September 14, 2023

Momentis Surgical Ltd.
Maya Shlomo
Head of QA & RA
3 Yahadut Canada St.
Or Yehuda, 6037503
Israel

Re: K232146
Trade/Device Name: Anovo Pedestal
Regulation Number: 21 CFR 878.4961
Regulation Name: Mountable Electromechanical Surgical System For Transluminal Approaches
Regulatory Class: Class II
Product Code: QNM
Dated: July 19, 2023
Received: July 19, 2023

Dear Maya 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 2023.09.14 09:07:10 -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: 06/30/2023 *See PRA Statement below*

510(k) Number *(if known)*

Device Name

Anovo Pedestal

Indications for Use *(Describe)*

The Anovo™ Pedestal is a reusable optional accessory to the Anovo™ Surgical System intended to assist in supporting and positioning the Robotic Control Unit (RCU).

The Anovo™ Pedestal, as well as the Anovo™ Surgical System, is an endoscopic instrument control system that is intended to assist in the accurate control of the Instrument Arms during indicated procedures. 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 Anovo™ Surgical System is restricted to prescription use only.

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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510(k) SUMMARY

Momentis Surgical Anovo Pedestal

Submitter

Momentis Surgical

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Date Prepared: 16-July-2023

Name of Device: Anovo™ Pedestal

Common or Usual Name: Anovo™ Pedestal

Regulatory Class: Class II

Product Code: QNM

Predicate Devices

Anovo™ RCUSS (Robotic Control Unit Support System) by Momentis Surgical Ltd., cleared under DEN190022.

Device Description

The Anovo™ Pedestal is an optional accessory for the Anovo™ Surgical System. The Anovo™ Pedestal is intended to hold the Robotic Control Unit (RCU) of the Anovo™ Surgical System, for use as an alternative to the existing Robotic Control Unit Support System (RCUSS), which was cleared as part of the Anovo™ System. The Pedestal allows the RCU to be mounted on a moveable cart instead of being bed mounted. Anovo™ Pedestal is comprised of the following components:

- Wheels Base includes four wheels enabling smooth movements of the Anovo Pedestal within the OR and hospital.

- Pedestal Main Body includes the motors of the linear, height and tilt notions, the RCU tray and adaptor, used to affix the RCU to the Pedestal, EMO button, handle to allow the user to comfortably move the Anovo™ Pedestal.
- Control panel attached to the Pedestal Handle serves as the Pedestal's User Interface and enables the user to operate all three motorized axes (height, tilt and linear), and includes enable buttons, that must be pressed by the user together with the motion buttons in order to enable motorized movement of the Anovo™ Pedestal
- Accessories include two types of cables: power supply - US power cord, 12 feet long, with locking aid to prevent unintentional disconnection connected to the main grid and provides power to the Anovo™ Pedestal; and Grounding Cable, used to connect between the Anovo™ Pedestal's equipotential pin to main grid protective earth to create potential equilibrium.

The Anovo™ Pedestal is reusable optional accessory for the Anovo™ Surgical System, intended to be covered by Sterile drape during the procedure and cleaned afterwards.

The Anovo™ Pedestal is an AC powered electrical device. Most of the Pedestal's components are connected to one main PCB board, which is powered by a 24V DC supplied from the power supply (connected to the main grid). The main PCB board consists of CPLD (Complex Programmable Logic Device) unit, which controls the vertical and tilt motions of the Pedestal, EMO, enable button and LEDs indications.

The addition of Anovo™ Pedestal does not require any changes to other components of the Anovo™ Surgical System.

Intended Use / Indications for Use

The Anovo™ Pedestal is a reusable optional accessory to the Anovo™ Surgical System intended to assist in supporting and positioning the Robotic Control Unit (RCU).

The Anovo™ Pedestal, as well as the Anovo™ Surgical System, is an endoscopic instrument control system that is intended to assist in the accurate control of the Instrument Arms during indicated procedures. 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 Anovo™ Surgical System is restricted to prescription use only.

Summary of Technological Characteristics

The Pedestal is substantially equivalent to the RCU Support System (RCUSS). Both are accessories to the Anovo™ Surgical System and are submitted under the same product code (QNM).

At a high level, the subject and predicate devices are based on the following same technological elements:

- The Pedestal has the same intended use and indications, and similar principles of operation as the previously cleared RCUSS (RCU Support System), both devices provide mechanical support for Robotic Control Unit during the procedure.
- Both Anovo™ Pedestal and RCUSS allow height, tilt and linear movements adjustments.
- The Pedestal as well as the RCUSS consist of three main functional parts, which have the same purpose of use: (A) base, (B) positioning body and (C) user interface.
- Both devices are covered by single-use Sterile Drape during the procedure and are not intended for patient contact.

The following technological differences exist between the subject and predicate devices:

- The Pedestal uses electrical AC supply mains as energy input and RCUSS is totally mechanical component, no energy is used
- Colored LEDS are used in Control Panel of Pedestal to reflect the status, versus visual color indications that were used in RCUSS
- Anovo™ Pedestal includes simple User Interface allowing the user to control the Pedestal movements and to position the RCU, RCUSS included control knobs, that were used as user interface, to allow control and positioning of RCUSS.

Performance Data

The Pedestal has successfully passed the whole range of verification and validation testing, including:

- EMC, Safety and usability testing according to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6
- Software Validation and verification testing
- Bench testing
- Labeling and training verification testing
- Life-span and environmental conditions evaluation
- Pre-Clinical Design validation: cadaver study
- Usability: Human Factors Formative and Summative Studies (according to requirements of IEC 62366, the FDA Usability Guidance Applying Human Factors and Usability Engineering to Medical Devices" (2016) with consideration to FDA's December 2022 draft guidance Content of Human Factors Information in Medical Device Marketing Submissions, and AAMI HE 75 guidance.

Bench Testing: Performance testing

A series of bench tests were performed to verify that Anovo™ Pedestal meets its design specifications.

These bench tests assessed the functionality and performance of the Pedestal with respect to its intended use, as an accessory to the Anovo™ Surgical System.

Specifically, the test cases assessed compatibility with other components of the Anovo™ System, structural and durability of the Pedestal and performance tests for the Pedestal. The testing also assessed general dimensional and mechanical strength considerations of the components.

In addition, labeling and training specifications verification was performed, that assessed the labeling of the device and conform that all markings, symbols and content of the labeling appear according to their specifications and to the in accordance with the requirements of risk analysis process.

The cleaning and disinfection process of Anovo™ was also tested as part of the bench testing and found to be compliant with the relevant requirements.

Life-span and environmental conditions were evaluated through technical report, and Anovo™ Pedestal was found to be compliant with anticipated lifespan of 7 years and environmental conditions for operation, storage and transportation defined in labeling of the device.

Pre-Clinical Design Validation: Cadaver Study

Momentis has performed design validation of the Anovo™ Pedestal in female cadaver models to ensure that the Anovo™ Pedestal meets its safety and performance requirements. The validation was performed by conducting procedures according to its intended use in an operating room environment. The specific objectives of the study were:

- Ensure stability of the RCU and Instrument Arms throughout the clinical procedure
- Evaluate docking and undocking stages of the RCU and Instruments Arms
- Evaluate the range of motion that the Pedestal provides, by conducting complete total hysterectomy with bilateral Salpingo-Oophorectomy

The testing was performed at the Pre-clinical Research and Development Unit (“GLPigs Laboratory”) of the Assaf Harofeh Medical Center in Zerifin, Israel.

The human female cadavers were chosen as the model for this study to simulate the human anatomy to evaluate access and reach to relevant anatomical regions and structures using the Anovo™ Pedestal while performing the indicated procedures with the Anovo™ Surgical System.

Procedures were performed with two (2) cadavers. A total of twelve (12) docking and undocking of the RCU and Instruments Arms were to be performed under the protocol at extreme conditions, at the range of surgical bed angles (between 20 to 30 degrees), not only in the normal use setup of 25 degrees. Two qualified surgeons performed the procedures.

Following each procedure, the operating surgeon evaluated various features related to the Pedestal’s performance and surgical tasks. The evaluation was performed by grading these features based on Likert’s scale (1-5). All surgical tasks and all the performance features met the pre-defined acceptance criteria (grading ≥3) with average grading ranging between 4.95 and 5, thus Anovo™ Pedestal was successfully validated for clinical use.

Usability: Human Factors Formative and Summative Studies were performed according to requirements of IEC 62366, the FDA Usability Guidance Applying Human Factors and Usability

Engineering to Medical Devices" (2016) with consideration to FDA's December 2022 draft guidance Content of Human Factors Information in Medical Device Marketing Submissions, and AAMI HE 75 guidance.

A total of 22 users evaluated Anovo™ Pedestal usage in simulated OR environment by performing predefined critical tasks after a short training session: 6 potential users participated in formative study; 16 users participated in summative validation study.

The test cases were issued based on the Anovo™ Pedestal's critical tasks of use flow and UFMEA (Use Failure Mode and Effects Analysis with severity greater than 3).

A test case passes if all participants eventually provided the correct response, expected by the investigator. For any issue or difficulty that occurred during the validation, an analysis was performed based on the subjective input and observational data was collected. The testing results demonstrated that all test cases met their acceptance criteria as defined in the protocol. Therefore, the objectives of the study have been successfully validated and Anovo™ Pedestal was found to be able to support safe and effective use of the Anovo™ System for its indicated procedures, similar to RCUSS, its predicate device.

Conclusions

The Anovo™ Pedestal is as safe and effective as the Anovo™ RCUSS (Robotic Control Unit Support System). The Pedestal has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. There are no differences in indications and the intended use of the device. In addition, the minor technological differences between the Anovo™ Pedestal and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrates that Anovo™ Pedestal is as safe as RCUSS, its predicate device. Thus, the Anovo™ Pedestal is substantially equivalent to RCUSS.