July 22, 2026

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

Re: K260804
Trade/Device Name: Anovo Surgical System (6Ne)
Regulation Number: 21 CFR 878.4964
Regulation Name: Modular electromechanical surgical system
Regulatory Class: Class II
Product Code: SCV
Dated: March 11, 2026
Received: March 12, 2026

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 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: 2026.07.22 09:26:15 -04'00'

Mark Trumbore, Ph.D.
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260804

Device Name
Anovo Surgical System (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 laparoscopic-assisted benign 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 single-site, natural orifice, transvaginal benign procedures:
• Total benign hysterectomy with salpingo-oophorectomy
• Total benign hysterectomy with salpingectomy
• Total benign hysterectomy
• Salpingectomy
• Oophorectomy
• Adnexectomy
• Ovarian cyst removal

Single-site and multi-port transabdominal benign procedures:
• 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	March 11th, 2026
Device Name:	Anovo Surgical System model 6Ne
Classification:	21 CFR 878.4964 Modular electromechanical surgical system, Product Code SCV, Class 2
Predicate:	Versius Surgical System (DEN230078)
Reference Device:	Anovo Surgical System model 6Ne (K251761)
Description:	The Anovo Surgical System is a robotic-assisted device intended to assist in the accurate control of endoscopic instruments in minimally invasive surgery. The subject Anovo Surgical System 6Ne is a modification of the reference device (K251761) to include a multi-port approach in the device labeling for transabdominal Ventral Hernia procedures. To support multiport access, the Anovo Surgical System 6Ne modifications include providing an additional Robotic Control Unit (RCU) in which the two Control Units of the reference are now separated (Control Unit I and Control Unit II). Each of the Control Units is mounted on Multi-port Pedestals as a floor-mounted support system, while maintaining the established system architecture, intended use, and fundamental operating principles of the cleared system. Only one (1) RCU can be used at a time, and thus the surgery is performed with 2 Instruments ARMs. The system includes the Endoscope Arm (FDA-cleared SOLOASSIST II by AKTORmed), which is an off-the-shelf optional accessory that can be connected to the Surgeon Console and allows the surgeon to control the endoscope's movements via the Surgeon Console. The Endoscope Arm is attached to the rail of the surgical table or mounted on the Endoscope Arm Cart and covered by Sterile Drape. The Endoscope Arm is transported and stored using a Trolley. The Anovo Surgical System's components are all connected using electrical wiring. The system is designed to be used in conjunction with standard commercially available Electrosurgical Generators and 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 laparoscopic-assisted benign 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 single-site, natural-orifice, transvaginal benign procedures:

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

Single-site and multi-port transabdominal benign procedures:
• Ventral Hernia

Comparison of Technological Characteristics:

The subject Anovo Surgical System 6Ne is substantially equivalent to the predicate Versius Surgical System. It also shares many technological features with the reference Anovo Surgical System (K251761), sharing the same intended use and similar technological characteristics, and principles of operation. All systems include a surgeon console, robotic units, support systems, instruments, and accessories, enabling independent control of surgical tools through abdominal ports under endoscopic visualization. The subject device supports a two-instrument, multiport configuration using two separate control units without changes to electrical functionality. It is therefore similar to the predicate in that it is a multimodular system. Technologically, the subject device also remains similar to the cleared Anovo Surgical System 6Ne (K251761), sharing the same fundamental design, principles of operation, and core technological characteristics. Additionally, there are no differences in the procedure for use of the system; the surgeon and surgical teams perform system set-up in the same manner, where the only difference is the multi-ports (specifically two ports) Vs. Single site of the instrument arms. Verification and validation testing, including bench, electrical safety and EMC, human factor, and cadaver studies, confirmed that the Anovo 6Ne is capable of performing its intended use. Therefore, the modifications have been evaluated for maintaining substantial equivalence.

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 and demonstrated that the Anovo System met its defined design requirements and specifications, including workspace, access, reachability, safety alerts, collision, and performance.

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 were 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)
- Guidance for Industry and Food and Drug Administration Staff - Content of Human Factors Information in Medical Device Marketing Submissions (May 29, 2026)

Representative US General Surgeons and OR Staff evaluated the Anovo Surgical System 6Ne, configured for multi-port, 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, configured for multi-port access can be used by representative users during the performance of multi-port transabdominal laparoscopic-assisted Ventral Hernia surgical procedures, while maintaining an adequate range of motion, appropriate spatial separation of components, and absence of collisions, unintended contact, or hazardous interference. 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.

Cadaver Study

Momentis has performed design validation using a female cadaver model to ensure that the Anovo Surgical System 6Ne, configured for multi-port access, meets its safety and performance requirements. The validation was performed by conducting procedures according to the intended use in an operating room environment.

A female cadaver model was selected for this study as it closely replicates human anatomy and provides a realistic environment for verifying proper setup and positioning of the multi-port carts, Control Units, and Endoscope Cart, as well as confirming appropriate camera orientation. The Anovo Surgical System 6Ne, configured for multi-port access used for Ventral Hernia procedures, met all the predefined specific requirements related to clinical compatibility, workspace, access, reach, collision avoidance, performance, and safety alerts.

Conclusion:

The subject and the predicate device have the same intended use, similar indications for use, and technological characteristics. The minor differences in indications for use and technological characteristics do not raise different questions of safety or effectiveness. The modification to the Anovo Surgical System 6Ne is addressed with the same types of data as were used to support the predicate device, and the outcome of the performance evaluation (design verification and validation) does not present any new risks.

In addition, the modified device appropriately addresses all the special controls in the existing classification regulation. Therefore, the subject Anovo Surgical System Model 6Ne is substantially equivalent to its predicate device.