Medtronic News

Medtronic Receives FDA Clearance for Reveal LINQ(TM) Insertable Cardiac Monitor (ICM) with TruRhythm(TM) Detection

Device Delivers Improved Accuracy and Streamlined Data for Clinicians

DUBLIN - Mar. 13, 2017 - Medtronic plc (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) 510(k) clearance for its Reveal LINQ(TM) Insertable Cardiac Monitor (ICM) with TruRhythm(TM) Detection, an advanced cardiac monitor offering improved accuracy to better identify abnormal heartbeats.

Reveal LINQ ICM with TruRhythm Detection offers exclusive algorithms that result in a 95 percent reduction in false bradycardia (slow heartbeat) episodes and a 47 percent reduction in false pause (brief absence of cardiac activity) episodes when compared with its predecessor, the Reveal LINQ(TM) ICM. The device also features a self-learning atrial fibrillation (AF - an irregular and often very fast heart rate) algorithm, which learns and adapts to a patient's heart rhythm over time. AF episodes, which are most likely to trigger false positives with ICMs, experienced a 49 percent reduction in false detections with the Reveal LINQ ICM with TruRhythm Detection when compared to the Reveal LINQ ICM.1

"ICMs help physicians find answers for patients at risk for cardiac arrhythmias to better manage a range of patient populations," said James Allred, M.D., electrophysiologist at Cone Health Medical Group Heartcare in Greensboro, N.C. "The enhancements with the Reveal LINQ ICM with TruRhythm Detection make it smarter by streamlining device data review so physicians can make decisions more accurately and quickly for patients."

Reveal LINQ ICM with TruRhythm Detection, which allows physicians to continuously and wirelessly monitor a patient's heartbeat for up to three years, is approximately one-third the size of an AAA battery (~1 cc). It is placed just beneath the skin through a small incision of less than 1 cm in the upper left side of the chest, using a minimally invasive procedure, and its presence is often nearly undetectable to the naked eye once the incision has healed. The device communicates wirelessly with a patient bedside monitor that uploads device data to the Medtronic CareLink® network; it is MR-Conditional, allowing patients to undergo magnetic resonance imaging (MRI), if needed.

"For nearly twenty years, Medtronic has led innovation in cardiac monitoring, including Reveal(TM), the world's first loop recorder, and Reveal LINQ, the world's smallest ICM," said Nina Goodheart, vice president and general manager of the Patient Monitoring & Diagnostics business at Medtronic. "We collaborated with hundreds of clinicians and analyzed more than 50,000 ECGs allowing us to pinpoint how we could redesign our algorithms to improve detection specificity, without compromising sensitivity."

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

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 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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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1 TruRhythm Detection Algorithms. Medtronic data on file. 2017.

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