidance Docs Under White House Review

by Brian Bossetta

This week, the US FDA announced that it had cleared Dexcom's Stelo Glucose Biosensor System, making it the first OTC device of its type available in the US. Additionally, the Office of Management and Budget took up guidance documents on cybersecurity and enforcement on diagnostics during emergencies, and recalls were announced by Medtronic, Ventec and Cardinal.

FDA Clears First OTC Continuous Glucose Monitor

The *Dexcom Stelo Glucose Biosensor System* became the first over-the-counter continuous glucose monitor (CGM) cleared for sale in the US on 5 March. The US Food and Drug Administration cleared the Dexcom Stelo for use by people aged 18 or over who do not use insulin. For example, it might be used by people treating diabetes with oral medication, or by individuals who wish to track the way food or exercise affects their blood sugar levels. It is not intended for use by people with problematic hypoglycemia.

The device consists of a wearable sensor that tracks blood sugar levels and sends the readings to an individual's smartphone. Each sensor can be worn for up to 15 days before being replaced.

"CGMs can be a powerful tool to help monitor blood glucose. Today's clearance expands access to these devices by allowing individuals to purchase a CGM without the involvement of a health care provider," said FDA device center director Jeff Shuren said. "Giving more individuals valuable information about their health, regardless of their access to a doctor or health insurance, is an important step forward in advancing health equity for U.S. patients."

Dexcom plans to start selling Stelo this summer.

Cybersecurity, Emergency Use Guidance Docs Reviewed By OMB

The US Food and Drug Administration seems to be teeing things up for a busy March. In addition to the *final rule on lab-developed tests*, two additional guidance documents are in the hands of the White House Office of Management and Budget.

The OMB is typically the last step before release, indicating the new guidance document is imminent. The *first guidance document* involves "select updates" to the premarket cybersecurity guidance document. The OMB finished its review on 28 February, meaning the final guidance can be issued at any time.

The OMB is also reviewing a guidance titled "*Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency*," which will likely outline the agency's planned approach for diagnostics regulation during future pandemics or other emergencies. That document reached the OMB on 7 March.

Class I Recall For Medtronic Catheter Tubing System

Medtronic Neurosurgery is recalling thousands of *DUET External Drainage and Monitoring System (EDMS) Catheter Tubing* units due to a potential for the catheter to disconnect from the patient line stopcock connectors.

The company initiated the recall of more than 45,000 various device models in January .

The EDMS is used for temporary drainage of cerebrospinal fluid (CSF) or CSF sampling in patients who have surgery for open descending thoracic aortic aneurysm (open TAA) or open descending thoraco-abdominal aortic aneurysm (open TAAA), or those who have had TAA or TAAA repair surgery and developed symptoms, such as paraplegia.

Should the catheter tubing disconnect, it could result in patient infections, cerebrospinal fluid leakage, over drainage of cerebrospinal fluid, and abnormality of the ventricles. Uncontrolled over drainage of cerebral spinal fluid could lead to neurological injury or death if the disconnection is undetected.

The company reports 26 injuries associated with the recall, but no deaths.

The FDA has labelled the recall class I.

Manufacturing Issue Prompts Recall Of Pediatric Breathing Package

Ventec Life Systems is recalling its *VOCSN Patient Breathing Package* (various Pediatric, Active, Oxygen, and Blue models) due to a manufacturing issue which causes the bonded spiral wrap to detach before or during ventilation. If this occurs, it can compromise the structural integrity, functionality, or cause blockage, stoppage, or leaks in the breathing circuit.

The FDA has designated the recall class I.

The use of the affected breathing package may cause serious injuries, such as failure to ventilate, incomplete ventilation, failure to oxygenate, complete or partial airway obstruction.

The FDA said risk of injury or death increases for pediatric patients who depend on the device.

There have been 15 complaints associated with the recall, but no reports of injuries or death.

The VOCSN (ventilator, oxygen concentrator, cough assist, suction, and nebulizer) Patient Breathing Package is intended to provide respiratory support for pediatric patients weighing at least 11 lbs. The patient breathing package may be used at home, the hospital, in institutional settings, or during the process of moving patients to and from different areas of a medical facility.

The Ventec active, oxygen, patient circuit delivers oxygen and has a breathing valve that opens and shuts.

The recall includes 150 devices manufactured in the US in March 2022.

Cardinal Expands Monoject Luer-Lock and Enteral Syringes Recall To Product Removal

In February, the FDA issued a *safety communication* warning consumers, health care providers, and health care facilities not to use certain recalled luer-lock and enteral syringes manufactured by *Cardinal Health, Inc.*. (Also see "*News We're Watching: CDRH Announces Cybersecurity Collaboration, Electrostim Faces Lawsuit, FDA Recalls And Approvals*" - Medtech Insight, 2 Feb, 2024.)

Now, Cardinal Health has *expanded* that action to a product removal.

Those recalled devices include products with codes FMF and PNR; specifically, Cardinal Health Monoject sterile Syringe Luer-Lock Tip Soft Packs (1, 3, 6, 12, 20, 35, and 60 mL) and Cardinal Health Monoject sterile Enteral Syringes with ENFit connection (1, 3, 6, 12, 35, and 60 mL), which are color-coded purple to denote enteral feeding only.

In total, the company recalled more than 26 million luer lock devices, which are used to inject fluid into or withdraw fluids from the body; and more than 701,000 enteral syringes, which are used to deliver fluid, feeding, or medications to a patient's feeding tube.

The company initiated the recall of the devices due to a change in manufacturing and rebranding efforts.

In June 2023, Cardinal Health began distributing Monoject syringes branded as "Cardinal Health Monoject syringes." These new syringes differ from the previously branded "Covidien Monoject syringes" as they have different dimensions and are made by a different contract manufacturer.

The dimensional changes made to the Cardinal Health Monoject syringes, when used with syringe pumps, PCA pumps, or enteral syringe pumps, may result in recognition, compatibility, and pump performance issues, such as overdose, underdose, delay in therapy, delay in occlusion alarms, and delay in feeding.

The FDA said there is potential that changes to the dimensions of any syringe could affect the performance of the device when used alone or with pumps.

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

To date, however, there have been no reports of death.