DE NOVO CLASSIFICATION REQUEST FOR HOMINIS SURGICAL SYSTEM

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 878.4961

CLASSIFICATION: Class II

PRODUCT CODE: QNM

BACKGROUND

DEVICE NAME: Hominis Surgical System

SUBMISSION NUMBER: DEN190022

DATE OF DE NOVO: April 17, 2019

CONTACT: Memic Innovative Surgery Ltd.
6 Yonatan Netanyahu,
Or Yehuda 6037604, Israel

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

LIMITATIONS

The sale, distribution, and use of the Hominis Surgical System is restricted to prescription use in accordance with 21 CFR 801.109.

The Hominis Surgical System may only be distributed 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.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS.

DEVICE DESCRIPTION

The Hominis Surgical System (see Figure 1) is a mountable electromechanical surgical system for transluminal approaches used in single-site benign hysterectomy and salpingo-oophorectomy surgical procedures through a transvaginal access point. The system consists of two (2) Hominis Arms, a Hominis Control Console, a Hominis Motor Units Assembly, and Hominis Surgical System Accessories (Hominis Sterile Drape, GYN Trocar Kit, Hominis System Cables, and Bed Fixation Kit). During clinical use, surgeons operate the Hominis Arms from the Hominis Control Console with a compatible and FDA-cleared third-party standard laparoscope (transumbilical) and visual guidance system.

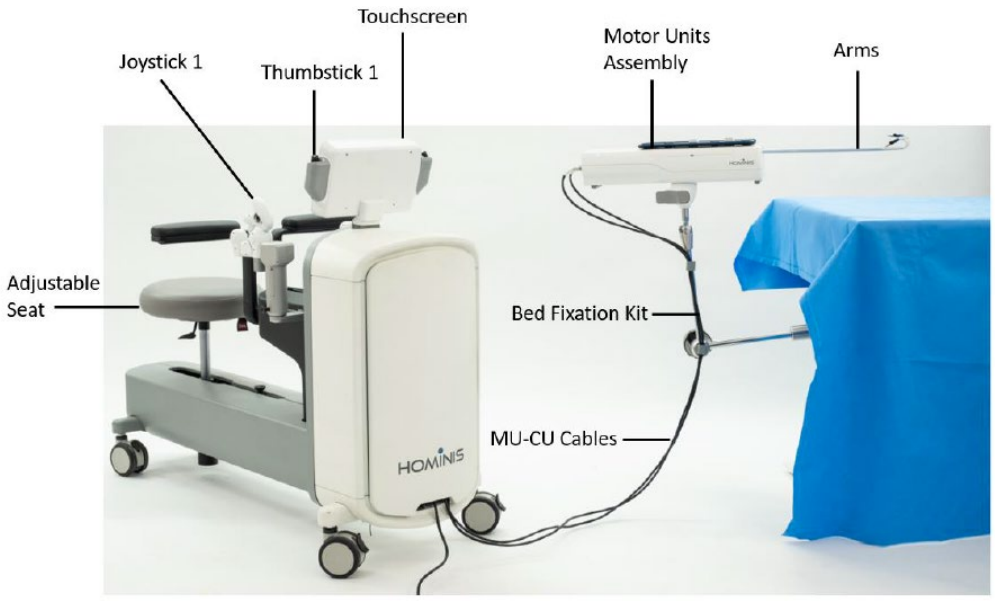

Figure 1: Hominis Surgical System

A description of each component is provided below:

Hominis Control Console
The Hominis Control Console is the main human-device interface, which includes an adjustable chair where the surgeon is seated and controls each Hominis Arm through the two (2) Motor Units. The Hominis Control Console contains the following key components: two (2) sets of arm controllers (joysticks and thumbsticks), an adjustable joystick stand, touchscreen with a graphics user interface (GUI), Manual Release Tool, power adapter, emergency-off button. The functions of the Hominis Control Console include:

- Providing guidance to the user for initialization of the Hominis Surgical System, both during procedure initiation and upon resumption from a paused state.
- Displaying status of the Hominis Surgical System components (e.g., connectivity of components, pause/resume status of the Hominis Arms, electrosurgical energy associations with the Hominis Arms, etc.).
- Controling and manipulating the Hominis Arms during the procedure using the two sets of arm controllers and buttons.
- Enabling the surgeon to adjust the position and orientation of the joysticks according to the surgeon's needs.
- Supplying power to the Hominis Surgical System by connecting the Hominis Control Console to the main supply.
- Containing buttons for powering the device (i.e. on/off) and emergency stop of the system.
- Housing the Manual Release Tool which is used during emergency extraction of the system to manually straighten the Hominis Arms.

Hominis Arm (Joystick) Controller
There are two (2) sets of arm controllers for the Hominis Surgical System: the two (2) thumbsticks and two (2) joysticks. The first set of arm controllers is the pair of thumbsticks (one thumbstick for each Hominis Arm) located at the sides of the screen. These thumbsticks are used at the beginning of each procedure in order to reach a baseline retroflexion, and for insertion and extraction of the arms. Similarly, a pair of joysticks (one joystick for each Hominis Arm) allows for the accurate control of the Hominis Arms with all the degrees of freedom for manipulating the tissue at the surgical site.

Hominis Arms
The Hominis Arms are sterile, single-use components that are inserted transvaginally to perform the indicated surgical procedures. Two identical Hominis Arms are connected to a Motor Unit, each of which corresponds to the respective hand of the surgeon as controlled by right or left thumbstick and joystick. The Hominis Arms include a rigid section (shaft), a flexible section (articulated section containing joints), and a handle. The end effector, located at the distal end of the flexible section, enables tissue grasping and displacement, and electrosurgical application of monopolar and bipolar energy.

End Effectors

The end effector is comprised of the spatula that can apply monopolar electrosurgical energy and a fenestrated grasper that can apply bipolar electrosurgical energy as well as grasp and manipulate the tissue. This is determined by connecting the corresponding Motor Unit to the generator with the appropriate electrosurgical cable and operating the generator's foot pedals. The end effectors are not intended for vessel sealing.

Hominis Motor Units Assembly

The Hominis Motor Units Assembly contain three (3) main components: A) an interface for insertion of the Hominis Arms, B) locking doors which secure the Hominis Arms once inserted, and C) a cable panel. There are two (2) Motor Units (MUs) within the housing unit and each MU drives one Hominis Arm independently with six (6) degrees of motion. The two MUs are similar in function and purpose with the right MU including an adaptor that enables mounting of the Hominis Motor Unit Assembly to the Bed Fixation Kit and a mechanism that controls the linear movement of the MUs and Hominis Arms. The Hominis Motor Units Assembly is also connected to the electrosurgical generator. Two (2) Hominis Sterile Drapes are provided to separate the MUs from the sterile field, to maintain sterility. Two (2) Hominis System Cables (or MU-CU cables) are supplied to connect the MUs to the to the Hominis Control Console.

Hominis Surgical System Accessories

Hominis Surgical System accessories listed below are provided with each Hominis Surgical System.

GYN Trocar Kit: The GYN Trocar Kit is comprised of several accessories that help to facilitate insertion of the Hominis Arms transvaginally. The GYN Trocar Kit contains a sterile trocar, short/long cannula, protective sheath, sheath gasket, blunt dilator, trocar introducer, and GYN Fixation Arm with GYN Guiding Rail. The GYN Trocar Kit allows for safe entry into the pelvic cavity through the Pouch of Douglas. Additionally, it maintains the pneumoperitoneum (via cannula and sheath gaskets) while guiding the Hominis Arms through the peritoneum.

Non-Sterile Bed Fixation Kit: The MUs are affixed firmly to the surgical bed via the Bed Fixation Kit, which includes a Surgical Fixation Arm and an extension rail. The Surgical Fixation Arm is attached to the MUs through the Motor Units Adaptor. The Hominis Arm can be attached to the surgical table directly or through the extension rail.

Third-party Devices

The Hominis Surgical System is intended to be used with the following third-party devices (these are not provided with the Hominis Surgical System) to enable the subject device to perform its intended purpose. Compatible third-party devices are listed in Table 1.

Table 1: Third-Party Devices Not Provided with the Hominis Surgical System

Components	Description	510(k) #	Sterile	Disposable
Electrosurgical Generator	Valleylab FT10™, electrosurgical generator manufactured by Covidien	K191601	No	No
Applied Medical GelPoint Mini Access	Surgical access port utilized with the GYN Trocar Kit to enable transvaginal	K191866	Yes	Yes

Platform	insertion of the Hominis Arms into the abdominal cavity.			
Auxiliary Port	A single port to be inserted transabdominally to support insertion of an off-the-shelf visualization system together with any additional off the shelf surgical instruments.	FDA-cleared devices	Yes	Reusable or disposable
Monopolar and Bipolar Electrosurgical Cables	Connects the Electrosurgical Generator to the Hominis Surgical System.	Monopolar (K143662) Bipolar (K981919)	No	No
Compatible Devices	Laparoscopic Camera and Visualization System (a k.a Tower and Scope). The Hominis Surgical System is used with a standard Operating Room visualization system, including monitors and an endoscope to enable visualization of the surgical site.	FDA-cleared devices	Device dependent	Device dependent
	The Hominis Surgical System can be used in conjunction with the following off-the-shelf manual laparoscopic instruments through the abdominal incision port, in accordance with the device's Intended Use: • Vessel Sealers • Scissors • Suction/Irrigator • Graspers	FDA-cleared devices	Device dependent	Device dependent

SUMMARY OF NON-CLINICAL/BENCH STUDIES

Non-clinical performance tests were performed to demonstrate that the Hominis Surgical System will perform as anticipated for its intended use and to mitigate the risks to health as outlined below.

BIOCOMPATIBILITY/MATERIALS

The purpose of testing all materials for biocompatibility and pyrogenicity is to mitigate the risk of adverse tissue reactions and infections for the patient.

All components are external communicating devices in contact with tissue/bone/dentin for limited duration (<(b) (4) hours). Therefore, the following tests – cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, and hemolysis – were performed according to applicable standards and guidance.

- ISO 10993-1 Fifth edition 2018-08 - *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*.
- ISO 10993-5: 2009/ revised 2014, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.*
- ISO 10993-10: 2010/ revised 2014, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.*

- ISO 10993-12: 2012, *Biological evaluation of medical devices – Part 12: Sample preparation and reference materials.*
- ISO 10993-4: 2017 *Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood.*
- ISO 10993-11: 2017 *Biological evaluation of medical device – Part 11: Tests for systemic toxicity.*
- ASTM F756: 2017 Standard Practice for Assessment of Hemolytic Properties of Materials
- United States Pharmacopeia 42, National Formulary 37, 2019. <151> Pyrogen Test.
- FDA Guidance: Use of International Standard ISO 10993-1: 2016, *"Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" - Guidance for Industry and Food and Drug Administration Staff.*

All testing and results were considered to be adequate and met the above standards.

STERILITY/REPROCESSING/PACKAGING/SHELF LIFE

The purpose of the sterility, reprocessing, packaging, and shelf life evaluations were to mitigate the risk of infection for the patient.

Each Hominis Arm is packaged with the Cannula Gasket and Sheath Gasket and provided in sterile condition. The arm and gaskets are packaged in a blister, pouched, and then boxed individually prior to sterilization. The boxed arm and gaskets are placed in shipping box and sterilized using Ethylene Oxide (EO) to a sterility assurance level (SAL) of 10^{-6}. Other device components are provided non-sterile for reuse. The Hominis Arm package was shelf-life tested using (b) (4) year accelerated aging in accordance with American Society of Testing and Materials (ASTM) F1980 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. In addition to testing the packaging integrity, functionality testing was performed for each of the components contained in the package. All test samples were sterilized (b) (4) prior to accelerated aging.

The Hominis Surgical System's reusable components are the Hominis Control Console, Hominis Motor Units Assembly, Bed Fixation Kit, and GYN Trocar Kit. The GYN Trocar Kit is a stainless-steel component that must be inspected before each use according to its reprocessing instructions and may be used unless any damage or failure is present. The life expectancy of the Bed Fixation Kit is two years. The GYN Trocar Kit must be cleaned and sterilized prior to reuse. Other reusable system parts require only low-level disinfection.

Reprocessing for reusable components was validated in accordance with Association for the Advancement of Medical Instrumentation (AAMI) TIR30, AAMI TIR12, the FDA guidance document titled, "Reprocessing Medical Devices in Health Care Settings: *ValidationMethods and Labeling – Guidance for Industry and Food and Drug Administration Staff"* (March 17, 2015), and ISO 17665-1. The GYN Trocar Kit reprocessing involves the following steps:

1. Disassembly and pre-cleaning
2. Manual cleaning
3. Rinsing after manual cleaning

4. Steam sterilization
5. Inspection prior to use

All testing and results were considered to be adequate and met the above standards.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The EMC and Electrical Safety was evaluated to mitigate the risk of electrical fault resulting in injury to patient or user.

The following Electrical/ Mechanical/Thermal Safety, and electromagnetic compatibility (EMC) testing has been performed:

- IEC 60601-1: 2012 reprint, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- IEC 60601-2-2: 2017, *Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*
- IEC 60601-1-2: 2014, *General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

All testing and results were considered to be adequate and met the above standards.

WIRELESS TECHNOLOGY

The Hominis Surgical System does not incorporate wireless technology.

SOFTWARE

The software was evaluated to mitigate the risks of thermal, electrical, and mechanical faults associated with device not working as intended due to the programming, and tissue perforation and/or injury due to system malfunctions.

The Hominis Surgical System Software consists four (4) separate modules – the Hominis Control Console software, the Hominis Motor Units Module software, the Power Logic Board software, and the Joystick Module software. The Hominis Control Console software presents the main user interface for the Hominis Surgical System and runs on the touchscreen computer of the Hominis Control Console. The remainder of the software modules control the functions of their respective hardware. The complete software is responsible for the following functions:

- Monitoring the Joysticks' movements.
- Driving the MUs (Motor Units) according to the Joysticks' movements.
- Displaying relevant information to the user.
- Enabling the user to configure certain aspects of the system through a graphical user interface.

The Hominis Surgical System software was developed in accordance with the following FDA guidance documents and standards:

1) FDA guidance document titled, *General Principles of Software Validation*, issued January 11, 2002
2) FDA guidance document titled, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued May 11, 2005
3) FDA guidance document titled, *Off-the-Shelf Software Use in Medical Devices*, issued September 27, 2019
4) IEC 62304, *Medical Device Software – Software Life-Cycle Processes*
5) ISO 14971*, Medical devices – Application of Risk Management to Medical Devices*

CDRH considers the software to be a major level of concern (LOC) because failure or latent flaw could directly result in death or serious injury to the patient or operator. Furthermore, a failure or latent flaw could indirectly result in death or serious injury of the patient or operator through incorrect or delayed information or through the action of a healthcare provider.

The submission contained all the elements of software documentation corresponding to a "major" level of concern, as outlined in the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." This includes documentation describing the software, firmware, software specifications, architecture design, software development environment, traceability, revision level history, unresolved anomalies and cybersecurity. The documentation provides sufficient information to conclude that the software will operate in a manner as described in the specifications. A hazard analysis was performed to characterize software risks including device malfunction and measurement related errors.

Overall, the software documentation contains sufficient detail to provide reasonable assurance that the software will operate in a manner described in the specifications. All testing and results were considered to be adequate and met the above standards.

CYBERSECURITY

Cybersecurity was evaluated to mitigate tissue perforation and/or injury due to system malfunction.

The Hominis Surgical System was evaluated for cybersecurity risks consistent with the FDA guidance document titled, *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, issued October 2, 2014.

The submission contained information about software malfunctions, malicious or otherwise, which could lead to patient harm, or the abilty to control/manipulate/affect the device remotely, whether by design or not. Software security information was provided demonstrating the device is protected from cyber vulnerability threats originating either via a local port or the network.

NON-CLINICAL PERFORMANCE TESTING – BENCH

The following bench tests were performed to mitigate the risks of thermal, electrical, and mechanical fault resulting in injury to patient or user, tissue perforation and/or injury due to system malfunction, user error resulting in patient injury

The bench tests characterize device performance and design verification for the Hominis Surgical System. All applicable testing was performed with provided and third-party devices. The descriptions and results of the bench tests are summarized in Table 2.

Table 2: Bench Test Summary

Test Description	Objective	Acceptance Criteria	Results
Electromechanical arm motion accuracy	Demonstrate that the Hominis Arm is able to reach the entire intended workspace based on pre-defined acceptance criteria.	Elbow and wrist can be fully rotated 360º Elbow flexion angle is 210º (b) (4) Shoulder flexion angel is 175º (b) (4) Shoulder can be rotated clockwise and counter clockwise no less than (b) (4) Gripper jaw range (b) (4)	Pass
Instrument Motion Accuracy	Demonstrate the accuracy of the surgical instruments and quantify the amount of unintended motion when under surgeon control.	Hominis Arm end-effector successfully pulls the ring through the wire without contact between both, at vertical, and horizontal orientation of the wire	Pass
System latency	Determine system latency of each tested degree of freedom to ensure that it is within the pre-defined acceptable range.	Minimal calculated system latency of each tested degree of freedom is no greater than (b) (4)	Pass
Droop Rate	Demonstrate under single fault conditions that the end-effector of the Hominis Arm does not droop or apply force under gravity based on the pre-defined acceptance criteria.	Maximal movement of the motor unit and Hominis Arm after power cut-off shall be (b) (4)	Pass
System components integrity, loading and mechanical properties	Demonstrate the component's rigidity, yield strength, ability to withstand anticipated loads, tensile forces and torque application (e.g., that the Hominis Arm can withstand application of anticipated forces, that Bed Fixation Kit and sustain the load of the Motor Units Assembly with Arms assembled, etc.) and evaluate the lift and pull force of the Arm.	Arm vertical deflection (b) (4) Lift force: lift load of (b) (4) Pull force: sustain load of (b) (4) Actuation Cable: withstand max load (b) (4) Elbow Spring: withstand torque condition of (b) (4) Wrist Spring: withstand torque condition of (b) (4) Torque Cable: withstand torque condition of (b) (4)	Pass

		Elbow Joint: sustain bending moment of (b) (4) Shoulder Joint: sustain bending moment of (b) (4)	
Electrosurgical compatibility	Active electrode (monopolar and bipolar) performance testing	Supports monopolar/bipolar energy delivery (b) (4) efficiency	Pass
Thermal effects on tissue	Evaluate the thermal effects on tissue caused by the electrosurgical functionalities (monopolar cutting/coagulation and bipolar coagulation) of the Hominis Arms	Histopathologic criteria: Monopolar Cutting - Extent of necrosis (at site or adjacent) is minimal or absent - Extent of edema is minimal or absent - Regular margins present at site Monopolar Coagulation - Extent of Necrosis (at site or adjacent) is moderate or less - Extent of edema is moderate or less - Regular Margins Bipolar Coagulation - Extent of Necrosis (at site or adjacent) is moderate or less - Extent of edema is moderate or less - Regular Margins	Pass
Arm simulated use testing	Demonstrate that the Hominis Arms maintain functionality for a full, worst-case surgical procedure.	Life Expectancy and Usage: Maintained full functionality and no visual damage after performing full simulated-use cycle of a hysterectomy procedure Insulation Sleeve Strength: Insulation sleeve is intact with no holes, tear, or other forms of damage. Insulation Sleeve Position: insulation sleeve is securely at the distal end after simulated-use cycle Bipolar Wire: - Bipolar wire is secured and maintains integrity after use of	Pass

		arms and full range of joint flexion - Bipolar wire is securied and maintains integrity at full range of motion of the gripper jaws - Bipolar wire is secured and maintains ingegrity after being articulated via wire protective sleeve. Gripper Screw: screw withstood maximal applied forces during usage	
System interfaces	Demonstrate that the system's components, when used together, are compatible and operate as expected.	Gear Interface: no noises here when Hominis Arms moved at all (b) (4) Handle Interface: Arm successfully	Pass
Electrical properties	Verify system grounding, insulation, ingress protection, power controls.	Jaw Insulation: - No DC current electrical conductivity on Gripper Jaws backsides - No AC Current electrical conductivity on test specimen - Impedence of Arm (b) (4)	Pass
GYN Trocar Kit bench testing	Demonstrate functional performance of the GYN Kit with respect to the vaginal access procedure, including assembly of the GYN Trocar Kit, compatibility with other components of the Hominis System, structural support for the Hominis Arms during transvaginal access, as well as the ability to maintain pneumoperitoneum.	Arm-Gyn Interface: - no damage occurred to the silicone sleeve or GYN protective sheath during insertion and extraction - insertion and extraction force no more than (b) (4) - torque during rotation of shoulder tube through GYN protective sheath no more than (b) (4) - Insulation sleeve remained fixed and undamaged during insertion	Pass
Bed Fixation Kit bench testing	Assess the physical and mechanical properties of the Bed Fixation Kit functional abilities with respect to mounting and securing the Motor Units onto the surgical bed and compatibility with interfacing components such as the Hominis Arms and sterile drape.	Load Bearing: Able to hold weight of fully extended arm with 8kg weight Table Mounting: Bed Fixation Kit adapter able to hold (b) (4) weight without damage	Pass

ANIMAL AND CADAVER PERFORMANCE TESTING

Performance testing was completed using animals and cadaver models to show that surgical procedures could be performed with the Hominis Surgical System and the associated 3rd party components and accessories as a system.[1]

A summary of the evaluation and results from these studies can be found in Table 3.

Table 3: Animal and Cadaver Performance Test Overview

Test	Purpose	Method	Results
GLP Ewe Study	The purpose of the animal studies were to evaluate the performance of the Hominis Surgical System in performing surgical tasks of laparoscopic transvaginal gynecological procedures in a live model.	**Design:** Hysterectomy with bi-lateral salpingo-oophorectomy) was performed transvaginally on five ewe models for a total of five surgical procedures utilizing the Hominis Surgical System. Ewe gynecological model was chosen for this study as it simulates the female reproductive organs, the clinical setting, anatomical environment risks, and transvaginal access. The studies included evaluations of procedure completion, surgical task performance, thermal spread, system performance, safety, and short-term outcomes and complications. **Endpoints:** Likert Scale (1-5) and Questionnaire - Performance and Surgical Tasks - Device Performance - Procedural Completion - Homostasis: Monopolar and Biopolar Coagulation	All procedures were successfully completed, including safely and successfully performing transvaginal access with the GYN Trocar Kit. No device-related complications or adverse events occurred, and the system performance successfully [redacted] score for the following evaluations - Performance and Surgical Tasks - Device Performance - Procedural Completion - Homostasis: Monopolar and Biopolar Coagulation - System Safety Evaluation

[1] FDA supports the principles of the "3Rs," to reduce, refine, and replace animal use in testing when feasible. We encourage submitters to consult with us if they wish to use a non-animal testing method which they believe is suitable, adequate, qualified for use with medical devices, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

Test	Purpose	Method	Results
		- System Safety Evaluation	
Cadaver Study	- Evaluating performance for anatomical access and reach - Evaluating performance for surgical task as part of workflow - Validating ability to complete intended surgical procedures in cadaver model - Validating performance working in human anatomy	**Design:** The cadaver study was performed by two surgeons on a total of five (5) female cadavers. The study consisted of performing transvaginal laparoscopic surgical hysterectomy with bi-lateral salpingo-oophorectomy. Each cadaver procedure had the following surgical steps performed to evaluate the entire workflow: cadaver positioning, system configuration, draping, system self-test, vaginal access, Hominis Arms (insertion, surgical procedures, and extraction), system disconnection, and specimen removal and vaginal cuff suturing. **Endpoints:** Likert Scale and Questionnaire - Performance and Surgical Tasks - Device Performance - Procedural Completion - Homostasis: Monopolar and Biopolar Coagulation - System Safety Evaluation	All procedures were successfully completed, including safely and successfully performing transvaginal access with the GYN Trocar Kit. No device-related complications or adverse events occurred, and the system performance successfully (b)(4) score for the following evaluations - Performance and Surgical Tasks - Device Performance - Procedural Completion

Results of the animal and cadaver study support that the Hominis Surgical System is capable of performing and completing specific surgical tasks as part of the indicated procedures workflow, minimizes thermal/electrical/mechanical damage at the intended anatomical sites, validates appropriate anatomical working space for trained users, and assures safe operation in addition to clinical performance testing.

HUMAN FACTORS

Human Factors Testing was performed to mitigate the risks of electrical, mechanical, and thermal faults or device-specific use error that result in injury to the patient or user. Usability testing was performed in accordance with FDA guidance document titled, *Applying Human Factors and Usability Engineering to Medical Devices*, issued February 3, 2016, to demonstrate the device usability.

Purpose

The usability validation study was conducted to evaluate whether the Hominis Surgical System, as designed, supports safe use by representative users when performing laparoscopic-assisted transvaginal gynecologic surgical procedures. The manufacturer-stated validation testing's purpose consisted of the following objectives:

1. Evaluate whether typical users can safely and effectively interact with the device;

2. Confirm that use-related risks have been appropriately captured and assessed in the UFMEA (Use Failure Mode Effects Analysis); or uncovering any previously unforeseen use errors.

3. Assess the effectiveness of the risk mitigation measures that have been applied during the Hominis Surgical System's design stage; and

4. Identify and validate the critical tasks and sub-tasks that were a part of the device use training program provided in the field.

Objective data and subjective feedback on the Hominis Surgical System's ease-of-use was also collected to inform future continuous usability improvement.

Study Design

A total of 71 users, of which there were 24 US surgeons and 16 US Operating Room (OR) staff, participated in the study, and performed critical tasks as teams, as applicable, in accordance with the clinical use scenario. Surgeon participants exhibited a wide range of clinical experience (0 - 40 years) and robotic surgical experience (0 - 10 years). A summary of the critical tasks and respective user roles can be found in Table 4. A summary of surgeon background experience separated by laparoscopic, vaginal, and robotic of the surgeons can be found in Table 5. US OR staff also varied in clinical experience (1 - 23 years), and robotic experience (0 - 10 years). A summary of all participants separated by region can be found in Table 6.

Table 4: Critical Tasks

Critical Task Procedure Step	Critical Tasks	User Roles
OR Setup	Configure System	Non-sterile OR staff
	Motor Units Installation	Non-sterile OR staff

Electrosurgery connections (these two critical tasks were performed together as a team)	Choose energy type	Non-sterile surgeon
	Connect electrosurgery cables	Sterile surgeon/OR staff
Arms mounting and draping (these three (3) critical tasks were performed together as a team)	Remove Hominis Arm from the blister (by holding the rigid portion)	Sterile OR Staff Non-sterile OR Staff
	Mount the Hominis Arm	Non-sterile OR staff
	Drape the System	Sterile OR staff
System Test	System self-test	Non-sterile surgeon
Joystick Test	Joystick test	Non-sterile surgeon
Vaginal Access	Vaginal access with the GYN Kit	Sterile surgeon
Docking (these two critical tasks were performed together as a team)	Dock System transvaginally	Sterile surgeon Non-sterile surgeon/OR staff
	Bed Fixation Kit locking - MU Fixation - Arm locking	
Surgical Steps	Retroflexion with use of navigation joysticks.	Non-sterile surgeon
	Manipulate instruments in retroflexion using the joysticks	Non-sterile surgeon
Surgical Steps	Connect/disconnect electrosurgery cables	Sterile surgeon Non-sterile surgeon/OR staff
Surgical Steps	Pause/Resume control of instruments	Non-sterile surgeon
Surgical Steps	Operate Arms to null configuration with use of navigation joysticks.	Non-sterile surgeon
Withdraw System	Withdraw Hominis Arms from surgical site	Sterile surgeon Non-sterile surgeon/OR staff
Relocate Surgical Fixation Arm away from patient	Relocate Bed Fixation Kit away from patient - Relocating Surgical Fixation Arm	Sterile surgeon Non-sterile surgeon/OR staff
Exchange Tool	Replacing an Arm	Non-sterile surgeon Sterile surgeon/OR staff
EMO Press and manual release	Manual Release Tool usage Emergency-off button usage	Non-sterile surgeon

Table 5: Surgeon Years-of-Experience Type

Experience Type	Range [Years]	Median [Years]	Number of Surgeons with no Experience	Number of Surgeons with less than five (5) years of Experience
Robotic	0-10	(b) (4)		
Vaginal	0-36			

Procedures				
Laparoscopic	0-40	(b) (4)		

Table 6: Participant Background Experience

	No. of U.S. Participants	Previous Experience with the Hominis Surgical System [# participants]	Previous Experience with Other Robotic Systems [# participants]	Average Experience (including residency and fellowship) [years]	Experience (including residency and fellowship) [min-max years]
U.S. Participants					
Surgeons	24	(b) (4)			1-40
OR Staff	16				1-23
All Participants (U.S. and Non-U.S.)					
Surgeons	50	(b) (4)			1-40
OR Staff	21				(b) (4)

The usability of the Hominis Surgical System was evaluated according to a transvaginal approach and use workflow. The study was conducted in a simulated OR and involved preoperative preparation and simulated surgical procedures, as well as emergency procedures that involved safety critical tasks.

Critical tasks are user tasks which, if performed incorrectly or not performed at all, could cause serious harm to the patient or user. Harm is defined to also include compromised medical care. The tasks related to each risk were given a severity assessment ((b) (4)) based on the UFMEA. The list of critical tasks was identified based on the potential harm associated with use-related issues (identified during the risk analysis process) that could arise from users inadvertently performing tasks incorrectly or failing to perform the necessary tasks.

Participants underwent a condensed training program with an emphasis on performing the critical tasks and sterile techniques within the surgical field. Condensed training considered worst-case scenario and training-decay was evaluated as part of use-related risk.

Evaluation

For each critical task, the expected and incorrect responses were pre-defined based on sub-tasks and risks associated with that critical task, respectively. Task success criteria looked at expected and incorrect responses, and completion of the task safely and effectively, is outlined in Table 7.

Table 7: Task Success Criteria for Each Critical Task

	Rating	Description
1	Successful	User completed the task safely and effectively.
2	Difficult	User completed the task safely and effectively but had significant hesitation or challenges while completing the task.

3	Close Call	User completed the task safely and effectively but performed it in a way that presented a potential for patient harm (i.e., near-miss).
4	Unsuccessful	User was unable to complete the task or did not complete the task safely and effectively.
5	Did not perform	User did not perform the task, but due to reasons not related to the system.

Each critical task was evaluated for successful completion and a test case for the critical tasks passes if all participants eventually provided the correct response. Ratings of difficult and close call were analyzed for possible root-cause but were considered to be a pass. Users were asked open-ended questions regarding the device in order to collect subjective feedback on usability aspects that might not have been observed during the objective data collection to seek difficult tasks and safety concerns. Any potential use problem (e.g. use errors, close calls, difficulty, hesitation, etc.) observed during the validation sessions was assessed for root cause and possible outcomes. The root cause of any observed use problems were analyzed for applicability to other critical tasks, harm to patient, and modifications to reduce or eliminate the use problem

The usability of the Hominis Surgical System was evaluated to ensure residual risk is at acceptable levels. If any new hazardous use scenarios were identified during testing, they were assessed according to the risk management process and found to be acceptable.

Results
Testing included a total of 50 surgeons and 21 OR staff, of which 24 US surgeons and 16 US OR Staff. The validation testing demonstrated all of the identified critical tasks were completed across the different user types within the surgical team, and that all test cases met their acceptance criteria as defined in both protocols by all users. Several cases were determined to be difficult, however upon analysis of the root causes and determination that the clinical consequence caused no harm to patient or minor prolongation of surgical procedure, no new hazardous use scenarios were identified and no modifications to critical tasks were made. The critical tasks identified became a part of the device use training program.

SUMMARY OF CLINICAL INFORMATION

I. Device Use Training Program

A training program was established to mitigate risk of use error that would result in patient injury due to lack of familiarity with the complex systems and functions of Hominis Surgical System.

Before operating the Hominis Surgical System, all users (surgeon and OR Staff) underwent the device use training to properly familiarize and operate the system.

Investigators Background

The surgeons that participated originated from Rambam hospital (Haifa, Israel) and Imelda hospital (Bonheiden, Belgium). A total of (b) (4) surgeons participated in the study and operated

with the system ((b) (4) surgeons at Imelda hospital and (b) (4) at Rambam hospital). All surgeons underwent the device use training program for the Hominis Surgical System. Collectively, the surgeons' experience in robotic surgery ranged from 0 to 10 years with three surgeons having never performed robotic procedures independently. The surgeons' experience in vaginal hysterectomies ranged from no experience to (b) (4) procedures in total; (b) (4) of the surgeons were novice users – (b) (4) had not performed vaginal hysterectomies and (b) (4) surgeon performed (b) (4) vaginal hysterectomies in total prior to using the system. The surgeons' experience in laparoscopic hysterectomies also ranged from no experience to (b) (4) procedures in total; (b) (4) of the surgeons were novice users – (b) (4) had not performed laparoscopic hysterectomies and (b) (4) surgeons performed (b) (4) or less laparoscopic hysterectomies in total prior to using the surgical system. The site information and experience per participating surgeon is provided in Table 8.

Table 8: Sites Information and Experience per Participating Surgeon

Sites and Number	Investigators and roll in the study	Clinical Experience after board certification [Years]	Experience w/ vaginal laparoscopic hysterectomy after board certification [Years/No of Operations]	Experience w/laparoscopic hysterectomy after board certification [Years/No of Operations]	Experience w/robotic hysterectomy after board certification [Years/No of Operations]	Number of cases performed as part of the study
Site #1	(b) (4)					
Site #2						

Training Program Design

The Hominis Surgical System device-specific use training program was a multi-phase, stepwise, human factors-validated program that provided understanding of the Hominis Surgical System, functional understanding of all components, and how each component was used as part of procedural workflow to perform the indicated surgical procedures.

The manufacturer developed and provided the device-specific use training program to the clinical management of the healthcare facilities. Additionally, the manufacturer offered guidance for the logistics and implementation requirements needed to establish the training program at the healthcare facility.

The training program included the following:

- Training professional healthcare users to demonstrate proper device setup/use/shutdown through the critical tasks, 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 during critical tasks that could result in patient harm due to unfamiliarity with the device features or functions.
- All users met pre-specified success criteria before moving towards clinical cases.
- Initial clinical cases were proctored.

The Hominis Surgical System may only be distributed 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.

The device-specific use training program will be updated as part of an evaluation process to maintain an effective training program. This will include the following information:

- Objective evaluations of users during each training phase to determine user competency and report unanticipated events (e.g. prolonged completion, unexpected performance, difficult tasks, etc.)
- Feedback on training will be collected from users
- Complaints and service reports will be periodically reviewed
- Data collected from clinical studies and post-market surveillance will be periodically reviewed for usability and use error risk analysis

Upon collection of this information, the training plan will be updated accordingly, and training staff appropriately instructed.

II. Pre-market Clinical Study

Purpose/Objectives

The pre-market clinical study:

- Established clinical assessment for the Hominis Surgical System for use in Total Transvaginal Laparoscopic Hysterectomy with Salpingo-Oophorectomy or Transvaginal Laparoscopic Hysterectomy with Salpingectomy for benign indications.
- Provided clinical endpoints to be compared to the study endpoints from clinical studies found as part of the literature review, to determine a safety and effectiveness profile

Study Design

A Multi-center, single arm, prospective study was conducted to clinically assess the safety and effectiveness of the Hominis Surgical System for use in Total Transvaginal Laparoscopic Hysterectomy with Salpingo-Oophorectomy or Transvaginal Laparoscopic Hysterectomy with Salpingectomy.

Duration: The total duration for the study was 14 months.

Sample Size: 30 subjects

Inclusion Criteria

1. Female above 18 years of age, inclusive.
2. Able to provide written informed consent.
3. Eligible for Total Transvaginal Laparoscopic Hysterectomy with Salpingo-Oophorectomy or Transvaginal Laparoscopic Hysterectomy with Salpingectomy and have an appropriate indication to go through this surgery.
4. Willing to undergo laparoscopic transvaginal procedure by Memic Hominis Surgical System.
5. Fit for robotic-assisted transvaginal surgery based on surgeon discretion.
6. Can undergo general anesthesia per anesthesiologist assessment.

Exclusion Criteria

1. Women with anatomical hazard for laparoscopy and/or vaginal and/or pouch of Douglas access (such as diagnosis of Crohn's disease, active Pelvic inflammatory disease (PID), active diverticulitis, severe peritoneal adhesions, frozen pelvis, obliterated vagina or sever rectovaginal
   endometriosis).
2. Women after pelvic radiation.
3. Women diagnosed with active intra-abdominal malignancy.
4. Women with general condition or illness incompatible for surgery.
5. Women who are pregnant.
6. Unwillingness or inability to follow the procedures outlined in the protocol.

Study Endpoints

The study endpoints were defined to clinically assess the Hominis Surgical System in transvaginal laparoscopic-assisted benign hysterectomy procedures.

Primary Endpoint: rate of unplanned conversion to open or laparoscopic approach [time frame: Intra-operative].

Key Secondary Endpoints:

1. Intra-operative procedural outcomes, including:
   - Intra-operative complications
   - All Adverse Events (AEs) and Serious Adverse Events (SAEs)
   - Bladder injury
   - Rectal injury
   - Operative time
   - Transfusion rate
   - Estimated Blood Loss (EBL)
   - Conversion rate (i.e., conversion to laparotomy, laparoscopy, other ports used in addition to vaginal and umbilical port).
   - Mortality
2. Post-operative procedural outcomes (from post-procedure through 6 weeks of follow-up), including:
   - Length of hospital stay
   - Post-operative complications

- All adverse events (AEs and SAEs)
- Bladder injury
- Rectal injury
- Transfusion rate
- Re-admission rate
- Re-operation rate
- Mortality

3. Procedure completion (completion of intraoperative procedure using the investigational device)
4. Vaginal tissue healing was documented until complete healing.

Follow-up: The subjects were evaluated immediately after the procedure, approximately 12 hours post-procedure, and before discharge. An additional follow-up visit occurred at six (6) weeks or longer in the case that complete vaginal cuff healing had not been achieved at 6 weeks.

Success Criteria

A clinical assessment of safety and effectiveness of the Hominis Surgical System can be established if the clinical endpoints met or were more favorable that the study endpoints obtained from the existing clinical studies collected from the literature review.

Clinical Study Results

Table 9 summarizes the patient demographics for the clinical study.

Table 9: Clinical Study Cohort

Cohort Characteristics	Pre-market Clinical Study
Patient Characteristics	
# of Subjects	30
Age Range [years]	37 – 79 (b) (4)
BMI Range [kg/m^2]	17.6 – 40.03 (b) (4)
Smoking Status [%]	(b) (4)
Patient Comorbities [%]	
Previous Abdominal Surgeries [%]	
Previous Cervical Surgeries [%]	
Uterus Characteristics	
Uterus Size Range [g]	(b) (4)
# with uterine weight >60g [%]	
# with uterine weight >125g [%]	
Uterine Length Range [cm]	
Uterine Width Range [cm]	
Retroverted Uterus [%]	
Compromised Vaginal Capacity [%]	
Compromised Vaginal Integrity [%]	
Pathologies	
Endometriosis [%]	
Adhesions [%]	
Adenomyosis [%]	
Fibroids [%]	
Fallopian Tube Cysts [%]	
Ovarian Tube Cysts [%]	

Effectiveness Results: 100% of the 30 procedures performed were completed electromechanically solely with the Hominis Surgical system, there were no conversions to open or manual laparoscopic surgery identified (primary endpoint of the clinical study) and no unplanned use of extraneous ports or instruments. Effectiveness Endpoints are listed in Table 9.

Safety Results: No intraoperative adverse events (AEs) were noted in the study. One postoperative complication, described as minor bleeding that responded to non-operative management in the form of hydration and observation. No transfusions were required. No reoperations, no readmissions and no mortalities were observed in the study. 23% (7 of 30 subjects) of the study subjects had relatively delayed vaginal cuff healing. All subjects healed within 9-14.5 weeks postoperatively. Safety Endpoints are listed in Table 10.

Tables 10 and 11 provide a summary of the results obtained from key secondary endpoints that were separated based on effectiveness and safety, respectively.

Table 10: Summary of Effective Endpoints

Effectiveness Endpoints	Intra-operative and Post-operative (30-day) outcomes
Conversion rate (i.e., conversion to laparotomy, laparoscopy, other)	None
Procedure completion	100%
Ports used in addition to vaginal and umbilical port)	None
Average Operative Time (range) [minutes]	57.07 (24-88)
Average length of hospital stay (range) [days]	3.2 (2-8)
Re-admission rate [%]	0
Re-operation rate [%]	0

Three patients had prolonged hospitalizations that were not found to be due to any specific post operative complication. One subject was hospitalized for eight (8) days due to back pain, she stayed for observation with no findings or additional treatment required. Another patient had a prolonged hospitalization for seven (7) days due to placement issues and one patient was hospitalized for five (5) days due to abdominal pain and as such stayed for observation with no findings or additional treatment required.

Table 11: Summary of Safety Endpoints

Safety Endpoints	Intra-operative	Post-Operative	
		Post-Procedure (perioperative)	Follow-Up (through 6-15 weeks)
Adverse Events (AEs) and Serious Adverse Events (SAEs) [%]	(b) (4)		
Bladder injury [# of patients]			

Rectal injury [# of patients]	(b) (4)
Transfusion rate	
Mortality [%]	
Point of entry, vaginal cuff and vaginal walls healing	
Cuff dehiscence rate	

1) Patient complained on back pain, CT scan was conducted and results were normal.
2) (b) (4) reported hot flashes (b) (4) weeks post-procedure; (b) (4) had cystitis (b) (4) weeks post-procedure and was treated with (b) (4) and resolved.
3) (b) (4) had a post-operative bleeding complication upon removal of vaginal plug on day (b) (4) post-surgery, there was some bleeding more than average. Based on site's standard of care, preventatively, a new vaginal plug was placed and (b) (4) was administered. No blood transfusions were required.
4) (b) (4) patient presented left clivus meningioma with compression of optic nerve; (b) (4) patient had a post operative urinary tract infection (UTI) that was managed with antibiotics.
5) (b) (4) patient had paresthesia, likely in the neck. Visit to ER resulted in no acute illness and discharged with plan for MRI
6) (b) (4) patients had vaginal cuff healing observed between (b) (4) weeks; all other patients had vaginal cuff healing by (b) (4) weeks.

The pre-market clinical study achieved the objectives of performing and clinically evaluating vaginal hysterectomy procedures using the Hominis Surgical System. The results showed equal or better clinical outcomes as compared to the study endpoints obtained from the clinical studies that were supplied by a literature review conducted by Memic.

III. Literature Review

Purpose/Objectives
The literature review was conducted to provide a comparison to clinically assess the Hominis Surgical System for hysterectomy procedures.

Literature Search
Data search from several literature databases, such as Medline, PubMed, Cochrane database, and Embase that were screened for randomized controlled trials, clinical trials, review and meta-analysis articles on the current medical knowledge and state of the art relating to different surgical approaches to hysterectomy. A search for clinical studies was also performed within the FDA 510(k) database. The search was conducted for the years 1995-2018.

The literature search was performed using the PRISMA literature search method with filters and a decision-making tree to determine the inclusion and exclusion of publications from the chosen databases. An overview of the search methodology and decision-making process for the comparator studies can be seen in Figure 2.

(b) (4)

Figure 2: Search Criteria and PRISMA Flowchart for the Literature Search and 510(k) Database Search Summary

The premarket clinical study performed by Hominis Surgical System is compared to Traditional Vaginal Hysterectomy and Robotic-Assisted Abdominal Hysterectomy in Table 12.

Table 12: Hominis Surgical System vs. Open Transvaginal Hysterectomy and Robotically Assisted Abdominal Hysterectomy

Comparator group	Author/ Year	Study Size (N)	Operation Time (Average, minutes)	Estimated Blood Loss (mL)	Length of Stay (days)	Transfusion Rate (%)	Intra-operative Adverse Events (%)	Post-operative Adverse Events (%)	Mortality (in-hospital – 30 days, %)	Reoperation Rate (%)	Readmission Rate (%)	Conversion Rate (%)	Bladder Injury (%)	Rectal Injury (%)	Cuff Dehiscence Rate (%)

Hysterectomy performed with Hominis Surgical System	NA	(b) (4)
Traditional Transvaginal Hysterectomy	Makinen [80][1] 2001	
	Lim [81][2] 2016	
Robotically-Assisted Abdominal Hysterectomy	Lim[81][3] 2016	
	Shah [46][4] 2017	
	Liu [49][6] 2014	
	Lim [50][8] 2010	
	Maenpaa [54][9] 2016	
	Chen [66][10] 2016	
	SOFAR [67][11] 2017	

[1] Makinen, Juha; Johansson, Jari; Tomas Candido; Tomas Eija; Heinonen, Pentti K ; Laatikainen, Timo; Kauko, Minna; Heikkinen, Anna-Mari; Sjoberg, Jari Morbidity of 10 110 hysterectomies by type of approach Human Reproduction Vol 16, No 7 pp 1473-1478, 2001

[2] Lim, Peter C ; Crane, John T ; English, Eric J ; Farnham, Richard W ; Garza, Devin M ; Winter, Mark L ; Rozeboom, Jerry L Multicenter analysis comparing robotic, open, laparoscopic, and vaginal hysterectomies performed by highvolume surgeons for benign indications International Journal of Gynecology and Obstetrics 133 (2016) 359-364

[3] Lim, Peter C ; Crane, John T ; English, Eric J ; Farnham, Richard W ; Garza, Devin M ; Winter, Mark L ; Rozeboom, Jerry L Multicenter analysis comparing robotic, open, laparoscopic, and vaginal hysterectomies performed by highvolume surgeons for benign indications International Journal of Gynecology and Obstetrics 133 (2016) 359-364

[4] Shah CA, Beck T, Liao JB, Giannakopoulos NV, Veljovich D, Paley P 1 J Gynecol Oncol 2017 Nov;28(6) e82

[5] Bladder injury was not reported however the publication reported the following urinary tract complications: 0%- Ureteral injury, 0 9%- urinary tract infection, (UTI) 0 9%- Urinary retention

[6] Liu H, Lawrie TA, Lu D, Song H, Wang L, Shi G Robot-assisted surgery in gynaecology Cochrane Database Syst Rev 2014 Dec 10;(12):CD011422

[7] Specifically: 10 – intraoperative complications, 10- post-operative complications and 4 - intraoperative injury

[8] Lim PC, Kang E, Park DH Learning curve and surgical outcome for robotic-assisted hysterectomy with lymphadenectomy: case-matched controlled comparison with laparoscopy and laparotomy for treatment of endometrial cancer J Minim Invasive Gynecol 2010 Nov-Dec;17(6):739-48

[9] Mäenpää MM, Nieminen K, Tomás EI, Laurila M, Luukkaala TH, Mäenpää JU Robotic-assisted vs traditional laparoscopic surgery for endometrial cancer: a randomized controlled trial Am J Obstet Gynecol 2016 Nov;215(5):588 e1-588 e7

[10] Chen SH, Li ZA, Huang R, Xue HQ Robot-assisted versus conventional laparoscopic surgery for endometrial cancer staging: A meta-analysis Taiwan J Obstet Gynecol 2016 Aug;55(4):488-94

[11] K171120; Robotic Assisted Surgery for Treatment of Gynecological Diseases: Pilot Study https://clinicaltrials gov/ct2/show/NCT03093675?term=ALF- X&draw=1&rank=1

*The time from insertion to removal of the Hominis system

**Evaluation method not specified (note: this data was inadvertently missing in the original literature review summary)

***The time from when the patient entered the operating room to when they exited (note: corrected data from original search reported in the De Novo request was: (b) (4) but should have been (b) (4)

^ None of the patients had prolonged hospital stay due to device-related issues Subject 01-01 (Imelda hospital) was hospitalized for four (4) days due to the surgeon being away at a congress In one of the sites the standard of care is four (4) hospitalization days (One (1) day before the procedure, one (1) day for the procedure and two (2) days post procedure) Subject 02-06 was hospitalized for eight (8) days due to back pain, her orthopedic doctor requested for a CT and as such she stayed for observation with no findings or additional treatment She was discharged with a VAS score of zero (0) and did not have any additional complains since discharge Patient 02-07 was hospitalized for seven (7) days as she requested to stay at the hospital because she has no family to take care of her; however, the patient had no complaints or clinical findings that would have required her to be hospitalized otherwise and was not given any additional treatments during the extended hospitalization Patient 02-15 was hospitalized for five (5) days due to abdominal pain and as such stayed for observation with no findings or additional treatment

CONCLUSIONS

The pre-market clinical study of the Hominis Surgical System provided by the sponsor showed reduced intra-operative and post-operative adverse rates, reduced operative time and hospital length of stay compared to traditional vaginal hysterectomy procedures. The Hominis Surgical

System also had reduced intra-operative and post-operative adverse events and decreased conversion rates to an open approach compared to robotically-assisted abdominal hysterectomy procedures.

POST-MARKET SURVEILLANCE

Memic, the manufacturer of the Hominis Surgical System, is required to complete post-market surveillance to mitigate use error across a broad and heterogenous user population to further mitigate risks of injury to patients and users (e.g. surgeons varying in surgical experience, experience with transvaginal procedures, and experience with robotic surgery devices) and determine the impact of the training program on user learning, behavior, and performance. Memic will conduct a post-market surveillance study in the form of a post-market registry study based on an FDA-agreed-upon protocol between the manufacturer and FDA. In addition, Memic will submit data and findings per the FDA-agreed upon protocol.

The post-market registry aims to collect the following clinical data and will use the reported clinical outcomes from the pre-market clinical performance testing and published literature studies to establish a baseline for comparison to evaluate the training program efficacy:

1. Operative Time (setup, docking, undocking, and total procedure time)
2. Length of Hospital Stay
3. Intraoperative Complications (bladder injury, rectal injury, etc.)
4. Transfusion Rate/Estimated Blood Loss
5. Conversion Rate (Unplanned conversions of the surgical procedure to open or manual laparoscopy)
6. Post-Operative Complications (through (b) (4) days, until resolution of the complication)
7. Readmission Rate
8. Reoperation Rate
9. Mortality
10. Vaginal Cuff Healing
11. Cuff Dehiscience

ANNUAL REPORTING

Annual Reporting serves to mitigate identified risks to health with patient or user injury related to thermal/electrical/mechanical faults, use error resulting in patient injury, infection, and tissue perforation due to system malfunctions.

Software-controlled, mounted electromechanical devices are complex with many interlinking components and interfaces that will undergo technological changes and evolutions to enhance device safety and effectiveness. The regulatory criteria in 21 CFR 807.81(a)(3) state that a premarket notification must be submitted in the case of "a change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process." However, even minor changes to a system component that do not rise to the level of requiring a premarket notification can unexpectedly magnify into clinically relevant device failure during use for this device. Therefore, it is critical that FDA understand even changes

made to the device that would not require a 510(k) submission to understand their impact on the safety and effectiveness of the device.

The annual reports will contain a cumulative summary, by year, of complaints and adverse events since date of initial marketing authorization, as well as 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.

LABELING

The Hominis Surgical System provides Instructions for Use and Reprocessing Instructions complies with the labeling requirements under 21 CFR 801.109 for prescription devices.

Important components of the labeling include:

- All data associated with the pre-market clinical study and from comparator clinical studies to address anatomical characteristics of a patient that might preclude using minimally invasive techniques.
- Devices not indicated for cancer treatment or oncologic disease must include a precaution statement in the labeling that demonstrations of safety, effectiveness, benefits, and risks 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.
- A description of the training program and a recommendation that device usage be reserved for qualified surgeons with expertise in laparoscopic gynecological surgery and vaginal hysterectomy procedures.
- Identifies the validated shelf-life for the single use components, disinfection instructions for reusable non-patient contacting components, and an up-to-date listing of all the compatible devices required for device-specific use but are not included with the Hominis Surgical System.
- The defined umbrella and covered procedures indicated for device use
- Detailed summary of collected post-market surveillance data
- Information regarding how the device is only for distribution to facilities that implement and maintain the device-specific use training program and ensure that users have completed the device-specific use training program

Labeling will be updated in accordance with data collected via annual reporting and post-market surveillance to provide up-to-date clinical performance data and training effectiveness data of the Hominis Surgical System.

See the labeling for a full list of contraindications, warnings, precautions, and limitations needed for safe use of the device.

RISKS TO HEALTH

Table 13 below identifies the risks to health that may be associated with use of a mountable electromechanical surgical system for transluminal approaches and the measures necessary to mitigate these risks.

Table 13: 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

SPECIAL CONTROLS

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.

BENEFIT/RISK DETERMINATION

Risks

General risks of the Hominis Surgical System include injury to patients or users due to use error, thermal/electrical/mechanical faults leading to patient harm, and/or tissue/organ perforation. Additional risks include thromboembolism, adverse tissue reactions infection(wound, surgical site, deep space), vaginal cuff dehiscence and/or delayed vaginal cuff healing, or hemorrhage. Use related error may also occur if surgeons or OR staff are insufficiently trained on safe and effective use of the device.

Risks of device-use and clinical study limitations are mitigated with warnings, precautions, training validated by human factors testing, and plan for a robust post-market registry with a larger patient and surgeon population. Due to the novel nature and workflow of the indicated surgical procedures (specifically the initial access technique) the manufacturer recommends the Hominis Surgical System to be used by surgeons with expertise in laparoscopic gynecological surgery and vaginal hysterectomies preocedures. This recommendation is intended to mitigate

the risks of this procedure being performed by surgeons without pre-procedure experience with transvaginal operations.

Annual reporting requirements are needed to address the complexity of the Hominis Surgical System with its numerous interlacing systems, users interfaces, and critical tasks that when failures occur can lead to patient and/or user injury. Minor changes to a system component can unexpectedly magnify into clinically relevant device failure during use. Such examples include properly disengaging the device during a software glitch so surgery can convert unhindered or being able to redirect the monopolar and bipolar energy to prevent thermal damage. Annual reports enable FDA to understand the totality of changes made to the device, changes made to the training program, and their collective connection to device changes and improvements, and ensure that the device will work as intended and therefore preventing interruptions to workflow during surgical procedures. Annual reports will also document all changes and complaints to be traced to specific complications with the use or functionality of the device.

The annual reports will discuss regular updates to the device-specific use training program that is effectively designed and informed by training evaluations, post-market surveillance data, and complaint/adverse event data, and therefore further mitigate use error.

Benefits

The following are the probable benefits of the Hominis Surgical System based on the data collected in clinical studies:

1. Reduced intra-operative and post-operative AE rates, operative time and hospital stay compared to traditional vaginal hysterectomy procedures.

2. Transvaginal approach removes the need for multiple abdominal incisions and allows for smaller abdominal incision sizes.

3. Seated or standing surgeon console for the operating surgeon.

4. Direct visualization and access to the pouch of Douglas.

5. Provide patients the benefits of traditional vaginal hysterectomy procedures who may have otherwise been excluded due to contraindications.

The pre-market clinical study provided prospective study data with the subject device on 30 patients undergoing vaginal hysterectomy procedures for benign indications. In this study, there were no major intraoperative events (including but not limited to bowel, bladder or major vascular injury) or major post operative adverse events (such as major bleeding, take backs to the operating room or death within six weeks of the procedures). Additionally, no procedures required conversion to manual laparoscopy or open procedures (100% effectiveness). While 23% of patients did have relatively delayed vaginal cuff healing, all completely healed by 9-14.5 weeks and there were no reported vaginal cuff dehiscence events. There were seven (7) post-

operative adverse events (b) (4) of subjects) captured, with three associated with possible device-related AEs: UTI, minor vaginal bleed, and cystitis.

Surgeons were able to successfully perform all transvaginal access procedures and the totality of the critical tasks safely. The Hominis Surgical System cases had no transfusions, no mortality, and no intraoperative adverse events, not raising any safety issues. The (b) (4) of patients that had relatively delayed vaginal cuff healing within the (b) (4) week range were still within the normal range for recovery. The three potential device-related AEs were posed minor risks to patient health and safety, and were followed-up and treated appropriately.

Nonetheless, because there are noted limitations of the clinical study with only (b) (4) study sites, 30 subjects, and only (b) (4) nitial surgeons that may limit the ability to capture a full adverse event profile, the assessments from the provided clinical study will be further characterized with the addition of post-market registry and annual reporting to monitor continued safety and effectiveness.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> 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

The probable benefits outweigh the probable risks for the Hominis Surgical System. The device provides benefits and risks that can be mitigated using general controls and the identified special controls.

CONCLUSION

The De Novo request for the Hominis Surgical System is granted and the device is classified under the following

Product Code: QNM
Device Type: Mountable electromechanical surgical system for transluminal approaches
Class: II
Regulation: 21 CFR 878.4961

References

1. The American College for Obstetricians and Gynecologists. Committee Opinion. Choosing the Route of Hysterectomy for Benign Disease. Number 701, June 2017
2. Robotically Assisted vs Laparoscopic Hysterectomy Among Women with Benign Gynecologic Disease, Wright JD, Ananth CV, Lewin SN, Burke WM, Lu YS, Neugut AI, Herzog TJ, Hershman DL., JAMA, February 20, 2013—Vol 309, No. 7.
3. Kovac SR. Guidelines to determine the route the route of hysterectomy. Obstet. Gynecol. 85,18–23 (1995).
4. 16. Richardson RE, Bournas N, Magos A. Is laparoscopic hysterectomy a waste of time? Lancet 345,36–41 (1995).
5. Querleu D, Cosson M, Paramentier D, Debodinance P. The impact of laparoscopic surgery on vaginal hysterectomy. Gynecol. Endosc. 2,89–91 (1993).
6. Johns A. Supracervical versus total hysterectomy. Clin Obstet Gynecol. 1997 Dec. 40(4):903-13.
7. Dorsey JH, Steinberg EP, Holtz PM. Clinical indications for hysterectomy route: Patient characteristics or physician preference? Am. J. Obstet. Gynecol. 173,1452–1460 (1995).).
8. Magos A, Bournas N, Sinha R, Richardson RE, O'Connor H. Vaginal hysterectomy for the large uterus. BJOG 103,246–251 (1996)
9. Darai E, Soriano D, Kimata P et al. Vaginal hysterectomy for enlarged uteri, with of without laparoscopic assistance: randomized study. Obstet. Gynecol. 97,712–716 (2001).
10. Harris MB, Olive DL. Changing hysterectomy patterns after introduction of laparoscopically assisted vaginal hysterectomy. Am. J. Obstet. Gynecol. 171,340–344 (1992).
11. Johnson N, Barlow D, Lethaby A, Tavender E, Curr L, Garry R. Methods of hysterectomy: systematic review and meta-analysis of randomised controlled trials. BMJ 330,1478–1486 (2005).
12. Brown DA, Frazer MI. Hysterectomy revisited. Aust. NZ J. Obstet. Gynecol. 31,148 (1991).
13. Querleu D, Cosson M, Parmentier D et al. The impact of laparoscopic surgery on vaginal hysterectomy. Gynaecol. Endosc. 2,89–91 (1993).
14. Summit RL, Stovall TG, Lipscomb GH, Ling FW. Randomized comparison of laparoscopy-assisted vaginal hysterectomy with standard vaginal hysterectomy in an outpatient setting. Obstet. Gynecol. 80,895–901 (1992).
15. Soriano D, Goldstein A, Lecuru F, Darai E. Recovery from vaginal hysterectomy compared to laparoscopy-assisted vaginal hysterectomy: a prospective, randomized, multicenter study. Acta Obstet. Gynecol. Scand. 80,337–341 (2001).
16. Summitt RL Jr, Stovall TG, Steege JF, Lipscomb GH. A multicenter randomized comparison of laparoscopically assisted vaginal hysterectomy and abdominal hysterectomy in abdominal hysterectomy candidates. Obstet. Gynecol. 92,321–326 (1998).
17. Kovac SR. Hysterectomy outcomes in patients with similar indications. Obstet. Gynecol. 95,787–793 (2000).
18. Van den Eeden SK, Glasser M, Mathias SD, Colwell HH, Pasta DJ, Kunz K. Quality of life, health care utilization, and cost among women undergoing hysterectomy in a managed-care setting. Am. J. Obstet. Gynecol. 178,91–100 (1998)