Medtronic News

Medtronic Announces FDA Submission for InterStim™ Micro Neurostimulator and SureScan™ MRI Leads

Smaller, Rechargeable Device Will Provide More Choices for Patients Suffering with Bladder and Bowel Control Issues
SureScan™ MRI Leads Will Provide Full-Body MRI Conditional Labeling

DUBLIN, Oct. 07, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced it has filed a pre-market approval (PMA) supplement with the United States Food and Drug Administration (FDA) for approval of its InterStim™ Micro neurostimulator and also its InterStim™ SureScan™ MRI leads. InterStim Micro is a rechargeable, implantable sacral neuromodulation (SNM) device to treat patients affected by overactive bladder, urinary urge incontinence, unobstructed urinary retention and fecal incontinence. The SureScan™ leads, which will be used in future implants of the recharge-free InterStim II system and rechargeable InterStim Micro system, are designed to provide full-body 1.5 and 3 Tesla MRI conditional labeling, pending FDA approval.

The rechargeable InterStim Micro device works by sending electrical impulses to the sacral nerves, normalizing the connections between the brain, bladder and bowel. It is 80% smaller than the current recharge-free InterStim II neurostimulator and could reduce the need for battery replacement surgeries due to its life of 15 years. Additionally, the SureScan full-body conditional MRI leads will enable patients to undergo imaging procedures that were not previously indicated under the current FDA approval for the InterStim II system.

“The FDA submission for InterStim Micro and SureScan MRI leads is a significant milestone for Medtronic and a leap forward in our 20-year history of leadership in sacral neuromodulation,” said Brooke Story, vice president and general manager of the Pelvic Health & Gastric Therapies business, which is part of the Restorative Therapies Group at Medtronic. “Our ultimate goal is to provide safe and effective treatments to patients affected by bladder and bowel dysfunction, and ensure they have a choice in selecting the most appropriate therapy for their unique situation.”

This submission, pending regulatory approval from the FDA, would position the Company to achieve approval for the InterStim Micro system and SureScan MRI leads in the spring of 2020, following a standard 180-day review process. The InterStim Micro system and SureScan MRI leads are not yet available for sale in the United States.

About Overactive Bladder

Overactive bladder (OAB) significantly impacts quality of life and can negatively affect social activities, exercise and cause disruptive nighttime voiding.1,2 Many sufferers are frustrated and embarrassed and limit their lives socially, professionally, and personally.3 However, 45% don't seek treatment and as many as seven in 10 stop using medications within six months due to intolerable side effects or unsatisfying results.4,5,6

Evidence points to OAB being caused by a miscommunication between the bladder and brain.7 Sacral neuromodulation, or gentle stimulation of the sacral nerves, delivered by the InterStim system is thought to normalize the brain-bladder communication pathway thereby restoring bladder function and alleviating symptoms. Restored function is defined as ≥50% reduction in dysfunctional voiding symptoms from baseline. The InterStim system is the only sacral neuromodulation solution proven to demonstrate sustained five-year efficacy and quality of life improvements for OAB.8

About Fecal Incontinence

Fecal incontinence (FI) is a distressing and disruptive chronic condition that is characterized by the inability to control bowel movements, which results in frequent accidents and leakage. People with FI report more depression and embarrassment, as well as lower quality of life compared to those without FI.9 Even though FI is treatable, 8.5 out of 10 adults haven't even told their doctor about their FI.10 The InterStim system is the only sacral neuromodulation solution proven to demonstrate sustained

five-year efficacy and quality of life improvements for FI.11

About Medtronic InterStim Therapy for Bladder and Bowel Control

Medtronic is the first and leading provider of neuromodulation solutions for bladder and bowel control issues. Sacral neuromodulation therapy delivered by the InterStim system was first approved over twenty years ago and has helped more than 300,000 patients worldwide.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies –alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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