February 26, 2021

Memic Innovative Surgery Ltd.
% Einav Yemini
Vice President, Regulatory Affairs and Quality Assurance
Memic Innovative Surgery Ltd
6 Yonatan Netanyahu Or Yehuda 6037604, Israel

Re: DEN190022
Trade/Device Name: Hominis Surgical System
Regulation Number: 21 CFR 878.4961
Regulation Name: Mountable electromechanical surgical system for transluminal approaches
Regulatory Class: Class II
Product Code: QNM
Dated: April 16, 2019
Received: April 17, 2019

Dear Einav Yemini:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Hominis Surgical System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Hominis Surgical System is an endoscopic instrument control system that is intended to assist in the accurate control of the Hominis Arms during single site, natural orifice laparoscopic-assisted transvaginal benign surgical procedures listed below. The Hominis 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 Hominis 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

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Hominis Surgical System, and substantially equivalent devices of this generic type, into Class II under the generic name mountable electromechanical surgical system for transluminal approaches.

FDA identifies this generic type of device as:

> **Mountable electromechanical surgical system for transluminal approaches**. A mountable electromechanical surgical system for transluminal approaches is a software-controlled, patient bed- and/or operating table-mounted electromechanical surgical system with human/device interfaces that allows a qualified user to perform transluminal endoscopic or laparoscopic surgical procedures using surgical instruments attached to an electromechanical arm.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 17, 2019, FDA received your De Novo requesting classification of the Hominis Surgical System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Hominis Surgical System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Hominis Surgical System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Thermal, electrical, or mechanical fault, or system malfunction resulting in tissue perforation or injury to patient or user	Non-clinical performance testing Electrical safety testing Electromagnetic compatibility (EMC) testing Software verification, validation, and hazard analysis Human factors assessment Clinical performance testing Annual reporting Labeling

Use error resulting in patient injury: • Dehiscence or delayed healing at the device access site • Hemorrhage • Thromboembolism • Transluminal risks	Non-clinical performance testing Human factors assessment Training Clinical performance testing Post-market surveillance Annual reporting Control on distribution Labeling
Adverse tissue reaction	Biocompatibility evaluation Pyrogenicity testing
Infection	Biocompatibility evaluation Pyrogenicity testing Sterilization validation Reprocessing validation Shelf-life testing Clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the mountable electromechanical surgical system for transluminal approaches is subject to the following special controls:

1. The device manufacturer must develop, and update as necessary, a device-specific use training program that ensures proper device setup/use/shutdown, accurate control of instruments to perform the intended surgical procedures, troubleshooting and handling during unexpected events or emergencies, and safe practices to mitigate use error.

2. The device manufacturer may only distribute the device to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program.

3. The device manufacturer must conduct and complete post-market surveillance, including an impact of the training program on user learning, behavior, and performance, in accordance with an FDA-agreed-upon protocol. The device manufacturer must submit post-market surveillance reports that contain current data and findings in accordance with the FDA-agreed-upon protocol.

4. The device manufacturer must submit a report to the FDA annually on the anniversary of initial marketing authorization for the device, until such time as FDA may terminate such reporting, which comprises the following information:
    i. cumulative summary, by year, of complaints and adverse events since date of initial marketing authorization; and
    ii. identification and rationale for changes made to the device, labeling or device-specific use training program, which did not require submission of a premarket notification during the reporting period.

5. Labeling must include:

    i. a detailed summary of clinical performance testing conducted with the device, including study population, results, adverse events, and comparisons to any comparator groups identified;
    ii. a statement in the labeling that the safety and effectiveness of the device has not been evaluated for outcomes related to the treatment or prevention of cancer, including but not limited to risk reduction, overall survival, disease-free survival and local recurrence, unless FDA determines that it can be removed or modified based on clinical performance data submitted to FDA;
    iii. identification of compatible devices;
    iv. the list of surgical procedures for which the device has been determined to be safe with clinical justification;
    v. reprocessing instructions for reusable components;
    vi. a shelf life for any sterile components;
    vii. a description of the device-specific use training program;
    viii. a statement that the device is only for distribution to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program; and
    ix. a detailed summary of the post-market surveillance data collected under paragraph (3) of this section and any necessary modifications to the labeling to accurately reflect outcomes based upon the post-market surveillance data collected under paragraph (3) of this section.

6. Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use.

7. Human factors validation testing must be performed and must demonstrate that the user interfaces of the system support safe use in an operating room environment.

8. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must include:

    i. Device motion accuracy and precision;
    ii. System testing;
    iii. Instrument reliability;
    iv. Thermal effects on tissue;
    v. Human-device interface;
    vi. Mounting hardware testing;
    vii. Workspace access testing; and
    viii. Performance testing with compatible devices.

9. Software verification, validation, and hazard analysis must be performed. Software documentation must include an assessment of the impact of threats and vulnerabilities on device functionality and end users/patients as part of cybersecurity review.

10. Electromagnetic compatibility and electrical, thermal, and mechanical safety testing must be performed.

11. Performance data must demonstrate the sterility of all patient-contacting device components.

12. Performance data must support the shelf life of the device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.

13. Performance data must validate the reprocessing instructions for the reusable components of the device.

14. Performance data must demonstrate that all patient-contacting components of the device are biocompatible.

15. Performance data must demonstrate that all patient-contacting components of the device are non-pyrogenic.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the mountable electromechanical surgical system for transluminal approaches they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 post-marketing 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Virag Patel at 301-796-0452.

Sincerely,

Jennifer R. Stevenson -S3

For Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health