yu

January 18, 2018

Medrobotics Corporation
Linda J. Varroso
Director, Regulatory Affairs
475 Paramount Drive
Raynham, MA 02767

Re: K172796
Trade/Device Name: Medrobotics Flex® Robotic System and Flex® Transabdominal Drive
Regulation Number: 21 CFR§ 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: II
Product Code: HET
Dated: December 21, 2017
Received: December 21, 2017

Dear Linda J. Varroso:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172796

Device Name
Medrobotics Flex® Robotic System and Flex® Transabdominal Drive

Indications for Use *(Describe)*
The Medrobotics Flex® Robotic System is intended to provide robot-assisted control of the Flex® Transabdominal Drive.

The Flex® Transabdominal Drive is intended to be used with ancillary equipment for endoscopy and endoscopic surgery. The Flex® Transabdominal Drive is indicated to provide robot-assisted visualization within the thoracic and abdominal cavities including female reproductive organs.

This instrument must not be used for observation or treatment of the heart and must not contact the heart or any area near the heart. This instrument must not come into contact with any device or therapeutic accessory that contacts the heart or any area near the heart.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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TRADITIONAL 510(K) SUMMARY

Medrobotics Flex® Robotic System and Flex® Transabdominal Drive (K172796)

This Summary of the Traditional 510(k) Substantial Equivalence Information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92. All data included in this document is accurate and complete to the best of Medrobotics' knowledge.

Submitter Name	Medrobotics Corporation
Submitter Address	475 Paramount Drive Raynham, MA 02767
Contact Person	Linda J. Varroso Director of Regulatory Affairs
Phone Number	508-692-6460
Fax Number	508-823-1703
Date Prepared	January 11, 2018
Device Trade Name	Medrobotics Flex® Robotic System and Flex® Transabdominal Drive
Device Common Name	Gynecologic Laparoscope and Accessories
Product Code	HET, Laparoscope, Gynecologic (And Accessories)
Classification	Class II pursuant to 21 C.F.R. § 884.1720, "Gynecologic laparoscope and accessories"
Predicate Devices	Olympus LTF-190-10-3D, Endoeye Flex 3D Deflectable Videoscope [K123365] A search of FDA's publicly available recall database shows that this product has not been the subject of a design related recall.
Reference Device	Flex® Robotic System (Colorectal) (K162330 and K172036). The proposed Flex® Transabdominal System is a modified version of the Flex® Colorectal System (K162330 and K172036). The minor changes between the two systems are intended to make the system suitable for the proposed transabdominal visualization indication for use.

Device Description

The Flex® Robotic System and Flex® Transabdominal Drive make up the Flex Robotic Transabdominal System. The system includes three (3) major components: Flex Console; Flex Cart/Base; and Flex Transabdominal Drive with camera. The Flex console is the primary user interface for controlling functionality of the Flex Transabdominal System. The Flex Cart/Base positions and manipulates the Flex Transabdominal Drive. The Flex Camera is a sterile, reusable component that is attached to the Flex Transabdominal Drive.

The Flex Transabdominal Drive is attached to the Flex Base and is introduced to the patient through a commercially available trocar. The physician provides input to manipulate the Flex Transabdominal Drive via the Physician Controller located on the Flex Console. The input from the Physician Controller generates the desired motion in the Flex Base resulting in driving and articulation of the endoscope inside the patient's anatomy. Manipulation of available camera controls allows the physician to achieve appropriate visualization of the target site.

The Flex® Robotic Transabdominal System is an operator-controlled flexible endoscope that provides the benefits of both a rigid endoscope and a computer-assisted controller. The Flex® Robotic Transabdominal System is a software-controlled device. The Flex® Robotic Transabdominal System allows for the endoscope to be introduced via an operator-controlled user interface easily providing visualization of structures in the thoracic and abdominal cavities, including female reproductive organs. Visualization is provided by a 3D camera attached at the distal end of the endoscope. The Flex® Robotic Transabdominal System is intended for professional use only in a hospital setting. The Flex® Robotic System is provided non-sterile and reusable. The Flex® Transabdominal Drive is provided sterile through EtO sterilization and is intended for single patient use. The patient-contacting components of the proposed system are all composed of biocompatible materials.

Indications for Use

The Medrobotics Flex® Robotic System is intended to provide robot-assisted control of the Flex® Transabdominal Drive.

The Flex® Transabdominal Drive is intended to be used with ancillary equipment for endoscopy and endoscopic surgery. The Flex® Transabdominal Drive is indicated to provide robot-assisted visualization within the thoracic and abdominal cavities including female reproductive organs.

This instrument must not be used for observation or treatment of the heart and must not contact the heart or any area near the heart. This instrument must not come into contact with any device or therapeutic accessory that contacts the heart or any area near the heart.

As shown in the comparison table below, the Flex® Transabdominal System and predicate system are both indicated for use in endoscopy and endoscopic surgery within the thoracic and abdominal cavities, including female reproductive organs. There are no substantive differences between the proposed and predicate indications for use.

	PROPOSED **Flex® Transabdominal System**	**PREDICATE DEVICE** **Olympus Medical Endoeye Flex 3D Deflectable Videoscope** **[K123365]**
Indications for Use	The Medrobotics Flex® Robotic System is intended to provide robot-assisted control of the Flex® Transabdominal Drive. The Flex® Transabdominal Drive is intended to be used with ancillary equipment for endoscopy and endoscopic surgery. The Flex® Transabdominal Drive is indicated to provide robot-assisted visualization within the thoracic and abdominal cavities, including female reproductive organs. This instrument must not be used for observation or treatment of the heart and must not contact the heart or any area near the heart. This instrument must not come into contact with any device or therapeutic accessory that contacts the heart or any area near the heart.	Indicated to be used with Olympus video system center, light source, documentation equipment, 3D processor, monitor, hand instruments, electrosurgical unit and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the thoracic and abdominal cavities including female reproductive organs. This instrument must not be used for observation or treatment of the heart and must not contact the heart or any area near the heart. This instrument must not come into contact with any device or therapeutic accessory that contacts the heart or any area near the heart.

Comparison of Technological Characteristics

The technological characteristics of the Flex Transabdominal System and the predicate device are compared in detail in the Table below. The minor differences in technological characteristics do not raise different questions of safety or effectiveness, as confirmed by the testing and validation activities described in the submission.

	PROPOSED **Flex® Transabdominal System**	**PREDICATE DEVICE** **Olympus Medical Endoeye Flex 3D Deflectable Videoscope [K123365]**
Operating Principles	Cable steered CMOS based video endoscope using electromechanical controls driven from a console based computer controlled physician handle	Cable steered 3D video endoscope using mechanical controls driven from the articulation levers in the scope handle
Energy Source	AC powered	AC powered
Software	Yes. Software-driven endoscope	Yes, but not for driving the endoscope
Hardware	Major hardware system components: - Flex Drive (endoscope) - Flex Console (including video monitor and joystick) - Flex Base - Flex Cart - Flex Camera (with light source)	Major hardware system components: - Deflectable 3D videoscope - 3D video processor/visualization unit - Evis Exera III Video System Center - Xenon light source
Operating Environment – Temperature	50° – 86° F (10° – 30° C)	50° – 104° F (10° – 40° C)
Operating Environment – Relative Humidity	15 – 75% relative humidity, non-condensing	30 – 85% relative humidity, non-condensing
Operating Environment – Air pressure	700 – 1060 hPA	700 – 1060 hPA
Anatomical Access	Scope gains access through a trocar	Scope gains access through a trocar

	PROPOSED **Flex® Transabdominal System**	**PREDICATE DEVICE** **Olympus Medical Endoeye Flex 3D Deflectable Videoscope [K123365]**
Scope Diameter	18 mm	10 mm
Scope Rigidity	Flexible / Semi-Rigid endoscope	Flexible tip endoscope
Scope Length	320 mm	370 mm
Advance / Retract	Electro-mechanically aided with physician controller on console. The system is locked in place and power is withdrawn from the motors prior to initiation of a surgical procedure.	Manual
Maximum Allowable Speed	Linear: 22 mm/s Articulation: 22 mm/s	Manual
Tip Articulation	0° – 110°	0° – 100°
Steering	Electromechanical joystick controls (the Physician Controller) on a console aid steering	Flexible tip is articulated by pushing/pulling steering cables using the articulation lever on the scope handle
Direct Visualization	Yes	Yes
Multi-Segmented Endoscope Structure	Yes	Yes
Semi-rigid follow the leader/guiding function	Yes	No
Electromechanically cable driven/controlled segments	Yes	No
3D flexible movements and tip orientation	Yes	No – rigid body only flexible at the distal end

	PROPOSED **Flex® Transabdominal System**	**PREDICATE DEVICE** **Olympus Medical Endoeye Flex 3D Deflectable Videoscope [K123365]**
Haptic feedback to user	Based on mechanical scope limits – Yes Based on patient anatomy – No	No
Fluid Lumen	No	No
Working Channel(s)	No	No
View Optics/Optical Sensor	Lens/Solid State Camera (CMOS)	Two CCDs
Optics – Pixels	1280 x 720	1080 x 601
Optics – CCD Type	Color	Color
Optics – Field of View	> 80°	80°
Optics – Direction of View	Forward / 0°	Forward / 0°
Optics – Depth of Field	25 – 60 mm	18 – 100 mm
Light Source	LED	EVIS EXERA III CLV-190 Xenon light source 300 watts—5000 lumens
Video Image Processing	Video Data Display	Imaging System 3D Visualization Unit 3D Visualization Unit (3DV-190)
Video Display	Standard color video display	Standard color video display

	PROPOSED **Flex® Transabdominal System**	**PREDICATE DEVICE** **Olympus Medical Endoeye Flex 3D Deflectable Videoscope** **[K123365]**
Sterilization	Flex Transabdominal Drive is provided Sterile – EtO (SAL 10^{-6}) for single patient use Flex Camera is provided non-sterile, reusable and requires cleaning and sterilization prior to use The Flex Base, Flex Cart, Stand, and Flex Console are provided non-sterile and require cleaning and disinfection prior to use	The predicate device is provided non-sterile and requires cleaning and sterilization prior to use
Electrical Safety & EMC	Complies with EMC standards for medical electrical equipment in IEC 60601-1-2	Complies with EMC standards for medical electrical equipment in IEC 60601-1-2

Summary of Non-Clinical Performance Testing

Bench Testing

The Flex® Robotic Transabdominal System has been tested in compliance with relevant sections of:

A. BS ISO 8600-1:2015, Endoscopes – Medical endoscopes and endotherapy devices, Part 1: General requirements
B. FDA Guidance – Hysteroscopes and Gynecologic Laparoscopes – Submission Guidance for a 510(k). Final: March 7, 1996

Testing in accordance with the Hysteroscopes and Gynecologic Laparoscopes guidance, included optical performance. Results from this testing are shown in the tables below.

Resolution / Working Distance

Device Name	**Proposed Flex Transabdominal System**	**Working Distance**
Image Quality Resolution	12.5 lp/mm @ 30mm 5.5 lp/mm @ 80mm	30 – 80 mm

Distortion

Device Name	Proposed Flex Transabdominal System
Distortion	<15%

Mechanical and System Verification Testing

Mechanical and system verification testing, and Flex Transabdominal Drive Functional Reliability were conducted under simulated use conditions.

Software

Medrobotics followed the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005), to classify the Flex® software as a "moderate level of concern." A justification was provided to support not providing new/additional testing beyond that which was provided to support clearance of the reference device.

Ship Testing

The Flex® Transabdominal System packaging complies with applicable ISTA standards regarding anticipated shipping conditions. A justification was provided to support not providing new/additional testing beyond that which was provided to support clearance of the reference device.

Electrical Safety – Electromagnetic Compatibility Testing

The Flex® Transabdominal System complies with the electrical safety and EMC standards IEC 60601-1, IEC 60601-1-2. A justification was provided to support not providing new/additional testing beyond that which was provided to support clearance of the reference device.

Biocompatibility

The Flex® Transabdominal Drive is the patient-contacting portion of the Flex® Transabdominal System. In accordance with *ANSI/AAMI/ISO/EN 10993-1:2009*, and the modified matrix in FDA Guidance Document "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'" (June 2016), the Flex® Transabdominal Drive is classified as "external communicating device," in contact with "tissue/bone/dentin" and "limited exposure" (≤ 24 hours). Information demonstrating the biocompatibility of the Flex® Transabdominal Drive has been provided. A justification was provided to support not providing new/additional testing beyond that which was provided to support clearance of the reference device.

Sterilization, Packaging, and Shelf Life for Single Use Flex® Transabdominal Drive

The Flex® Transabdominal Drive is supplied sterile and is a single use device. The Flex® Transabdominal Drive is sterilized via ethylene oxide (EtO). The EtO cycle has been validated to a sterility assurance level (SAL) of 10^{-6}, in accordance with the following standards:

- ISO 11135:2014, Sterilization of health care products – Ethylene Oxide
- AAMI TIR 28:2016, Product adoption and process equivalence for ethylene oxide sterilization
- ANSI/AAMI/ISO/EN 10993-7:2008, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

The Flex® Transabdominal Drive is stable over the labeled shelf life.

Cleaning and Sterilization of Reusable System Components

The Flex Transabdominal System includes a reusable component, the Flex® Camera, which is provided non-sterile. The Flex® Camera is intended to be cleaned and sterilized before each use. The recommended cleaning and sterilization instructions were adopted from the cleared reference device. The Flex® Camera is limited to 10 uses.

The Flex® Transabdominal System also consists of reusable capital equipment supplied non-sterile. The Flex Base, Flex Cart, Stand, and Flex Console, with the exception of the monitor, are intended to be cleaned and disinfected before each use. None of these components have direct patient contact during a surgical procedure. The Monitor is intended to be cleaned before each use. These pieces of equipment are intended to be covered prior to each use with sterile drapes. The recommended cleaning and disinfection instructions were adopted from the cleared reference device.

Conclusion Based on the performance testing, the Medrobotics Flex® Transabdominal System has been shown to be as safe and effective for its stated intended use as the predicate device to which substantial equivalence is claimed.