October 2, 2024

Momentis Surgical Ltd.
Maya Leib Shlomo
VP Qa/ra
6 Yoni Netanyahu Street
Or Yehuda, 6037604
Israel

Re: K241907
Trade/Device Name: Anovo Surgical System (model 6N)
Regulation Number: 21 CFR 878.4961
Regulation Name: Mountable Electromechanical Surgical System For Transluminal Approaches
Regulatory Class: Class II
Product Code: QNM
Dated: June 30, 2024
Received: July 1, 2024

Dear Maya Leib Shlomo:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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: 2024.10.02 15:03:01 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241907

Device Name

Anovo Surgical System (model 6N)

Indications for Use *(Describe)*

The Anovo Surgical System is an endoscopic instrument control system that is intended to assist in the accurate control of the Instrument ARMS during single site, natural orifice transvaginal and trans-abdominal benign laparoscopic-assisted surgical procedures listed below. The Anovo Surgical System is indicated for use in adult patients. It is intended to be used by trained physicians in an operating room environment.

The representative uses of the Anovo Surgical System are indicated for the following benign procedures:

- Total benign hysterectomy with salpingo-oophorectomy
- Total benign hysterectomy with salpingectomy
- Total benign hysterectomy
- Salpingectomy
- Oophorectomy
- Adnexectomy
- Ovarian cyst removal
- Ventral hernia

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Submitter	Momentis Surgical Ltd. 6 Yoni Netanyahu St. Or Yehuda, Israel 6037604
Contact Person:	Maya Leib Shlomo, VP of QA/RA Maya.leib@momentissurgical.com Tel.: 972-5-088-52822
Date:	June 30, 2024
Device & **Classification Name:**	Anovo™ Surgical System Mountable Electromechanical Surgical System for Transluminal Approachs Product Code QNM, Class 2
Predicate Device: **Reference Device:**	Hominis Surgical System DEN190022 Anovo™ Pedestal K232146
Description:	The Anovo™ Surgical System is a mountable electromechanical surgical system used in single-site surgical procedures through a transvaginal or transabdominal access point. The system consists of two (2) Anovo™ Instrument ARMS, Anovo™ Surgeon Console, Anovo™ Robotic Control Unit, and accessories (Anovo™ Pedestal, Anovo™ Access Kit and Anovo™ Sterile Drape for Robotic Control Unit). The Instrument ARMS are connected to the RCU, which is attached to the Pedestal. The physician sits at the Anovo™ Surgeon Console and controls the Instrument ARMS by manipulating the ARMS Controllers. While manipulating the Instrument ARMS, the physician views the surgical site through a standard OR visualization system using a laparoscopic camera inserted through an abdominal port and views the main user interface at the Anovo™ Surgical System Surgeon Console. The Anovo™ Surgical System Surgeon Console is located outside of the sterile zone. The system is designed to be used with an Electrosurgical Generator. The Anovo™ Surgical System is operated in conjunction with standard commercially available laparoscopic surgery visualization systems.
Indications for Use:	The Anovo™ Surgical System is an endoscopic instrument control system that is intended to assist in the accurate control of the Instrument ARMS during single site, natural orifice transvaginal and trans-abdominal benign laparoscopic-assisted surgical procedures listed below. The Anovo™ Surgical System is indicated for use in adult patients. It is intended to be used by trained physicians in an operating room environment. The representative uses of the Anovo™ Surgical System are indicated for the following benign procedures: • Total benign hysterectomy with salpingo-oophorectomy • Total benign hysterectomy with salpingectomy • Total benign hysterectomy • Salpingectomy • Oophorectomy • Adnexectomy

• Ovarian cyst removal
• Ventral hernia

Comparison of Technological Characteristics:

With respect to technology, the Anovo™ Surgical System is the same as the predicate and reference Devices. The purpose of this submission was to expand the indication for use which was the treatment of Ventral Hernias in male and female patients.

Performance Evaluation:

The following performance testing was conducted to demonstrate substantial equivalence to the predicate and reference devices:

Pre-Clinical Cadaver Study

Cadaver testing demonstrated that the Anovo™ Surgical System can successfully access and reach anatomical structures during the execution of transabdominal laparoscopic ventral hernia procedure, perform all surgical tasks to complete transabdominal laparoscopic ventral hernia repair.
The Anovo™ Surgical System met all the predefined specific requirements related to transabdominal clinical compatibility, performance, and safety.

Human Factors

Human Factors and Usability Engineering Process was performed according to the requirements of:

- ISO/IEC 62366-1:2015, Medical devices – Application of usability engineering to medical devices.
- Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016)

Representative users evaluated the Anovo™ Surgical System usage in simulated OR environment by performing predefined critical tasks after a training session.

The Human Factor Usability Validation demonstrated that the Anovo™ Surgical System supports safe and effective use by representative users during the performance of laparoscopic transabdominal general surgery procedures. The analysis of the results demonstrated that all relevant use-related risks were found to be acceptable and there is no residual use-related risk.

Clinical Study

A multi-center, single-arm, prospective study was performed to clinically assess the Anovo™ Surgical System for use in performing laparoscopic Ventral Hernia repair. The Clinical Study was performed in two sites outside the Unites States (in Belgium and Israel) and included 30 subjects undergoing ventral hernia repair. A summary of the baseline demographics for subjects is provided in **Table 1**.

Table 1: Ventral Hernia Subject Demographics

Variable Name	Ventral Hernia Study (N=30)
Age (years)	
Min-Max (years)	22-79
Mean (SD)	50.8 (16.1)
Median	36
Lower/Upper bound 95% CI	44.8-56.9
Gender	
Male	22 (73.3%)
Female	8 (26.7%)
BMI (kg/m²)	
Min-Max (kg/m²)	18.9-36.2
Mean (SD)	26.2 (3.8)
Median	23.6
Lower/Upper bound 95% CI	24.8-27.6
Smoker	
Current	6 (20%)
Former	7 (23.3%)
Never	17 (56.7%)
Alcohol Consumption	
No	17 (56.7%)
Yes	13 (43.3%)
Race	
African American or Hispanic	0
Not African American or Hispanic	30 (100%)

The study included post-surgery safety visits: an in-clinic visit two weeks following the procedure, and one telephone follow-up, 4 weeks after the surgery.

The primary endpoint was successfully met as there were no instances of conversion to open surgery or to laparoscopy approach during the surgeries for all 30 subjects enrolled. All surgeries took place as expected. The data collected in this clinical investigation points to a favorable safety provide of the Anovo™ Surgical System in ventral hernia surgeries. No Adverse Event, Adverse Device Event or Serious Adverse Event intra-operatively. Postoperatively, there were no Adverse Device Event or Serious Adverse Event. The data collected reinforces the positive safety profile of Anovo™ Surgical System in ventral hernia repair surgeries.

The summary of the clinical investigation data is provided in **Table 2**

Table 2: Summary of Secondary Endpoint Results

Secondary Endpoint	Intraoperative	Post-Procedure (Perioperative)	Follow-Up (through 6 weeks)
Procedure completion	30 (100%)	N/A	N/A
Conversion rate	None	N/A	N/A
Any additional ports used	None	N/A	N/A
Unplanned surgical activities	None	N/A	N/A
Average Operative Time (range) [minutes]	64.1 (33-124)	N/A	N/A
Complications [%]	0	3.33*	0
Adverse Events (AEs) [%]	0	16.66*	0
Serious Adverse Events (SAEs) [%]	0	0	0
Bowel injury [# of patients]	0	0	0
Wound Seroma [# of patients]	0	1*	0
Surgical Site Infection [# of patients]	0	0	0
Blood Loss	0	N/A	N/A
Average length of hospital stays (range) [days]	N/A	1 (1-2)	N/A
Mortality [%]	0	0	0

* Not device related

In addition, the following performance testing were conducted on the predicate and reference devices:

Bench Testing
Bench testing demonstrates that the subject device's design output meets the design input requirements. The testing conducted consisted of mechanical and functional verification.

Software Testing
Software development process and software testing including verification and validation testing, were performed in according to the current version of IEC 62304 and FDA's Guidance for Industry and FDA Staff "Content of Premarket Submissions for Device Software Functions".

Cybersecurity
Anovo™ Surgical System implements robust security controls to safeguard the integrity and security of the system's operation.

Cybersecurity testing was performed, and the information provided in this submission demonstrates compliance with section 524B of the FD&C Act consistent with current “FDA Guidance: Cybersecurity in Medical Devices - Quality System Considerations and Content of Premarket Submissions”.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical Safety and EMC testing was conducted using a third-party Accredited laboratory in accordance with the current versions of IEC 60601-1 (basic safety and essential performance), IEC 60601-1-6 (usability), IEC 60601-1-2 (Electromagnetic disturbances), and IEC 60601-2-2 (high-frequency surgical equipment).

Biocompatibility
The Anovo™ Surgical System contains direct and indirect patient-contacting components, including the Instrument ARM and Access Kit. All patient-contacting components were classified as “external communicating devices in contact with tissue/bone/dentine for limited duration (<24 hours)” per ISO 10993-1:2018, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process, and FDA’s guidance document titled, Use of International Standard ISO 10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” (September 2023).

Sterilization
The Anovo™ Instrument ARM is an EtO-Sterilized single-use component. The Anovo™ Access Kit is a steam-sterilized reusable component.
Sterilization validation study was conducted to demonstrate the effectiveness, consistency, and reproducibility of the EtO and Steam sterilization processes.

Conclusion:

The Anovo™ Surgical System is substantially equivalent to the predicate and reference devices. The device has the same intended uses and similar indications for use as the predicate. The expanded indications are addressed with the same types of data as were used to support the predicate devices and the outcome of the performance evaluation (design validation, human factor and clinical trial) do not present any new risks. There are no differences in the technological characteristics of the device compared to the predicate. In addition, the device for the expanded indications appropriately addresses all of the special controls in the existing classification regulation. Therefore, the Anovo™ Surgical System to be substantially equivalent to treat Ventral Hernias.