

Johnson & Johnson Submits OTTAVA™ Robotic Surgical System to the U.S. Food and Drug Administration

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Data from Investigational Device Exemption (IDE) study in Roux-en-Y gastric bypass procedures used to support application for De Novo classification

Second IDE approved for U.S. clinical trial for OTTAVA in inguinal hernia procedures

NEW BRUNSWICK, N.J.--(BUSINESS WIRE)-- Johnson & Johnson today announced that the company has submitted the OTTAVA™ Robotic Surgical System to the U.S. Food and Drug Administration (FDA) in an application for De Novo classification. Leveraging data from the Investigational Device Exemption (IDE) study, the company has applied for marketing authorization in multiple procedures in general surgery within the upper abdomen.

"We have taken learnings from Johnson & Johnson's 140 years in surgery, our decades of leadership in minimally invasive surgery, and the experiences robotic surgeons and hospitals have had over the past 20 years to design a soft tissue robotic system built for the future of surgery," said Hani Abouhalka, Company Group Chair, Surgery, MedTech, Johnson & Johnson. "I am proud of the design decisions and major scientific efforts that have gone into the system to support surgeons and successfully complete our first clinical trial, and I look forward to reaching the next milestone on our path to commercialization."

Data from first clinical trial supporting submission

First cases in the OTTAVA IDE study were completed in early 2025 at Memorial Hermann-Texas Medical Center by Dr. Erik Wilson*, Chief of Minimally Invasive and Elective General Surgery UT Health Houston and the lead investigator for the clinical study.

OTTAVA's unique unified architecture, surgical instrumentation powered by Ethicon expertise, and future connection to the **Polyphonic™ digital ecosystem** are designed to address the unmet needs of surgeons and their teams. The Company filed data from the completed clinical trial with the aim of showcasing safety and effectiveness and supporting the system's ability to perform a variety of procedures. Given OTTAVA's novel architecture and differentiated technological capabilities, the company filed a De Novo classification request and is targeting an indication covering multiple procedures in general surgery within the upper abdomen, such as gastric bypass, gastric sleeve, small bowel resection and hiatal hernia repair.

"The IDE study builds on a significant body of preclinical evidence we have generated demonstrating the impact of the OTTAVA system and provides critical clinical evidence on the system performance," said Peter Schulam, M.D., Ph.D., Chief Scientific Officer, MedTech, Johnson & Johnson. "Surgeon investigators across several hospitals led this important study to further clinical evidence in support of minimally invasive, robotic-assisted surgery for the benefit of clinical teams, hospitals, and patients."

Second clinical trial approved in hernia repair

OTTAVA is designed as a multi-specialty soft-tissue surgery robot, supporting a broad range of procedures across patient anatomy and surgical specialties, including the most complex surgeries that require a multi-quadrant approach. In late 2025, Johnson & Johnson received IDE approval to begin a U.S. clinical trial for OTTAVA in inguinal hernia procedures, one of the most common surgeries in the U.S.¹

The OTTAVA robotic system is under development and is not authorized to be marketed or sold in any market. For more information, visit: <http://thenext.jnjmedtech.com/surgical-robotics>.

About Surgical Solutions from Johnson & Johnson MedTech

Across Johnson & Johnson, we are tackling the world's most complex and pervasive health challenges. For over 100 years, we have helped advance surgical care through our innovative portfolio across wound closure, adjunctive hemostats, surgical stapling and instruments, robotics and digital solutions. Together, with clinicians and healthcare experts around the world we are progressing what's next in surgery to better solve patient needs in metabolic and cardiovascular disease, cancer, and aesthetics and reconstruction. For more, visit <https://thenext.jnjmedtech.com>.

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow and profoundly impact health for humanity.

Learn more about our MedTech sector's global scale and deep expertise in cardiovascular, orthopaedics, surgery and vision solutions at <https://thenext.jnjmedtech.com>. Follow us at @JNJMedTech and on LinkedIn.

Cautions Concerning Forward-Looking Statements

The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com, www.investor.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

Footnotes

*Dr. Wilson is a paid consultant for Johnson & Johnson MedTech.

¹ IQVIA Hospital Procedure Data Set, 2023 actuals

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