May 2, 2025

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

Re: K251056
Trade/Device Name: 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: April 3, 2025
Received: April 4, 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: 2025.05.02 14:11:37 -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.	K251056

Please provide the device trade name(s).

Anovo Instrument ARM Curved Scissors ;
Anovo Instrument ARM Hook Electrode

Please provide your Indications for Use below.

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.

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 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

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)

K251056

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:	April 3, 2025
Device Name:	Anovo® Instrument ARM Curved Scissors and Anovo® Instrument ARM Hook Electrode
Classification:	Mountable Electromechanical Surgical System for Transluminal Approachs Product Code QNM, Class 2
Predicate Device:	Anovo® Instrument ARM Curved Scissors and Anovo® Instrument ARM Hook Electrode (K243182)
Description:	The Anovo Instrument ARM Curved Scissors and Anovo Instrument ARM Hook Electrode (“Subject Device”) are optional instruments for the Anovo Surgical System. The purpose of this submission is to update the product labeling of the Anovo Instrument ARM Curved Scissors and Anovo Instrument ARM Hook Electrode to include compatibility with the Anovo Surgical System Model 6Ne. The Anovo Surgical System Model 6N and Model 6Ne are almost identical, with the main difference being in the user interface. Both models are endoscopic instrument control systems that are intended to assist in the accurate control of the Instrument ARMS during single site, natural orifice laparoscopic-assisted transvaginal benign surgical procedures. Both system’s models comprise a Surgeon Console operated by a non-sterile surgeon, two sterile instruments (Instrument ARMS) actuated by the non-sterile, Robotic Control Unit (RCU). Both systems allow the physician to operate the Instrument ARMS from the Anovo Surgeon Console by manipulating the ARMS Controllers under visual guidance.

No changes were made to the Instrument ARM Curved Scissors and Anovo Instrument ARM Hook Electrode or any of the Anovo Surgical System Components for the scope of this submission.

Indications for Use:

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.

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 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

Comparison of Technological Characteristics:

The subject Anovo Instrument ARM Curved Scissors and Anovo Instrument ARM Hook Electrode are sterile, single-use components inserted transvaginally into the pelvic cavity to manipulate the tissue and perform the surgery. The subject devices are identical to their predicate devices in terms of intended use, indication for use, design, technology, and performance specifications.

The modification to the labeling to include the use of the instruments with the Anovo Surgical System Model 6Ne does not affect the technical characteristics or principles of operation. No changes were made to the

Instrument ARM Curved Scissors and Anovo Instrument ARM Hook Electrode or any of the Anovo Surgical System Components 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 modification to the predicate device.

Design validation in female cadaver models was performed to evaluate the compatibility of the FDA-cleared Anovo Instrument ARM Hook Electrode and Curved Scissors with the Anovo Surgical System 6Ne (an FDA-cleared system), which is an enhanced configuration of Model 6N, including an enhanced Surgeon Console and Robotic Control Unit.

The Instrument ARM Hook Electrode and Curved Scissors used with the Anovo Surgical System model 6Ne met all the predefined specific requirements related to transvaginal clinical compatibility, performance, and safety.

Conclusion:

The subject of this 510(k) is to modify the labeling of the cleared Anovo Instrument ARM Curved Scissors and Anovo Instrument ARM Hook Electrode and include compatibility with the FDA-cleared Anovo Surgical System Model 6Ne.

The subject and predicate devices are identical in terms of intended use, indication for use, design, technology, and performance specifications.

Based on the presented information, together with the Validation testing, it can be concluded that the subject Anovo Instrument ARM Curved Scissors and Anovo Instrument ARM Hook Electrode, when used with the Anovo Surgical System Model 6Ne, are substantially equivalent to the predicate device.