GI Windows Surgical, adds 510(k) Clearances with Flexagon Self-Forming Magnets and Endoscopic Delivery System

WESTWOOD, MA, UNITED STATES, June 16, 2025 /EINPresswire.com/ -- GI Windows Surgical, a leader in next-generation medical devices, today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its, FlexagonTM -Self -forming Magnets, Laparoscopic and Endoscopic delivery system . GI Windows Surgical is designing a revolutionary anastomosis technology that enables less invasive surgery for patients, marking the first significant breakthrough in the field in over 40 years.

Dr Erik Wilson, Chief Medical Officer of GI Windows Surgical declared “the Flexagon self-forming magnet represents a significant leap forward in surgical innovation. This technology integrates laparoscopic delivery, advanced robotics, and endoscopic delivery to enable better minimally invasive procedures. The devices are designed to reduce operative time, standardize anastomotic techniques and minimize complications— redefining the standard of care in surgery.”

“FDA clearance of FlexagonTM marks a pivotal milestone, not just for our company, but for the future of minimally invasive surgery,” said Brian Tinkham, CEO of GI Windows Surgical. “Our team is excited for the next phase of our business.”

The FDA-clearance is for magnetic compression anastomosis, the Flexagon System is a self-aligning, sutureless, and staple-free technology designed to facilitate anastomosis while leaving behind no foreign material. Clinical evidence for the Flexagon System continues to support the efficacy of this approach. To date, there are no reported leaks, bleeds or obstructions attributed

to this sutureless, staple-free technique.(1)

About GI Windows Surgical:
GI Windows Surgical is the global leader in magnetic anastomosis and less invasive delivery of self-forming magnets. A Massachusetts based medical device company dedicated to developing the first fundamental breakthrough in anastomosis technology in both delivery and tissue fusion, located in Westwood, MA.

(1) U.S. Food and Drug Administration. 510(k) No. K243482. Clearance for Magnetic Compression Anastomosis System (Flexagon System). June 11, 2025.

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