July 8, 2025

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

Re: K251761
Trade/Device Name: Anovo Surgical System (Model 6Ne); Anovo Instrument ARM Curved Scissors ; Anovo Instrument ARM Hook Electrode
Regulation Number: 21 CFR 878.4961
Regulation Name: Mountable Electromechanical Surgical System For Transluminal Approaches
Regulatory Class: Class II
Product Code: QNM
Dated: June 8, 2025
Received: June 9, 2025

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: 2025.07.08 09:08:21 -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

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.	

Please provide the device trade name(s).

Anovo Surgical System (Model 6Ne);
Anovo Instrument ARM Curved Scissors ;
Anovo Instrument ARM Hook Electrode

Please provide your Indications for Use below.

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 laparoscopic-assisted transvaginal and transabdominal 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 benign procedures:
• Total benign hysterectomy with salpingo-oophorectomy
• Total benign hysterectomy with salpingectomy
• Total benign hysterectomy
• Salpingectomy
• Oophorectomy
• Adnexectomy
• Ovarian cyst removal
• Ventral Hernia

The Anovo Instrument ARM Curved Scissors is indicated for use for tissue manipulation including cutting, dissecting, and coagulating and cutting using monopolar energy.
The Anovo Instrument ARM Hook Electrode is indicated for use for tissue manipulation including dissecting, and coagulating and cutting using monopolar energy.
The Anovo Instrument ARM Curved Scissors and the Anovo Instrument ARM Hook Electrode are intended for use with the Anovo Surgical System.

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)

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 8th, 2025
Device Name:	Anovo Surgical System model 6Ne Anovo Instrument ARM Curved Scissors and Anovo Instrument ARM Hook Electrode
Classification:	21 CFR 878.4961 Mountable Electromechanical Surgical System for Transluminal Approaches Product Code QNM, Class 2
Predicate Device:	Anovo Surgical System model 6N (K241907)
Description:	The Anovo Surgical System model 6Ne (6N enhanced) was the subject of the Premarket Notification K242157, which was cleared on October 21, 2024, for use based on the Anovo 6N (predicate) Indication for Use cleared at the time the Anovo 6Ne was submitted. A subsequent 510(k) clearance (K250591) addressed the addition of the Endoscope Arm as an off-the-shelf accessory. The Anovo Surgical System Model 6N was the subject of the Premarket Notification K241907 for expanding the Indication for use to include transabdominal access and Ventral Hernia procedure, which was cleared on October 2, 2024. The Instrument ARM Hook and Scissors were evaluated and found safe and effective for use with the Anovo model 6N (K243182) and with model 6Ne (K251056). Under the scope of this submission, the Anovo Surgical System Model 6Ne, including Instrument ARM Curved Scissor and Hook Electrode, are the subject of labeling unification to include Ventral Hernia through transabdominal access.

The Anovo Surgical System model 6Ne (6N enhanced) 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 transabdominal laparoscopic-assisted benign surgical procedures.
The Anovo Surgical System Model 6Ne ("Subject Device") is an enhanced configuration of the Anovo Surgical System 6N ("Predicate Device"). The Anovo Surgical System Model 6Ne enhances the experience by incorporating Off-the-Shelf controllers to the Surgeon Console, including minor modifications in the Robotic Control Unit to support those controllers and allowing the use of an Off-the-Shelf Endoscope Arm as an optional accessory. Those modifications were performed mainly for commercialization and user experience and do not impact the key functionalities of the device. The system enhancements do not impact the system Instruments or accessories.
No changes were made to the Anovo Surgical System or its accessories for the scope of this submission. 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 as performed with the cleared Anovo 6Ne, where the only difference is transabdominal versus transvaginal access and the entry of the Instrument ARMs through these access ports, which is performed in the same manner as performed with the cleared Anovo 6N.

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
• Ventral Hernia

The Anovo Instrument ARM Curved Scissors is indicated for use for tissue manipulation including cutting, dissecting, and coagulating and cutting using monopolar energy.
The Anovo Instrument ARM Hook Electrode is indicated for use for tissue manipulation including dissecting, and coagulating and cutting using monopolar energy.
The Anovo Instrument ARM Curved Scissors and the Anovo Instrument ARM Hook Electrode are intended for use with the Anovo Surgical System.

Comparison of Technological Characteristics:

The Anovo Surgical System Model 6N and Model 6Ne are nearly identical; Model 6Ne is an enhanced configuration of the 6N. The Anovo Surgical System Model 6Ne enhances the experience by incorporating Off-the-Shelf controllers into the Surgeon Console, including minor modifications in the Robotic Control Unit to support those controllers, and allowing the use of an Off-the-Shelf Endoscope Arm as an optional accessory. Those modifications were performed mainly for commercialization and user experience and do not impact the key functionalities of the device. The system enhancements do not impact the system Instruments or accessories.
No changes were made to the Anovo Surgical System, the Anovo Instrument ARM Curved Scissors, and Anovo Instrument ARM Hook Electrode, or any system component for the scope of this submission.

Performance Evaluation:

In accordance with the Design Control process, risk analysis was conducted to evaluate the impact of the labeling unification with Anovo 6N (predicate device) to include Ventral Hernia through transabdominal access.
Design validation in female cadaver models was performed to evaluate the Anovo Surgical System Model 6Ne supports the safe, effective, and complete performance of transabdominal laparoscopic Ventral Hernia Repair procedures.
The Anovo Surgical System model 6Ne met all the predefined specific requirements related to transabdominal clinical compatibility, performance, and safety.

Conclusion:

The Anovo Surgical System Model 6Ne (6N enhanced) is an enhanced configuration of the Anovo Surgical System 6N. The subject is the same in terms of intended use, indication for use and performance specifications to the predicate device and substantially equivalent in terms of design and technology.
The Instrument ARM Hook and Scissors were evaluated and found safe and effective for use with the Anovo model 6N (K243182) and with model 6Ne (K251056).

Under the scope of this submission, the Anovo Surgical System Model 6Ne, including Instrument ARM Curved Scissor and Hook Electrode, are the subject of labeling unification to include Ventral Hernia through transabdominal access.
No changes were made to the Anovo Surgical System or its accessories for the scope of this submission. 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 as performed with the cleared Anovo 6Ne, where the only difference is transabdominal versus transvaginal access and the entry of the Instrument ARMs through these access ports, which is performed in the same manner as performed with the cleared Anovo 6N.

Based on the presented information, together with the Validation testing, Risk assessment, and Design Control Summary, the use of the Anovo Surgical System 6Ne, including the Anovo Instrument ARM Curved Scissors and Anovo Instrument ARM Hook Electrode, in Ventral Hernia procedures do not present new risks. In addition, the subject device appropriately addresses all of the special controls in the existing classification regulation. Therefore, the Anovo Surgical System Model 6Ne, is substantially equivalent to its predicate device.