Medtronic News

Medtronic Gains FDA Clearance, CE Mark for LINQ II™ Insertable Cardiac Monitor (ICM)

Next Generation ICM Offers Remote Programming with Improved Longevity and Enhanced Accuracy

DUBLIN, July 07, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has received U.S. Food and Drug Administration (FDA) clearance and CE (*Conformité Européenne*) Mark approval for its LINQ II™ insertable cardiac monitor (ICM) with remote programming, which enables clinicians to optimize device settings without the need for patients to return to the office or hospital. The LINQ II system also delivers improved device longevity (4.5 years*1) compared to other ICMs and enhanced accuracy to correctly detect abnormal heart rhythms, simplifying the diagnosis and monitoring of patients.

LINQ II is a small (one-third the size of a AAA battery), wireless ICM for patients with abnormal heart rhythms who experience infrequent symptoms including dizziness, palpitations, syncope (fainting) and chest pain, thereby requiring long-term monitoring or ongoing management. The device will be commercially available in the U.S. and Europe later this summer.

“In the current COVID-19 environment, the LINQ II system offers patients a seamless way to experience ongoing connectivity between their device and their physician, while reducing the need for in-office visits,” said Rob Kowal, M.D., Ph.D., chief medical officer of the Cardiac Rhythm and Heart Failure division, which is part of the Cardiac and Vascular Group at Medtronic. “LINQ II gives physicians actionable data to help diagnose underlying heart conditions and define treatment protocols for patients with atrial fibrillation (AF) or other abnormal heart rhythms.”

The LINQ II device incorporates many of the features of LINQ with TruRhythm™ plus improvements that differentiate the device from other ICMs:

- Accuracy and Streamlined Workflows: The LINQ II device has the lowest published rates of AF false detections compared to previous ICMs.2-5 It also has an industry-exclusive Premature Ventricular Contraction (PVC) detector to help with patient diagnosis; PVCs are extra, abnormal heartbeats that begin in the ventricles, and disrupt the heart rhythm. Additionally, clinicians spend 33 percent less time reviewing ICM transmissions,6 resulting in potential office efficiencies and reduced costs due to more streamlined workflows.
- Remote Programming: The LINQ II ICM offers remote programming, which reduces the need for patients to come into the office to have their device settings adjusted – a benefit for both patients and physicians, especially during the current COVID-19 pandemic.
- Remote Patient Management: Patients with the LINQ II ICM can choose one of two monitoring options to fit their lifestyles and increase remote monitoring compliance, potentially leading to improved patient outcomes:
    - Patients can use their smartphones to automatically transfer device data via the MyCareLink Heart™ mobile app using BlueSync™ technology that enables secure communication via Bluetooth.
    - Patients who are unable or prefer not to use a cell phone can transmit device data with the MyCareLink Relay™ Home Communicator.
- Increased Longevity: The LINQ II device offers an extended duration of continuous monitoring at 4.5 years*1. Continuous monitoring gives physicians greater insights into patient data, aids in diagnoses and helps them manage chronic cardiac arrhythmias.

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 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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* Nominal settings

1LINQ II™ Clinician Manual. M974764A001.
2BiotronikBioMonitor™ 2 Technical Manual. 2017.
3NölkerG, et al. J Cardiovasc Electrophysiol. 2016;27:1403-1410.
4Confirm Rx™ ICM DM3500 FDA Clearance Letter. 2017.
5PürerfellnerH, et al. Europace. 2018;20:f321-f328
6Alert Analysis for LINQ II with TruRhythm and LINQ II, Medtronic data on file, 2020.

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