October 21, 2024

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

Re: K242157
Trade/Device Name: Anovo Surgical System (Model 6Ne)
Regulation Number: 21 CFR 878.4961
Regulation Name: Mountable Electromechanical Surgical System For Transluminal Approaches
Regulatory Class: Class II
Product Code: QNM
Dated: July 23, 2024
Received: July 23, 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: 2024.10.21 08:41:09 -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
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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)*

Device Name

Anovo Surgical System (Model 6Ne)

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 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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:	July 23, 2024
Device & Classification Name:	Anovo™ Surgical System Model 6Ne Mountable Electromechanical Surgical System for Transluminal Approachs Product Code QNM, Class 2
Predicate Device:	Hominis Surgical System DEN190022
Description:	The Anovo™ Surgical System Model 6Ne is an electromechanical surgical system for transluminal approaches used in single-site benign hysterectomy and salpingo-oophorectomy surgical procedures through a transvaginal access point. The system consists of two (2) Instrument ARMs, a Surgeon Console, a Robotic Control Unit Assembly, and System Accessories (Sterile Drape, Vaginal Access Kit, Cables, and Pedestal). During clinical use, surgeons operate the Instrument ARMs from the Surgeon Console with a compatible and FDA-cleared third-party standard laparoscope (transumbilical) and visual guidance system. Anovo™ Surgical System 6Ne, including Anovo™ Surgeon Console 6Ne and Anovo™ Robotic Control Unit 6Ne, is an additional enhanced configuration of the Anovo™ 6N, with Anovo™ Surgeon Console 6N and Anovo™ Robotic Control Unit 6N ("Predicate Device") that was the subject of a De Novo request (DEN190022). There are no differences in the system instruments and accessories compared to the Anovo™ 6N, and the Surgeon Console and Robotic Control Unit Model 6Ne will be offered with the same Instrument and accessories.
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 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

Comparison of Technological Characteristics:

The Anovo™ Surgical System Model 6Ne is based on the authorized Anovo™ Surgical System Model 6N ("predicate device" DEN190022) and, therefore they are technologically similar. Both systems include a Surgeon Console, Robotic Control Unit, Instrument ARMs, and accessories. The Instrument ARM and accessories compatible with the Model 6N are also compatible with the Model 6Ne System.
Anovo™ Surgical System Model 6Ne improves the user interface by incorporating enhanced controllers into the Surgeon Console and introducing new features including clutching, annotation, antegrade for better hand posture, and haptic feedback that indicate the surgeon to maintain the ARMs Controllers within the Instrument ARMs Range of Motion. Those modifications were for user experience, and they do not impact the key functionalities of the device.

Performance Evaluation:

The following performance testing was conducted to demonstrate substantial equivalence to the predicate device:

Bench Testing
Bench testing demonstrates that the subject device's design output meets the design input requirements. The testing conducted consisted of dimensional measurements and 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 6Ne 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 80601-2-77 (basic safety and essential performance of

robotically assisted surgical equipment), IEC 60601-1-2 (Electromagnetic disturbances), IEC 60601-4-2 (Electromagnetic Immunity), and IEC 60601-2-2 (high-frequency surgical equipment).

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 US Surgeons evaluated the Anovo™ Surgical System 6Ne usage in a simulated OR environment by performing predefined critical tasks after a training session.

The Human Factor Usability Validation demonstrated that the Anovo™ Surgical System 6Ne supports safe and effective use by representative users during the performance of transvaginal laparoscopic-assisted surgical 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.

Pre-Clinical Cadaver Study

Momentis has performed design validation of the in female cadaver models to ensure that the Anovo™ Surgical System 6Ne meets its safety and performance requirements. The validation was performed by conducting procedures according to its intended use in an operating room environment.

A female cadaver model was chosen for this study as it simulates the human anatomy and allows evaluation of system's ability to access and reach the relevant anatomical regions and structures during surgical procedures that are part of the Indications for Use.

The study consisted of performing transvaginal laparoscopic-assisted surgical procedures on five (5) Cadavers by two (2) trained Surgeons. Following each procedure, the operating surgeon evaluated various features related to the System's performance and surgical tasks.

The results were analyzed and demonstrated that the Anovo™ Surgical System model 6Ne can successfully perform all surgical tasks to complete transvaginal laparoscopic-assisted surgical procedures.

The Anovo™ Surgical System 6Ne met all the predefined specific requirements related to clinical compatibility, performance, and safety.

Conclusion:

The Anovo™ Surgical System Model 6Ne is substantially equivalent to the predicate device. The device has the same intended uses and indications for use as the predicate. The subject device has similar technological characteristics and principles of operation as the predicate device. The technological differences between the Anovo™ Surgical System 6Ne and

its predicate device do not raise different questions of safety or effectiveness. Furthermore, the same type of non-clinical testing was performed to demonstrate the safety and effectiveness of the predicate device which also addressed the verification and validation of the subject device. No additional risks were identified in the completed testing. In addition, the subject device appropriately addresses all of the special controls in the existing classification regulation. Therefore, the Anovo™ Surgical System 6Ne is substantially equivalent to its predicate device.