



U.S. FDA Grants GI Windows Medical Corp. Breakthrough Device Designation for Magnetic Anastomosis Technology

West Bridgewater, MA--(September, 2020) – GI Windows Medical Corp, a clinical-stage, privately-held medical device company pioneering new advancements in anastomosis technology announced the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for the self-forming magnetic compression anastomosis device indicated for small bowel end to end anastomosis for ileostomy reversal or tissue resection.

The Breakthrough Devices Program is a voluntary program for select medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide GI Windows with priority review and interactive communication regarding device development and clinical trial protocols, during the premarket review process.

“GI Windows has developed a compelling technology that may provide several significant benefits for our patients with colorectal disease.” said Dr. Christopher Thompson, Director of Endoscopy, Professor of Medicine Harvard Medical School at Brigham & Women’s Hospital, “This is an exciting time in healthcare with the FDA working closely with the companies designated as having disruptive technology, to help improve the access for our patients.”

The GI Windows technology is designed to help surgeons deliver less invasive solutions via magnetic compression anastomosis, allowing clinicians to improve patient outcomes and reduce healthcare costs by creating new capabilities in healthcare.

“This designation is a major milestone for GI Windows, as we aspire to change the paradigm in anastomosis creation throughout the GI tract. Our entire team has worked hard in developing the technology and evidence to achieve this designation from the FDA,” said Brian Tinkham, President & CEO of GI Windows. “We look forward to working collaboratively with the FDA to help prioritize development and access for patients.”

About Surgical Anastomosis:

According to Truven Commercial and Medicare (2010-2015), US colorectal complication rates remain high with anastomotic leaks, surgical site infections and bleeding causing high re-admission rates and increasing the overall cost to the healthcare system.

About GI Windows

GI Windows Corp is a clinical-stage, venture-backed medical device company dedicated to developing the first fundamental breakthrough in anastomoses technology in both delivery and tissue fusion. GI Windows is currently sponsoring numerous trials to evaluate the safety, efficacy, and durability of the magnetic anastomosis creation throughout the GI tract. The company was spun out of Beacon Endoscopic (acquired by Covidien in 2014). GI Window's is currently headquartered in West Bridgewater, MA.

For more information on GI Windows, please visit <https://www.giwindows.com> or Twitter @WindowsGi