Medtronic News

Medtronic Receives FDA Breakthrough Designation for the Emprint™ Ablation Catheter Kit

Minimally Invasive Option Has Potential to Provide Long-Term Management of Lung Malignancies While Protecting Lung Function

DUBLIN, April 27, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has received Breakthrough Device Designation status from the U.S. Food and Drug Administration (FDA) for the Emprint™ ablation catheter kit – an investigational device not yet approved or cleared in the United States. The catheter is intended to be used in conjunction with the Emprint™ microwave generator and Medtronic lung navigation platform to provide a minimally invasive, localized treatment of malignant lesions in the lung, and it can be used together with standard of care therapy when indicated.

The FDA Breakthrough Device Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide Medtronic with priority review and interactive communication regarding clinical trial designs through to commercialization decisions.

Current clinical guidelines for the management of malignant lung lesions support a multimodal approach, which may include surgery, radiotherapy, and/or systemic drug therapy depending on the tumor stage. Because patients with lung malignancies have been shown to have survival benefit from a combination of systemic and local therapy, less invasive local treatment modalities such as the Emprint ablation catheter kit have been developed.[1] Using an endoluminal approach, the Emprint ablation catheter kit will be studied with the Medtronic lung navigation system to allow for accurate delivery of microwave energy to the targeted lung lesion(s). Clinical guidelines recommend incorporating local therapies such as thermal ablation, in combination with systemic therapies when suitable.

Though not yet available in the United States, the Emprint ablation catheter kit is CE Marked and the NAVABLATE study completed enrollment of 30 subjects in Europe and Hong Kong in 2020.

"This new technology has allowed me to personalize treatment of lung lesions for each patient, particularly lesions that may be challenging to manage," said Mr. Kelvin Lau, MA, DPhil, FRCS(CTh), a consultant thoracic surgeon at St. Bartholomew's Hospital, London, and principal investigator for the NAVABLATE study.

The Medtronic lung navigation platform enables precise and accurate placement of the ablation catheter within the target lesion, which is critical for the success of this minimally invasive procedure.[2] With 15 years of experience, the navigation platform has been used in more than 200,000 lung procedures.

"At Medtronic, we strive to transform outcomes by taking bold actions to ensure that patients with tumors in the lung receive care sooner, less invasively, and more effectively," said Emily Elswick, vice president and general manager, Lung Health & Visualization, within the Surgical Innovations business, which is part of the Medical Surgical Portfolio at Medtronic. "Breakthrough designation from the FDA is just the first-step in realizing our broader commitment to providing less invasive treatment options to patients with lung disease."

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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[1] Uhlig J, Case MD, Blasberg JD, Boffa DJ, Chiang A, Gettinger SN, Kim HS. (CAN BE "et al."); JAMA Netw Open. 2019 Aug 2;2(8):e199702. doi: 10.1001/jamanetworkopen.2019.9702.

[2] Bhadra K, MattingleyJ, Pritchett M. Electromagnetic navigation bronchoscopy with advanced fluoroscopy-based localization and intraprocedural local registration for the evaluation of peripheral pulmonary nodules. Paper presented at: CHEST Annual Meeting; October 23, 2019; New Orleans, LA.

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