

**From:** Bluestem <info@bluestemcapital.com>

**Sent:** Thursday, May 18, 2023 11:21 AM

**Subject:** News from Virtual Incision Corp

We are pleased to share this press release and encourage you to visit the company's website to see the impressive team this company has put together and to learn more about MIRA.

---

## **The MIRA Surgical System Proceeds to FDA Substantive Review for Market Authorization under the De Novo Classification Pathway**



Virtual Incision Has Achieved a Significant Milestone in its De Novo Request and is Closer to Potential Commercial Readiness

**Lincoln, Neb.** – May 18, 2023 – Virtual Incision Corporation today announced its De Novo request was submitted and is under substantive review by the U.S. Food and Drug Administration (FDA). The submission seeks authorization to market the MIRA Surgical System for use in bowel resection procedures and comes on the heels of Virtual Incision's completed Investigational Device Exemption (IDE) clinical study.

If granted, MIRA will become the first robotic-assisted surgery (RAS) device to obtain marketing authorization through the De Novo pathway for use in bowel resection procedures, making it a trailblazer in soft tissue robotics. Beyond granting Virtual Incision the ability to commercialize MIRA in the U.S. for its intended use, authorization may lay the foundations for expanded procedural indications, entry into international markets, additional instruments and accessories, and future generations of the surgical system.

"Throughout the history of RAS, only a few companies have managed to reach this significant milestone," said John Murphy, president, and chief executive officer of Virtual Incision. "If we are successful with our submission, the FDA De Novo pathway will establish MIRA in a brand-new medical device category of miniaturized RAS. Our design is disruptive and highly differentiated among the current landscape of available and emerging technologies. We are proud of the data we collected, as they demonstrate the capabilities of MIRA in one of the most complex multi-quadrant abdominal procedures. We also observed many operational efficiencies that make the miniaturized approach so unique and potentially scalable to the millions of patients who could be candidates for RAS each year."

If Virtual Incision obtains marketing authorization, the company plans to initiate a limited launch of MIRA in select centers across the United States. These centers will aim to leverage the efficiencies created with MIRA to expand the number of patients they can treat with RAS. Their experiences will serve as best practices for the broader launch. In the longer term, the objective is to enable wide adoption in any healthcare facility for any patient undergoing abdominal surgery.

### **About the MIRA Surgical System**

MIRA is the world's first miniaturized robotic-assisted surgery (RAS) system. Its small, sleek form

factor is designed to offer the benefits of RAS during abdominal surgical procedures without the logistical inefficiencies of traditional mainframe robotics. The easily accessible device weighs approximately two pounds and offers internal triangulation with shoulders, arms, and infinite wrist roll inside of the body. It can be used in any operating room – a dedicated mainframe room is unnecessary. With its drape- and dock-free design and portability, MIRA is quick to set up, clean up, and move between cases. Its conveniently accessible design positions it to be used as a standalone system or a complementary tool for facilities that already own a mainframe. With MIRA, every operating room is RAS-ready. The MIRA Surgical System is an Investigational Device and is not available for sale.

### **About Virtual Incision**

Virtual Incision is on a mission to simplify robotic-assisted surgery (RAS), so more patients and their surgeons can access its benefits every day. Headquartered in Lincoln, Nebraska, and holding over two hundred patents and patent applications, the company is developing MIRA, the first-of-its-kind miniature RAS platform. Virtual Incision's goal is to make every operating room RAS-ready. For more information, visit our website or follow us on LinkedIn and Twitter.

### **Cautionary Note Regarding Forward-Looking Statements**

This communication contains statements that constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include but are not limited to, statements regarding our plans, beliefs, expectations, assumptions, and other statements that are not necessarily historical facts. You are cautioned that these forward-looking statements are only predictions and involve risks and uncertainties. Further, any forward-looking statement speaks only as of the date on which it is made, and we do not intend to update or revise any forward-looking statements. This communication also contains market data related to our business and industry which includes projections that are based on several assumptions we believe are reasonable and most significant to the projections as of the date of this communication. If any of our assumptions prove to be incorrect, our actual results may significantly differ from our projections based on these assumptions.

---

If you have questions about this press release or any of your Bluestem-managed funds, we invite you to contact us.

***The Bluestem Team***