

Medtronic Expands ENT Portfolio with FDA Clearance of NIM Vital™ Next Generation Intraoperative Nerve Monitoring System and Acquisition of Ai Biomed Corp.

New Technologies Address Most Common Challenges During Head and Neck Surgery

DUBLIN, Oct. 29, 2020 /[PRNewswire](#)/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance of the NIM Vital™ nerve monitoring system, which enables physicians to identify, confirm, and monitor nerve function to help reduce the risk of nerve damage during head and neck surgery.¹ The NIM Vital system uses proprietary technology to provide detailed intraoperative nerve condition data that informs surgical strategy,² increases operative efficiency and precision,³ and helps protect patients' quality of life.⁴

The company also announced further enhancement of its ENT portfolio with the recent acquisition of privately-held Ai Biomed Corp., maker of the PTeye™ parathyroid detection system. The only probe-based technology of its kind,⁵ the PTeye system is designed to help confirm parathyroid tissue identified visually by the physician during thyroid surgery.

"Protecting critical structures during surgery has evolved to an extensive system that brings crucial information to the surgeon's hands and eyes," said Gregory Randolph, M.D., professor of Otolaryngology, Claire and John Bertucci endowed chair in Thyroid Surgical Oncology at Harvard Medical School and surgeon at Massachusetts Eye and Ear Infirmary. "There are things we can't do with our eyes and our hands. Both the NIM Vital and PTeye systems empower surgeons to improve their procedures, and Medtronic continues to provide these types of important operative solutions."

"The addition of these two technologies builds on our 20-year legacy of providing innovative solutions that assist surgeons during critical head and neck procedures," said Vince Racano, vice president and general manager of the ENT business, which is part of the Restorative Therapies Group at Medtronic. "By offering these complementary technologies – the NIM Vital system to protect crucial nerves and the PTeye system to help confirm parathyroid tissue identified visually by the surgeon – we're helping physicians address two of the most common challenges during these procedures."

About the NIM Vital Intraoperative Nerve Monitoring System

Even with detailed knowledge of anatomy and surgical skill, motor nerves can sometimes be difficult to identify during surgery due to disease, a previous operation, or normal anatomical variations.^{6,7} Clinical evidence demonstrates the benefits of intraoperative nerve monitoring for nerve preservation and as a risk-minimizing tool.^{2,3,8}

The NIM Vital system enables surgeons to locate and identify nerves, monitor and control manipulation effects, and confirm nerve integrity prior to completing the surgery. Proprietary technology provides real-time feedback on nerve function during intermittent or continuous monitoring so surgeons can adjust course as needed. A large touch-screen and streamlined interface provide an intuitive, guided workflow with enhanced visualization.⁹ Now available in the United States, the NIM Vital system is also CE marked for distribution outside the U.S.

About the Ai Biomed Corp. Acquisition and the PTeye System

The acquisition of Ai Biomed Corp. expands upon intraoperative technology like the NIM Vital platform and supports the Medtronic goal of using innovative technologies to improve head and neck surgery. The PTeye system helps confirm parathyroid tissue identified visually by the physician, which is a crucial step in thyroid surgery.

The most common type of thyroid surgery involves partial or full removal of the thyroid glands. During thyroid procedures, it is important for surgeons to identify and preserve parathyroid tissue so that it is not inadvertently removed, which may result in hypocalcemia, or low calcium levels. Hypocalcemia can cause numbness in fingers and toes, muscle cramps in legs and feet, irritability, and seizures.¹⁰

The acquisition of Ai Biomed Corp. is the seventh in a series of tuck-in acquisitions that Medtronic has made in calendar year 2020. The revenue and earnings contribution is expected to be immaterial to the Medtronic ENT business in the first year and accretive thereafter. In addition, this transaction is expected to meet Medtronic's long-term financial metrics for acquisitions. Additional terms of the agreement are not being disclosed. The Ai Biomed Corp. facility in Santa Barbara, Calif., and its employees joined Medtronic ENT as part of the acquisition.

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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