February 3, 2025

Momentis Surgical Ltd.
Maya Leib Shlomo, VP of QA/RA
6 Yoni Netanyahu Street
Or Yehuda, 6037604
Israel

Re: K243182
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: September 30, 2024
Received: September 30, 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: 2025.02.03 09:53:08 -05'00'

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)*

K243182

Device Name

Anovo Instrument ARM Curved Scissors;
Anovo Instrument ARM Hook Electrode

Indications for Use *(Describe)*

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

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.**

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|---|---|
| **Submitter** | Momentis Surgical Ltd.<br>6 Yoni Netanyahu St.<br>Or Yehuda, Israel 6037604 |
| **Contact Person:** | Maya Leib Shlomo, VP of QA/RA<br>Maya.leib@momentissurgical.com<br>Tel.: 972-5-088-52822 |
| **Date:** | September 30, 2024 |
| **Device Name:** | Anovo™ Instrument ARM Curved Scissors and Anovo™ Instrument ARM Hook Electrode |
| **Classification:** | Mountable Electromechanical Surgical System for Transluminal Approachs<br>Product Code QNM, Class 2 |
| **Predicate Device:** | Anovo™ Instrument ARM Grasper end-effector (DEN190022) |
| **Description:** | The Anovo™ Instrument ARM Curved Scissors and Anovo™ Instrument ARM Hook Electrode are optional instruments for the Anovo™ Surgical System Model 6N.<br>The Anovo™ Surgical System Model 6N with Instrument ARM Grasper end-effector (“Predicate Device”) was the subject of a De Novo request (DEN190022) for transvaginal access to gynecological procedures and was granted a marketing authorization in February 2021. Both the Anovo™ Instrument ARM Curved Scissors and Hook Electrode are intended to be used with the Anovo™ Surgical System.<br>The Anovo™ Surgical System comprises the Anovo™ Surgeon Console operated by a nonsterile surgeon, two sterile instruments (Instrument ARMS) actuated by the non-sterile, Anovo™ Robotic Control Unit (RCU). The system allows 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 Anovo™ Surgical System 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:**

Both the subject and predicate devices are sterile, single use component, inserted transvaginally into the pelvic cavity to manipulate the tissue and perform the surgery. Each Instrument ARM consists of an End Effector, a flexible section (joints), a rigid section, and a handle.

The only difference between the subject and predicate devices is the end-effector and the type of electrosurgery energy. The predicate device includes Grasper end-effector and it is powered by bipolar and monopolar electrosurgery energy, while the subject devices include Curved Scissors and Hook Electrode end-effectors and they are powered only by monopolar energy.

Importantly, there are no changes to the Anovo™ Instrument ARM Grasper, the RCU, or the other components of the Anovo™ Surgical System related to the optional Instrument ARMs that are the subject of this submission and no changes to the user interface. Moreover, there are no differences in the procedure for use of the Instrument ARMs. Two Instrument ARMs are

connected to the Robotic Control Unit, each of which corresponds to the respective hand of the surgeon as controlled by right or left ARMs Controllers.

**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 mechanical and functional verification.

**Pre-Clinical Animal Study**

Momentis has performed design validation of the Anovo™ Instrument ARM Hook Electrode and Anovo™ Instrument ARM Curved Scissors in three (3) sheep (ewe) model to ensure that the Anovo™ Instrument ARM Hook Electrode and Anovo™ Instrument ARM Curved Scissors meet their safety and efficiency performance requirements.
The results were analyzed and demonstrated that the safety and performance of the Monopolar Instruments ARM Hook Electrode and Curved Scissors that were used with the Anovo™ Surgical System Model 6N, in performing the required surgical tasks in transvaginal laparoscopic gynecologic procedures were demonstrated successfully.

**Thermal Damage**

Thermal effects testing on ex vivo animal tissue was performed to evaluate the thermal effects on tissue caused by the electrosurgical functionalities of the Anovo™ Instrument ARM Hook Electrode and Anovo™ Instrument ARM Curved Scissors. This testing was designed in accordance with FDA’s Guidance Document, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery (March 2020) and Draft Guidance Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling (March 2024).
Specifically, thermal spread on representative tissue samples by the subject device electrosurgical features were compared through independent histopathological analysis to that of comparable FDA-

cleared off-the-shelf tools, and it was demonstrated that the thermal effects of the Anovo™ Instrument ARM Hook Electrode and Anovo™ Instrument ARM Curved Scissors is equivalent to that of the cleared devices.

**Biocompatibility**

Biocompatibility testing was performed according to ISO 10993-1:2018 and FDA guidance "*Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process*", September 2023 requirements including the following tests:

- Cytotoxicity
- Irritation
- Sensitization
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemolysis

**Conclusion:**

The subject devices are additional optional accessories for use with the Anovo™ Surgical System Model 6N in addition to the predicate Instrument ARM with Grasper end-effector previously cleared for use with the Anovo™ Surgical System (DEN190022).

The subject devices and the predicate device have the same indication for use, similar intended use and principles of operation, and the same technological characteristics. The minor technological differences between the Anovo™ Instrument ARM Curved Scissors and Anovo™ Instrument ARM Hook Electrode and its predicate device raise no new questions of safety or effectiveness.

The results of the performance data, including bench testing, pre-clinical Animal testing, and tissue thermal damage provide reasonable assurance of safety and effectiveness of the device for its proposed intended use and demonstrate that the Anovo™ Instrument ARM Curved Scissors and Anovo™ Instrument ARM Hook Electrode are as safe as the Anovo™ Instrument ARM Grasper end-effector, its predicate device. Thus, the Anovo™ Instrument ARM Curved Scissors and Anovo™ Instrument ARM Hook Electrode are substantially equivalent to the Anovo™ Instrument ARM Grasper end-effector.