



ENDOQUEST ROBOTICS

Enabling Endoluminal & Single-Incision Surgery



US FDA Grants Investigational Device Exemption (IDE) to EndoQuest™ Robotics for Its Flexible Robotic System

EndoQuest will commence its PARADIGM clinical trial for endoluminal robotic colorectal surgery at five leading US hospitals in early 2025

Houston, TX, Dec 10, 2024 (GLOBE NEWSWIRE) -- The US Food and Drug Administration (FDA) has granted EndoQuest Robotics, Inc., a privately-held pioneer in the development of flexible endoluminal robotic technologies, an Investigational Device Exemption (IDE) for its pivotal colorectal clinical study, *Prospective Assessment of a Robotic-Assisted Device in Gastrointestinal Medicine (PARADIGM)*. [Link: <https://clinicaltrials.gov/study/NCT06133387?term=endoquest&rank=1>]

This landmark multi-center, open-label, prospective study will evaluate EndoQuest's state-of-the-art Endoluminal Surgical (ELS) System's safety and performance in robotic endoscopic submucosal dissection (ESD) procedures for the removal of colorectal lesions. Fifty subjects will participate across five leading US healthcare institutions, including Brigham and Women's Hospital (Boston), Mayo Clinic (Scottsdale), Cleveland Clinic (Cleveland), AdventHealth (Orlando), and HCA Healthcare (Houston).

"This IDE approval marks a significant milestone in EndoQuest's mission to revolutionize minimally invasive surgery," said Eduardo Fonseca, interim CEO of EndoQuest Robotics. "Our flexible robotic technology has the potential to transform colorectal surgical outcomes, empowering physicians with

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Company Announcement, Product / Services Announcement, Press releases, Regulatory information, Clinical Study

innovative tools to deliver less invasive, scar-free procedures. We're excited to proceed to human cases and move one step closer to initiating the next paradigm of surgery."

"We're thrilled to have received approval from the FDA to start our clinical trial," said Dr. Todd Wilson, chief medical officer and chairman of the scientific advisory board of EndoQuest Robotics. "This technology represents the evolution we have been waiting for to finally perform endoluminal surgery, which could redefine what's possible in minimally invasive colorectal procedures and potentially allow a significant number of patients to avoid invasive operations like colectomies."

The ELS System is designed to solve the technical challenges and decrease the learning curve associated with complex endoluminal procedures such as ESD. The ELS System enables endoluminal procedures with the visualization, precision, and main tenets of conventional surgical technique, allowing for surgical tasks and maneuvers not currently possible in advanced endoscopy. A pre-clinical ESD study presented at Digestive Disease Week (DDW2024) in 2024 demonstrated that the ELS System had superior procedural outcomes, a shorter learning curve, and reduced procedure time versus the conventional technique. [Link: [https://www.giejournal.org/article/S0016-5107\(24\)01723-1/abstract](https://www.giejournal.org/article/S0016-5107(24)01723-1/abstract)]

About EndoQuest Robotics

EndoQuest Robotics is a leading innovator in the development of transformative endoluminal robotic technologies. EndoQuest is focused on addressing unmet needs in gastrointestinal (GI) medicine and endoluminal surgery by enabling physicians with unprecedented surgical access, precision, and flexibility. The company's proprietary technology is designed to navigate and perform scar-free procedures through the body's natural orifices, allowing for the least invasive surgical approach. Since EndoQuest Robotics was founded, the company has collaborated extensively with healthcare providers, researchers, and industry partners to advance the development of its revolutionary flexible robotic system with the goal of improving patient outcomes and redefining a new standard in minimally invasive surgery. For additional information, visit the company's website at www.endoquestrobotics.com.

Release Tags

EndoQuest Robotics,
Surgical Robotics System,
endoluminal colorectal
surgery

EndoQuest's Flexible Robotic System is under development, has not been cleared by the FDA, and is not yet available for commercial sale in the United States.

For media inquiries or further information about EndoQuest Robotics and its groundbreaking advancements in flexible endoluminal robotics, please contact:

Media Contact

Lisa Owens

The Mullings Group

lowens@mullingsgroup.com

+1-210-601-6647

Contact:

Eduardo Fonseca

EndoQuest Robotics

eduardo.fonseca@endoquestrobotics.com

(713) 515-2065