



EndoQuest™ Robotics Submits Investigational Device Exemption (IDE) Application for Its Flexible Robotic System

Novel scar-free robotic technology may define a new standard in minimally invasive surgery.

HOUSTON, TX – Nov 14, 2024 – EndoQuest Robotics, Inc., a privately held medical device company and pioneer in the development of flexible endoluminal robotic technologies, has submitted an Investigational Device Exemption (IDE) application for its pivotal colorectal clinical study. EndoQuest's mission is to transform surgical outcomes for minimally invasive surgery (MIS) with its groundbreaking flexible robotic system.

This IDE will enable EndoQuest to begin their *Prospective Assessment of a Robotic-Assisted Device in Gastrointestinal Medicine (PARADIGM)* study, which is a prospective, multi-center, open-label study. With an expected enrollment of 50 subjects, the PARADIGM study will be conducted at five leading U.S. healthcare facilities, including Brigham and Women's Hospital (Boston), Mayo Clinic (Scottsdale), Cleveland Clinic (Cleveland), AdventHealth (Orlando), and HCA Healthcare (Houston).

As part of the PARADIGM study, globally recognized gastroenterologists and colorectal surgeons will perform robotic endoscopic submucosal dissection (ESD) procedures for removal of colorectal lesions using the EndoQuest Robotics Endoluminal Surgical (ELS) System. Results from a pre-clinical ESD study presented earlier this year at Digestive Disease Week (DDW2024) 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)]

The IDE submission is subject to review by the U.S. Food and Drug Administration (FDA) and must be approved prior to initiating this study. The review process is expected to take a minimum of 30 days, with the total duration of the review to depend on a variety of factors, including the extent of potential comments, questions, and any additional information requested by the FDA.

"Once approved, our IDE enables the ELS System to ship to clinical sites and be studied for safety and efficacy. While not yet commercialized, it is a critical step forward and drives value in the company as the future benchmark for ESD and other minimally invasive procedures," said Eduardo Fonseca, interim CEO of EndoQuest Robotics.

"There is a significant unmet need for improved treatment of colorectal disease in the U.S.," said Dr. Todd Wilson, chief medical officer and chairman of the scientific advisory board of EndoQuest Robotics. "The robotic ESD procedure provides the opportunity to clearly demonstrate the potential benefits of our flexible robotic system in terms of outcomes, complications, healthcare costs, and much more, and should ultimately pave the way for the system to revolutionize a wide and growing range of other procedures across the globe."

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.

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

