October 19, 2017

Medrobotics Corporation
John D. Bonasera
Vice President of Clinical, Regulatory and Quality Affairs
475 Paramount Drive
Raynham, MA 02767

Re: K170453
Trade/Device Name: Medrobotics Flex® Robotic System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOB, EOX, GCI
Dated: September 14, 2017
Received: September 15, 2017

Dear John D. Bonasera:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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)*
K170453

Device Name
Medrobotics Flex Robotic System

Indications for Use *(Describe)*
The Medrobotics Flex® System is a device that is intended for robot-assisted visualization and surgical site access to the oropharynx, hypopharynx, and larynx in adults (≥ 22 years of age). The Flex System also provides accessory channels for compatible flexible instruments used in surgery.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TRADITIONAL 510(K) SUMMARY

Flex® Robotic System

This Summary of the Traditional 510(k) Substantial Equivalence Information is being submitted in accordance with the requirements of 21 CFR 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	John D. Bonasera Vice President of Clinical, Regulatory, and Quality Affairs
Phone Number	508-692-6460
Fax Number	508-823-1703
Date Prepared	October 18, 2017
Device Trade Name	Flex® Robotic System
Device Common Name	Nasopharyngoscope (flexible or rigid)
Product Code	EOB
Classification	The Medrobotics Flex System has been classified as Class II according to 21 C.F.R. §874.4760
Predicate Devices	The Medrobotics Flex® System, K150776.
Device Description	The Flex® Robotic System is an operator-controlled flexible scope that provides the benefits of both a rigid endoscope and a computer assisted controller. The Flex® Robotic System allows for the scope to be introduced via an operator-controlled user interface easily providing visualization and access of structures within the oropharynx and hypopharynx and larynx. Visualization is provided by a HD 2D/3D digital camera attached at the distal end of the scope. The Flex Robotic System's scope also provides two accessory channels for use of varied flexible instruments.
Intended Use	The Medrobotics Flex® System is a device that is intended for robot-assisted visualization and surgical site access to the

	oropharynx, hypopharynx, and larynx in adults (≥ 22 years of age). The Flex System also provides accessory channels for compatible flexible instruments used in surgery.
Substantial Equivalence	The Medrobotics Flex® Robotic System is substantially equivalent to the predicate device the Medrobotics® Flex System.
Summary of Performance Testing	The Flex® Robotic System has been subjected to and successfully tested for function, performance, and safety as per FDA-recognized standards IEC 60601-1 and IEC 60601-1-2, and biocompatibility and toxicity of the patient contacting materials per ISO-10993-1. It has been tested and met acceptance criteria per FDA-recognized standards for the establishment of shelf life, shipping, and validated for sterility by ETO and moist heat to a SAL of 10^{-6}. Processes by which the user may clean and sterilize certain reusable components have been validated in accordance with FDA-recognized standards. Summaries of this testing are provided below.

Bench Testing

The following verification and/or validation testing was performed to confirm that the Flex Robotic System, as a whole, and its components met their performance specifications:

- Reliability Testing
- Vision and Video Subsystem and System Testing
- Subsystem and System Software Verification and Validation Testing
- Reusable Camera Testing
- Ship Testing
- Mechanical Requirements Testing
- Safety Subsystem Testing
- System Electrical and Board Requirements Testing

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 Robotic System software as a "moderate level of concern." The software was verified and validated, and the software verification and validation documents were prepared and presented in accordance with FDA's guidance document.

Ship Testing

Testing was performed per applicable ISTA standards to demonstrate that all modified components of the Flex Robotic System could withstand anticipated shipping conditions.

Usability/Human Factors Testing

Medrobotics performed usability and human factors testing of the Flex Robotic System. Such testing was performed in accordance with FDA Guidance Document "Applying Human Factors and Usability Engineering to Medical Devices" (February 3, 2016). In addition, Wiklund's Usability Testing of Medical Devices was used as a reference.

This testing assessed the performance of the Flex® Robotic System when used by representative end users (i.e., surgeons and nurses/technicians) in accordance with the instructions for use after having been trained on how to use the system. The testing demonstrated that the Flex® Robotic System design meets the intended user requirements and facilitates safe and effective user interactions.

Electrical Safety

The Flex® Robotic System has been tested to demonstrate electrical safety and compliance with:

- IEC 60601-1 Ed: 3.1, Medical Electrical Equipment, Part 1: General Req. for Safety
- ANSI/AAMI ES60601-1:2005/(R)2012, Issued: 2012/01/17, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance with C1:2009/(R)2012 and A2:2010/(R)2012
- IEC 60601-1-6: 2010, Edition 3.0, Version: 2010/01/27, Medical electrical equipment – Part 1- 6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62366: 2007, Edition 1.0, Issued: 2007/10/18, Ed. 1, Medical Devices – Application Of Usability Engineering To Medical Devices
- IEC 60601-1-4: 2000, Edition 1.1, Issued 2000/04/01, Medical electrical systems – Part 1- 4: General requirements for safety – Collateral standard: Programmable electrical medical systems

Electromagnetic Compatibility Testing

The Flex® Robotic System was tested and determined to be in compliance with:

- EN 60601-1-2:2007/AC:2010, Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class A for non-life supporting equipment

- IEC 60601-1-2, Ed. 3.0, Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class A for non-life supporting equipment

Biocompatibility

The Flex® Drive and Flex Camera contains the patient contacting portions of the Flex® Robotic 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 Drive and Flex Camera is classified as "external communicating device," in contact with "tissue/bone/dentin" and "limited exposure" (≤24 hours). Biocompatibility testing was performed in accordance with the standard and guidance or a rationale for not testing was provided for all patient contacting components.

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

The Flex® Drive is supplied sterile and is a single use device. The Flex® 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:

- ANSI/AAMI/ISO 11135-1:2007, Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO TIR 11135-2:2008, Sterilization of health care products – Ethylene Oxide – Part 2: Guidance on the application of ANSI/AAMI/ISO 11135-1
- AAMI TIR 28:2009, 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

Functional testing has been performed to demonstrate the Flex Drive is stable over the labeled shelf life.

Cleaning and Sterilization of Reusable System Components

The Flex Robotic System includes reusable components, the Flex® Camera and Flex® Instrument Support which are provided non-sterile. These components are intended to be cleaned and sterilized before each use. The recommended cleaning and sterilization instructions were validated in accordance with the following standards:

- AAMI TIR12:2010, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI TIR30:2011, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

- EN ISO 17664:2004, Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ANSI/AAMI ST81:2004/(R)2010, Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO TS 15883-5:2005, Washers-disinfectors – Part 5: Test soils and methods for demonstrating cleaning efficacy
- ANSI/AAMI ST77:2013, Containment devices for reusable medical device sterilization
- ANSI/AAMI ST79:2010, A1:2010, A2:2011, A3:2012, A4: 2013, (R)2014 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ANSI/AAMI/ISO 14937:2009, Sterilization of health care products – General requirements for characterization of sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 17665-1:2006, Sterilization of health care products – Moist heat – Requirements for the development, validation and routine control of sterilization process for medical devices
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Document issued on March 17, 2015, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Device Evaluations
- ISO 17665-2:2009, Sterilization of health care products – Moist heat – Part 2: Guidance of the application of ISO 17665-1

Conclusion	Based on the indications for use, performance testing, pre-clinical study data and technological characteristics, the Medrobotics modified Flex® Robotic System been shown to be as safe and effective for its stated intended use as the predicate device, Medrobotics Flex System, to which substantial equivalence is claimed.

Technological Characteristics

Device Name	PROPOSED Flex Robotic System [K170453]	PREDICATE Flex System [K150776]	Similarities and Differences
Operational Principles	Cable steered CMOS based video endoscope using electromechanical controls to traverse three-dimensional space without external support due to its articulated segment technology and the ability to alternate from a flexible to rigid state. The system is driven from a console based computer controlled physician handle.	Cable steered CMOS based video endoscope using electromechanical controls to traverse three-dimensional space without external support due to its articulated segment technology and the ability to alternate from a flexible to rigid state. The system is driven from a console based computer controlled physician handle.	**Same**. The Flex Robotic System and the predicate are both cable steered endoscopes which traverse three-dimensional space without external support due to its articulated segment technology and the ability to alternate from a flexible to rigid state. Both the Flex Robotic System and the predicate use electromechanical controls to aid steering. Both are driven from a console based computer controlled physician handle.
Anatomical Access	Trans-oral access is gained through use of a retractor	Trans-oral access is gained through use of a retractor	**Same**. The Flex Robotic System and the predicate Flex System require use of a retractor to gain entry to the anatomy.
Access for Compatible Instruments	Compatible flexible instruments through accessory channels on the Flex Drive	Compatible flexible instruments through accessory channels on the Flex Drive	**Same**. The proposed and predicate systems both allow for use of compatible flexible instruments through the scope instrument channels.
Scope Rigidity	Flexible / Semi-Rigid endoscope	Flexible / Semi-Rigid endoscope	**Same**. The proposed and predicate devices are both flexible / semi-rigid endoscopes.
Advance/retract	Electromechanically aided with physician controller on console	Electromechanically aided with physician controller on console	**Same**. The Flex Robotic System and the predicate Flex System are advanced and retracted with the assistance of electromechanical controls driven by the physician controller on the console.

Device Name	PROPOSED Flex Robotic System [K170453]	PREDICATE Flex System [K150776]	Similarities and Differences
Steering	Electromechanical joystick controls (the Physician Controller) on a console aid steering	Electromechanical joystick controls (the Physician Controller) on a console aid steering	**Same**. The Flex Robotic System and predicate Flex System utilize the identical physician controller.
Direct Visualization	Yes, during entire procedure in 2D. 3D visualization is an option that can be enabled by the user.	Yes, during entire procedure in 2D	**Similar**. The Flex Robotic System and the predicate allow the physician to maintain direct visualization of the anatomy of interest during the entire procedure in 2D. The option of selecting 3D demonstrated in user testing is a minor difference that does not raise new or different questions of safety or effectiveness
Multi-Segmented Endoscope Structure	Yes	Yes	**Same**. The Flex Robotic System and the predicate are both multi-segmented structures.
Semi-rigid follow the leader / guiding function	Yes	Yes	**Same**
Electromechanically cable driven / controlled segments	Yes	Yes	**Same**
3D flexible movements and tip orientation	Yes	Yes	**Same**

Device Name	PROPOSED Flex Robotic System [K170453]	PREDICATE Flex System [K150776]	Similarities and Differences
Haptic feedback to user	Yes	Yes	**Same.** The Flex Robotic System and the Flex System both provide haptic feedback to the user when the scope reaches the limits of the pre-defined (by the system specifications) workspace.
Fluid Lumen	Yes	Yes	**Same**
Working Channel(s)	Yes 4.7 mm in diameter	Yes 4.7 mm in diameter	**Same**
View optics / Optical Sensor	Two Glass Lens Two Solid State CMOS sensors with 1920x1080 resolution	One Glass Lens One Solid State CMOS sensor with 1280x720 resolution	**Similar**. The proposed camera incorporates two Solid State CMOS sensors with higher resolution and two glass lens assemblies that provide a minimum resolvable feature size to 40um. The predicate camera incorporates one Solid State CMOS sensor and one glass lens assembly that provide a minimum resolvable feature size to 70um. The camera performance and reliability testing that was executed, demonstrates that this minor difference does not raise new or different questions of safety or effectiveness

Device Name	PROPOSED Flex Robotic System [K170453]	PREDICATE Flex System [K150776]	Similarities and Differences
Light Source	4 LEDs, 2 located above the lens assemblies and 2 located below the lens assemblies	6 LEDs, All LEDs are located above the lens assembly	**Similar**. The proposed Flex Robotic System has updated the quantity and location of the LEDs in the camera to provide a more consistent illumination. The LEDs and light output are identical between the two systems. The illumination performance testing that was executed demonstrates that this minor difference does not raise new or different questions of safety or effectiveness

Device Name	PROPOSED Flex Robotic System [K170453]	PREDICATE Flex System [K150776]	Similarities and Differences
Real Time Video	2D Video Data Display User selectable 3D visualization	2D Video Data Display	**Similar.** The proposed system includes an option for the user to select either a 2D and/or a 3D visualization mode. The user testing demonstrates that the option of selecting 3D is a minor difference that does not raise new or different questions of safety or effectiveness

Device Name	PROPOSED Flex Robotic System [K170453]	PREDICATE Flex System [K150776]	Similarities and Differences
Camera Housing	Stainless Steel construction with transparent windows. Windows are placed in front of the LEDs to allow light to pass through the camera housing. A window is also placed in front of the lens assemblies to ensure that the camera can remain sealed during the sterilization process.	Ultem construction with a transparent window. The window is located in front of the LEDs to allow light to pass through the camera housing. The lens does not sit behind a transparent window, instead, it protrudes through the distal end of the housing.	**Similar.** Same: • Both housings contain electronics and sensor to enable a distally mounted camera • Both housings are sealed to prevent ingress of fluid Differences: • Proposed camera has transparent windows located in front of the lens assemblies while the predicate Flex Camera lens assembly protrudes from the distal side of the Flex Camera. This ensures that the camera housing can remain sealed for sterilization purposes and this design also isolates the imaging window from the illumination windows so no stray light from the illumination LEDs pass into the video, reducing contrast of the video. The camera performance, reliability, sterilization and biocompatibility testing demonstrate that this minor difference does not raise new or different questions of safety or effectiveness

Device Name	PROPOSED Flex Robotic System [K170453]	PREDICATE Flex System [K150776]	Similarities and Differences
Vision Electronics	2 printed circuit board assemblies to enable the passing of video data	2 printed circuit board assemblies to enable the passing of video data	**Similar.** Same: • Both proposed and predicate systems have 2 printed circuit boards responsible for processing, transmitting, and displaying live video • Both proposed and predicate systems have been designed and tested to conform to IEC60601-1 Edition 3.1 (2012) Differences: • Proposed system uses a ruggedized external connector to connect the camera cable to the Flex Base while the existing system used an integrated board level connector • Proposed system uses cable harnesses instead of mating connectors in the Flex Base. This design enables the transmission of high speed signals while maintaining signal integrity. • Proposed system uses a different data protocol to transmit the video data from the camera to the first video board. This is a design requirement of the updated imaging sensors described above. The vision performance testing that was executed demonstrates that these minor differences do not raise new or different questions of safety or effectiveness

Device Name	PROPOSED Flex Robotic System [K170453]	PREDICATE Flex System [K150776]	Similarities and Differences
Graphical User Interface	Touchscreen based interface located on the Flex Console Monitor	Touchscreen based interface located on the Flex Console Monitor	**Similar.** Same: • Both systems provide 2D visualization on the Flex Console Monitor • Both systems provide a touchscreen interface to control system settings and preferences • Both systems display information and error messages in identical ways • Both systems have the same controls for driving modes, robot control and robot feedback Differences: • Proposed system has the ability to switch between 2D and 3D visualization on the external displays • Proposed system has the ability to choose which lens to view when in 2D mode • Proposed system has the ability to display a 3D calibration image on an external display to ensure proper placement of the external monitor The user testing that was executed demonstrates that the option of selecting 3D and the ability to select the active lens to visualize when in 2D mode is a minor difference that does not raise new or different questions of safety or effectiveness

Device Name	PROPOSED Flex Robotic System [K170453]	PREDICATE Flex System [K150776]	Similarities and Differences
Biocompatibility	Proposed Flex Camera is made of the following materials: • Stainless steel housing • glass windows on distal tip • silicon strain relief • PEBAX cable Patient contacting materials have been shown to be biocompatible after testing to ISO 10993	Predicate Flex Camera is made of the following materials: • Ultem • glass windows on distal tip • silicon strain relief • PEBAX cable Patient contacting materials have been shown to be biocompatible after testing to ISO 10993	**Similar.** Similarities: • Both systems have identical materials in the strain reliefs, and cable components • Both systems have been analyzed for biocompatibility with respect to 10993-1 for in vitro cytotoxicity, irritation and skin sensitization, and systemic toxicity Differences • The plastic camera housing was replaced with a stainless-steel housing • The glass used in the lens window is different grade of glass, but it is biocompatible. The biocompatibility testing demonstrates that these minor material differences do not raise new or different questions of safety or effectiveness

Device Name	PROPOSED Flex Robotic System [K170453]	PREDICATE Flex System [K150776]	Similarities and Differences
Sterilization	Flex Drive is provided Sterile Sterilization method for the Flex Camera is moist heat sterilization	Flex Drive is provided Sterile Sterilization method for the Flex Camera is moist Ethylene Oxide	**Similar:** Both the proposed and predicate Flex Drives are provided sterile. The camera in the predicate device is sterilized by ETO. The camera for the proposed device is sterilized by moist heat. The S.A.L of both methods is validated to be 10^{-6}. The sterilization validation testing that was completed demonstrates that these minor material differences do not raise new or different questions of safety or effectiveness
Electrical Safety & EMC	Passed the applicable electromagnetic compliance (EMC) and electrical safety requirements of IEC 60601-1-2 and IEC 60601-1	Passed the applicable electromagnetic compliance (EMC) and electrical safety requirements of IEC 60601-1-2 and IEC 60601-1	**Same**