August 20, 2026

Virtual Incision
Florence Beck
VP Clinical and Regulatory Affairs
1501 Old Cheney Rd.
Lincoln, Nebraska 68512

Re: K260817
Trade/Device Name: MIRA Surgical System
Regulation Number: 21 CFR 878.4962
Regulation Name: Table Mounted Miniaturized Electromechanical Surgical System
Regulatory Class: Class II
Product Code: SAB
Dated: July 20, 2026
Received: July 20, 2026

Dear Florence Beck:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MARK TRUMBORE -S
Digitally signed by MARK TRUMBORE -S
Date: 2026.08.20 18:32:26 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260817

Please provide the device trade name(s).

MIRA Surgical System

Please provide your Indications for Use below.

The MIRA Surgical System is a miniaturized robotic assisted surgery device intended to assist in the visualization of tissues and provide accurate and precise control of surgical instruments to grasp, retract, dissect, and suture while maintaining hemostasis with electrocautery during manipulation of tissues.

The device is indicated for mobilization of the colon during minimally invasive colectomy in adults at least 5'0" (1.52 m) tall and having a weight of at least 100 lbs (45.36 kg).

The MIRA Surgical System is also indicated for minimally invasive benign (sub-) total hysterectomy with or without salpingectomy in adults with a uterine size not exceeding 12 cm longitudinally on imaging, at least 5'0" (1.52 m) tall and having a weight of at least 100 lbs (45.36 kg), and a BMI less than 40kg/m2.

It is for prescription use only and is to be used by trained physicians in any operating room environment in accordance with the representative surgical procedures listed in the MIRA Surgical System User Manual.

Please select the types of uses (select one or both, as applicable).

Prescription Use (Part 21 CFR 801 Subpart D) ☒
Over-The-Counter Use (21 CFR 801 Subpart C) ☐

VIRTUALINCISION

510(k) Summary

I. SUBMITTER INFORMATION

Submitter: Virtual Incision Corporation
1501 Old Chaney Rd
Lincoln, NE 68512

Contact: Florence Beck
VP Clinical and Regulatory Affairs
Phone Number: 352-275-7267
Email: florence.beck@virtualincision.com

Date Summary Prepared: August 20, 2026

II. DEVICE INFORMATION

Trade/Device Name:	MIRA Surgical System
Common Name:	Table mounted miniaturized electromechanical surgical system
Regulation Number:	21 CFR 878.4962
Regulatory Class:	Class II
Product Code:	SAB
Submission Type:	Traditional 510(k)

III. PEDICATE DEVICE INFORMATION

Predicate Device: MIRA Surgical System (DEN230025)

IV. DEVICE DESCRIPTION

The MIRA Surgical System is a miniaturized robotic assisted surgery device consisting of an integrated package designed to enable soft tissue surgery using a minimally invasive approach. The MIRA Surgical System refers to the system and all of its components. The system consists of a Surgeon Control Console, Companion Cart, Surgical Minibot with Sterilization Tray, Surgical Camera with Sterilization Tray, Support Arm Assembly with Sterilization Tray, and single use MIRA Surgical Instruments and Accessories. These are described below:

Surgeon Control Console: The Surgeon Control Console contains a main processor that performs system-level control functions and system monitoring. The Console includes a main display showing the real-time video feed from the Surgical Camera, hand input devices, pedal inputs, and an interactive touchscreen. The Minibot and Surgical Camera are controlled by the surgeon seated at the Surgeon Control Console.

Companion Cart: The Companion Cart is a mechanical cart used to hold the Interface Pod, Electrical Surgical Unit (ESU) and serves as a staging shelf for the Minibot and Surgical Camera.

The Interface Pod is a box that serves as a single point connection for the Minibot, Surgical Camera, and ESU to the Surgeon Control Console. The ESU is bolted to the companion cart and has a unique connector that can only interface with the Minibot device.

Surgical Minibot with Sterilization Tray: The Surgical Minibot is a reusable device component with two arms that is inserted into the insufflated abdominal cavity through a disposable insertion port to perform surgery. Single-use sterile MIRA Surgical Instruments are installed in the Minibot arms. The Minibot is robotically controlled by the surgeon.

Surgical Camera with Sterilization Tray: The Camera is a reusable articulating endoscope used to visualize the surgical target. The Camera mechanically interfaces with the Minibot and can be robotically articulated by the surgeon.

Support Arm Assembly with Sterilization Tray: The Support Arm Assembly is a reusable device component used to hold the Minibot in place. The device is easily adjustable to many positions and orientations. The proximal end of the Support Arm mounts to the surgical table rail using a rail clamp. The distal end attaches to the Minibot Clamp to hold the Minibot.

Surgeon Chair: An off-the-shelf adjustable surgeon chair is provided with the MIRA Surgical System. The following single-use sterile disposables are used with the MIRA Surgical System:

MIRA Surgical Instruments: MIRA Instruments come in various configurations and are customized to connect into the Minibot arms to grasp, retract, dissect, and suture while maintaining hemostasis with electrocautery during manipulation of tissues.

Camera Nest and Lumen Plug Kit: The Lumen Plug is placed onto the Minibot to prevent lubricant and debris from entering the Minibot lumen during insertion. The Nest is placed on the Minibot to connect to the Camera.

V. INTENTED/INDICATION FOR USE

The MIRA Surgical System is a miniaturized robotic assisted surgery device intended to assist in the visualization of tissues and provide accurate and precise control of surgical instruments to grasp, retract, dissect, and suture while maintaining hemostasis with electrocautery during manipulation of tissues.

The device is indicated for mobilization of the colon during minimally invasive colectomy in adults at least 5'0" (1.52 m) tall and having a weight of at least 100 lbs (45.36 kg).

The MIRA Surgical System is also indicated for minimally invasive benign (sub-) total hysterectomy with or without salpingectomy in adults with a uterine size not exceeding 12 cm longitudinally on imaging, at least 5'0" (1.52 m) tall and having a weight of at least 100 lbs (45.36 kg), and a BMI less than 40kg/m2.

It is for prescription use only and is to be used by trained physicians in any operating room environment in accordance with the representative surgical procedures listed in the MIRA Surgical System User Manual.

VI. COMPARISONS OF INTENTED USE/INDICATIONS FOR USE AND TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The intended use of the MIRA Surgical System remains unchanged and continues to fall under the general product code SAB: table mounted, miniaturized electromechanical surgical system. Devices classified under this code are intended to enable a qualified user to perform robotic assisted, minimally invasive surgical procedures including the mobilization of tissue within the intra-abdominal cavity and along the colon.

The proposed indication expands upon the currently cleared use by adding minimally invasive benign hysterectomy as an additional specialty and anatomic location within the abdomen and to add suturing as a task provided by the surgical instruments. As part of this expansion, clinical performance testing evaluated the system in the umbrella surgical procedure benign hysterectomy. Representative surgical procedures under this umbrella have been added to the MIRA Surgical System User Manual.

Clinical Evidence generated under an IDE clinical trial supports that the inclusion of these gynecological procedures does not introduce new or increased procedural risks beyond those within the predicate intended use and remains comparable to those expected with minimally invasive surgical techniques. Like the existing indication, the MIRA Surgical System performs as intended in the intended patient population with an acceptable safety profile compared to hysterectomy procedures performed with traditional laparoscopic surgery.

VII. TECHNOLOGICAL COMPARISON

Both the subject MIRA Surgical System and predicate MIRA Surgical System (DEN230025) have the same technological characteristics and intended use. All components and accessories included in the predicate are included in the subject device.

The subject device expands MIRA Surgical Instrument Family to include single use sterile Needle Drivers to allow for suturing. Like the predicate MIRA Surgical Instruments, the subject device is intended to assist in the visualization of tissues and provide accurate and precise control of surgical instruments. They are installed onto the Minibot and serve as the hands of the system, functioning in a similar fashion to manual laparoscopic instruments. Like the predicate, they have similar dimensional profile, are single use, disposable, and made of biocompatible materials. Packaging, sterilization, shelf-life, installation, use, and removal of the Needle Drivers are the same as the Bipolar Grasper except that there are no electrocautery contacts within the instrument nor electrocautery function. All performance testing passed and did not produce any unexpected issues of safety or effectiveness. The introduction of Needle Drivers does not pose any additional risk and does not affect safety or effectiveness or raise

different types of questions of safety and effectiveness as demonstrated by bench, animal, and clinical performance testing. The Needle Driver Instruments are substantially equivalent to the predicate.

This submission is also intended to bring the agency up to date on all incremental non-significant changes made to the predicate device and implemented through internal design control process since the initial De Novo authorization to the current subject device in this submission. There are no modifications to the intended use, fundamental scientific technology, or principles of operation. Completed testing demonstrated that the subject device continues to perform in accordance with its specifications. The subject device complies with the same standards and special controls as the predicate device. Below is a comparison summary of the technological characteristics.

Design: The subject device and the predicate device have the same design. Both are a miniaturized robotic assisted surgery device consisting of an integrated package designed to enable soft tissue surgery using a minimally invasive approach. Both consist of the same components and function. Some engineering changes to hardware of the predicate device components were replaced with similar parts on the subject device due to part obsolescence and/or to improve reliability and manufacturability of the device. A risk-based assessment of the hardware changes did not identify new risks or significantly modified existing risks. Minor software updates to the predicate device were implemented to resolve software anomalies and improve functionality but did not impact the intended use or the usability by the user. Design verification and/or validation activities did not produce any unexpected issues of safety or effectiveness.

Materials: Both the subject device and predicate device consist of biocompatible patient contacting materials. Some patient contacting materials on the surgical instruments and Minibot of the predicate device were replaced with similar biocompatible materials on the subject device. A risk assessment did not identify any new or increased biocompatibility concerns. Design verification and/or validation activities did not produce any unexpected issues of safety or effectiveness.
Principle of Operation: Both the subject device and predicate device have the same principles of operation listed in the device description.
Energy Source: Both the subject device and predicate device use bipolar and monopolar energy via single use surgical instruments from the same ESU located on the Companion Cart.

Conclusion: The predicate and proposed MIRA Surgical Systems have the same intended use and similar technological characteristics and principles of operation. In addition to nonsignificant design changes, a needle driver instrument has been added to aid in surgical suturing. The labeling has been changed to add suturing and the expanded indication statement and listed as new representative surgical procedures in the User Manual. Completed performance testing (Bench, Animal, and Clinical) and continued adherence to Special

Controls supports a determination of substantial equivalence to the predicate MIRA Surgical System (DEN230025).

VIII. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

Non-clinical performance testing demonstrated that the subject device continues to meet the performance specifications and Special Controls as intended under anticipated conditions of use. This is supported by anatomical studies, human factors validation, Software testing, System-wide, and System-component verification and validation testing.

Cadaver and Synthetic Cadaver Studies- MIRA Surgical System was extensively evaluated in the cadaveric and synthetic models to support the proposed indication. This anatomic data demonstrates that the device met User Needs and performed as intended under anticipated conditions of use without incidents that would indicate the potential of device related adverse events.

Animal Performance Testing- Acute and Chronic GLP testing demonstrates that the device performed as intended under anticipated conditions of use. Like the predicate, all surgical tasks pertinent to the hysterectomy procedure were completed successfully. The subject device was able to accurately and precisely control the MIRA surgical instruments without excessive adverse events. This was confirmed by histopathology and gross examination of the affected organs and surrounding tissues.

Human Factors- Human Factors validation testing for the subject device was completed with the expanded surgeon user group (minimally invasive gynecological surgeons). Like the predicate, the device/user interfaces of the system support safe use in all use environments.
Clinical Performance: Clinical performance testing for the expanded indication of the MIRA Surgical System was completed in the US under Investigational Device Exemptions (IDE).

A prospective multi-center, multi-operator, non-randomized, consecutively enrolled clinical evaluation study was conducted in 35 patients presenting with an indication for benign hysterectomy. The mean age was 46.1 years, with a range of 25 to 74 years. The mean body mass index (BMI) was 29.2 kg/m^2, ranging from 21.5 to 41.5 kg/m^2. The clinical profile of enrolled subjects were representative of the intended patient population. Patients were followed for at least 42 days post-surgical procedure.

Outcomes:
The results of the study demonstrated that the MIRA Surgical System performed as intended in a clinical use environment. In 34 of 35 (97.1%) clinical cases, the procedures were successfully

completed with no conversions to alternative surgical techniques and with full vaginal cuff healing as expected at the last follow-up visit. The specimen weight ranged from 31.2 g to 384 g, with a mean uterine weight of 136.1 g and a median of 117.0 g. The MIRA Surgical System was able to adequately and primarily dissect, expose the uterus and adnexal tissues, perform the colpotomy, and close the vaginal cuff with the MIRA surgical instruments. Hemostasis could be maintained with the MIRA monopolar scissors and bipolar graspers alone in all 34 subjects. There were no malignancies reported in the pathology reports.

Safety Assessments:
The MIRA Surgical System demonstrated an acceptable safety profile.

- There were no intraoperative device or procedure related serious adverse events (SAE) reported.
- There were no postoperative device or procedure related SAEs reported.
- There was one SAE reported deemed unrelated to the device or unrelated to the procedure.
- Incidence of clinically relevant adverse events were within expected levels when compared to the published literature.

There were no deaths or unanticipated adverse events. One reported serious adverse event unrelated to both the device and the procedure was anemia secondary to pre-operative menorrhea, only diagnosed following surgery. Nine subjects (25.7%) experienced ten non-serious, clinically relevant adverse events (two intraoperative Grade I related to the device, five postoperative Grade I related to the procedure, and three postoperative Grade II related to the procedure; per Clavien-Dindo grading). All events are resolved without sequelae. These adverse events were within expected levels.

IX. CONCLUSIONS

In 35 U.S. subjects undergoing total hysterectomy for benign indications, the MIRA Surgical System met its primary effectiveness endpoint and demonstrated a favorable safety profile. The device achieved high procedural completion rates, reliable hemostasis with minimal blood loss, short length of stay, complete cuff healing, and complication rates consistent with standard minimally invasive hysterectomy. These findings support the safety and effectiveness of the system in the intended patient population.

The clinical evidence generated demonstrates that the MIRA Surgical System performs as intended in the intended patient population with an acceptable safety profile compared to procedures performed with traditional laparoscopic surgery. The expansion of this indication does not introduce new or increased procedural risks beyond those within the predicate

intended use and remains comparable to those expected with minimally invasive surgical techniques.

Nonclinical testing demonstrated that the subject device performs as intended in the intended conditions of use in accordance with performance specifications and confirm the implemented component modifications and addition of the needle drivers do not present different questions of safety or effectiveness than the predicate device The subject device complies with the same standards and special controls as the predicate device. Thus, the device is substantially equivalent to the predicate.