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News We're Watching: MedRhythms App Gets FDA Clearance, Recalls For Megadyne And Draeger, Elixir Stent Trial Moves Ahead

by Marion Webb

This week, companies including MedRhythms, Allergan and Urotronic announced FDA clearances; Quest and Envision launched a prostate cancer test; and the FDA designated two recalls as class I.

MedRhythms Wins FDA Clearance For Digital Therapeutics To Improve Walking In Stroke Patients

MedRhythms, Inc. announced on 15 July that it has received US Food and Drug Administration clearance for MR-001, marketed as InTandem, a digital therapeutic to treat walking deficits in chronic stroke patients.

The Portland, Maine-based digital therapeutics company first received breakthrough device designation for MR-001 from the FDA in 2020, and earlier this year successfully completed a pivotal clinical trial.

"Today is a historic day for MedRhythms and an essential accomplishment as we work to bring a new care solution to the 3.5 million people who struggle with mobility and independence long after the incidence of a stroke," said Brian Harris, CEO and co-founder of MedRhythms. "During my time as a clinician at Spaulding Rehabilitation Hospital, I saw the positive impact that standardized interventions using music could have on the mobility of my patients. I am honored and proud that our team has committed to our mission of translating these interventions into evidence-based medical devices that can be utilized in home settings, breaking down several historic barriers to access."

InTandem combines sensors, music and the company's clinical algorithms to provide evidence-based rhythmic auditory stimulation that engages the motor system to improve functional outcomes over time. To start a session, the patient clips sensors onto each shoe, puts on

headphones and begins to walk. As the patient walks to the beat of a personalized music selection, the sensors collect real-time gait data, which serves as a basis for individualized clinical interventions. By constantly assessing the synchronization of the brain's auditory and motor systems with an external auditory rhythmic cue, and quality of walking, MedRhythms can progress a patient toward an objective goal. (Also see "*MedRhythms On First-To-Market Track With Prescription Music Therapy For Chronic Stroke*" - Medtech Insight, 11 Aug, 2022.)

The company didn't give an exact timeline but said that InTandem will be available soon in select markets.

FDA Approves Injectable Skin Enhancement Device

The US Food and Drug Administration last month approved *SKINVIVE by JUVÉDERM*, a dermal filler from *Allergan Aesthetics*. The product is an injectable gel implant designed to add definition or reduce the appearance of lines and wrinkles in specific areas of the face.

SKINVIVE by Juvéderm is an injectable hyaluronic acid gel indicated for intradermal injection to improve facial skin smoothness of the cheeks in people 21 years of age and older. It contains a small amount of lidocaine, a local anesthetic.

According to the FDA, in a clinical study of 209 participants, SKINVIVE was found to be effective at improving facial skin smoothness in the cheeks. This effect lasted for at least six months.

However, the FDA advises that those with severe allergies with a history of anaphylaxis; or known presence of multiple severe allergies; a known sensitivity or allergy to gram-positive bacterial proteins; or any known allergies to lidocaine, should not use the product.

Burn Risk Leads To Class I Recall Of J&J Electrodes

Megadyne Medical Products Inc. has initiated a *recall* of MEGA 2000 and MEGA SOFT reusable patient return electrodes, which are used during electrosurgery to direct an electrical current back to the electrosurgical unit and lessen the risk of overheating.

The company recalled 21,200 devices distributed in the US between March 2021 and May 2023 after reports of burn injuries to both adult and pediatric patients. Burn injuries from the devices can be as serious as third-degree requiring medical intervention, including potential surgery.

Megadyne reports 63 injuries, but no deaths related to this issue. The FDA has labelled the recall class I, its most serious type.

Ethicon Inc., a subsidiary of Johnson & Johnson, acquired Megadyne in 2017.

FDA Okays Urotronic Catheter System for BPH

The FDA has approved a treatment from *Urotronic Inc* for benign prostatic hyperplasia (BPH), a noncancerous enlargement of the prostate that affects many men, especially those over 60 or older, the company announced.

Urotronic's Optilume BPH Catheter System, according to the company, is a minimally invasive surgical therapy (MIST) that combines mechanical dilation using a proprietary double-lobe balloon with concurrent localized delivery of paclitaxel for the treatment of lower urinary tract symptoms (LUTS) secondary to BPH.

The company said it won approval from the FDA after completing two clinical trials: the PINNACLE trial, which evaluated Optilume against a sham treatment in 148 patients, and the EVEREST trial, which evaluated functional improvement in urine flow and LUTS in 80 patients after treatment with the Optilume.

Those treated with Optilume showed significant and immediate symptomatic and functional improvements, according to Urotronic, including improvement in the International Prostate Symptom Score (IPSS), the standard metric that measures urinary symptoms.

Major Trial Of Elixir's Adaptive Stent Moves Forward

The INFINITY SWEDEHEART trial has completed enrollment, *Elixir Medical Corp* announced on 13 July.

The 2,400-patient randomized trial compares percutaneous coronary intervention with Elixir's DynamX coronary bioadaptor stent to PCI with Medtronic's Resolute Onyx zotarolimus-eluting stent. (Also see "*Start-Up Spotlight: Elixir Works To 'Uncage' The Coronary After Intervention*" - Medtech Insight, 5 Apr, 2021.)

The trial includes 2,400 "real-world" patients from 14 sites across Sweden. The primary endpoint is target lesion failure after one year.

DynamX is a cobalt chromium coronary scaffold with a sirolimus-eluting bioresorbable polymer. Unlike other drug-eluting stents that stay rigid in the coronary, DynamX features "uncaging elements" located at low-stress points to allow the stent to flex while maintaining radial strength. The investigators expect this flexibility will reduce the risk of adverse events normally

associated with coronary stents. (Also see "*Cardio Catch-Up: Gel For Fixing Heart Attacks, 'Uncaged' Coronary Stents, And More*" - Medtech Insight, 16 Jun, 2022.)

"For more than 20 years, generations of drug-eluting stents have offered no hard clinical benefits beyond the first year for the treatment of ischemic heart disease and no advancements have been made to address the annual non-plateauing adverse events," said principal investigator David Erlinge of Lund University in Sweden.

Stefan James of Uppsala University, the chairman of the trial's steering committee, said "This trial is conducted through a robust national Swedeheart registry and includes patients we typically see in our practices, with both chronic and acute coronary syndromes, and will provide important data to potentially change the future of treatment."

INFINITY SWEDEHEART is the fourth trial of Elixir Medical's robust DynamX Bioadaptor clinical evidence program, which includes of nine company-sponsored and investigator-initiated studies enrolling more than 9,000 patients total.

Most recently, one-year data from the BIOADAPTOR RCT trial data showed DynamX can restore the pulsatility of the treated vessel while at least matching the overall performance of Resolute Onyx. (Also see "*News We're Watching: Premom Data Privacy Settlement, Labcorp Owes $372m For Patent Violations, Elixir Stent Trial Success*" - Medtech Insight, 19 May, 2023.)

Quest, Envision Launch Prostate Cancer Test Through AmeriPath

Quest Diagnostics Incorporated and *EnVision Technologies Inc.* are launching a new tissue-based prostate cancer biomarker lab test through Quest's subspecialty pathology business, AmeriPath.

The test is available to physicians throughout the US, except in New York.

Quest developed and validated the laboratory test through an intellectual property license agreement with Envision, an Adelaide, Australia-based clinical diagnostics company that has developed unique staining technology and novel cancer biomarkers – EV1, EV2 and EV3.

A 2022 study at the University of South Australia examined 112 patient samples with the three Envision biomarkers and a conventional pathologic assessment based on hematoxylin and eosin-stained tissue alone. Following the conventional test, the new-biomarker test "upgraded" 22% of the samples to a higher cancer grade and "downgraded" 20% of the samples. Results of the study are published in Pathology.

According to Quest Diagnostics, diagnoses of prostate and breast cancer continue to lag behind

pre-pandemic levels. “We expect this service to help fill a clinical gap affecting millions of men for staging, diagnosis and treatment for prostate cancer," said Kristie Dolan, the general manager of Quest Diagnostics oncology business.

Envision CEO Peter Pursey said, “Our patented technology provides a novel approach to visualizing prostate cancer tissue and improving accuracy in grading the cancer by pathologists. We expect the test to enhance current prostate cancer histology practice and improve the information available to clinicians, enabling them to better align cancer grades with treatment options."

Battery Issue Leads To Class I Recall For Draeger Medical

The FDA has designated a *recall* of 300 ventilators from *Draeger Medical Inc.* as class I, citing the risk of the device shutting down from battery depletion.

Draeger initiated the recall of its Oxylog 3000 Plus Emergency and Transport Ventilator in June after receiving reports of stopped ventilation due to the battery issue. The FDA also said the ventilator may not automatically switch back to using AC power when it is plugged in and may continue using the battery until it is depleted causing the ventilation to stop.

Further, a battery alarm does occur with this issue.

Stopped ventilation could result in respiratory distress, lack of oxygen, slow heartbeat, or the heart stopping, and other severe injuries, including death.

Draeger Medical reports six complaints related to this issue, but no injuries or deaths.

The recalled ventilator is designed for patients being transported via ambulance or aircraft or being moved throughout a hospital.

10 Health Tech Companies Join Cedars-Sinai Innovation Initiative

The *Cedars-Sinai Accelerator* program’s ninth class will include 10 health tech companies from across the globe focusing on a variety of healthcare solutions — from devices to treat sepsis, heart failure, and stroke to virtual reality platforms to manage pain and anxiety.

Each company chosen for the three-month program will receive a $100,000 investment from Cedars-Sinai as well as hands-on experience and mentorship from the hospital’s researchers, administrators, and clinicians in developing and refining practical applications to their products.

A list of the companies can be found *here*.