DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 16, 2015

Medrobotics Corporation
Mr. John D. Bonasera
Director of Regulatory Affairs
475 Paramount Drive
Raynham, MA 02767

Re: K150776
Trade/Device Name: Medrobotics Flex 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: June 16, 2015
Received: June 18, 2015

Dear Mr. 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 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 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

Malvina 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150776

Device Name
Medrobotics Flex® 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."

510(k) Summary
Medrobotics Flex System (K150776)

Date prepared: July 16, 2015

Applicant's Name and Address

Applicant	Medrobotics Corporation
Address	475 Paramount Drive Raynham, MA 02767
Telephone Number	508-692-6460 x 254
Fax Number	508-832-1703
Contact Person:	John D. Bonasera
Title	Director of Regulatory Affairs

Name of the Device

Trade Name:	Flex® System
Common Name:	Nasopharyngoscope (flexible or rigid)
Classification Name	Nasopharyngoscope (flexible or rigid) and accessories
Device Classification:	II
Primary Product Code:	EOB
Subsequent Product Codes:	EOX and GCI
FDA Regulation	21 C.F.R. § 874.4760

Predicate Device

The legally marketed predicate device to which substantial equivalence is claimed:

1. The Vision-Sciences Flexible Endoscope with digital video processor and Disposable EndoSheath® System, K072073, K102733 ("Vision-Sciences System"), and

2. The NeoGuide Navigator Endoscopy System, K052930, K070622 ("NeoGuide System").

Reference Device

The Flex System was also compared to the Hansen Medical Vascular Catheter Control System, K111004, because both devices employ a physician controller located at the physician console/workstation to drive and articulate the scope/catheter.

Device Description

The Flex System is an operator-controlled flexible endoscope that provides the benefits of both a rigid endoscope and a computer assisted controller. The Flex System allows for the

endoscope to be introduced via an operator-controlled user interface, providing visualization and surgical site access to structures within the oropharynx, hypopharynx, and larynx. Like some other video endoscopes, visualization is provided by a digital camera incorporated in the distal end of the endoscope. The Flex System's endoscope 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

Medrobotics believes that the subject device is substantially equivalent to the Vision Sciences System and the NeoGuide System. As shown in the comparison table (Table 3) at the end of this section, the Flex System has very similar functionality and the same intended use as the predicate devices.

Summary of Performance Testing

The subject device has been successfully tested for function and performance in bench, usability/human factors, animal, and clinical studies. In addition, the Flex System has been evaluated for electrical safety and electromagnetic compatibility, and biocompatibility and toxicity testing of the patient-contacting materials. The components of the Flex System have been tested and met acceptance criteria per FDA recognized standards for the establishment of labeled shelf life, shipping, sterilization, cleaning, and disinfection, as applicable.

Bench Testing

The following testing was performed to verify that the Flex System, as a whole, and the components met their performance specifications:

- Flex System Components, Mechanical Engineering Verification
- Flex System Components, Mechanical Engineering Verification– Disposable Reliability
- Flex System Components, Mechanical Engineering Verification– Base Reliability
- Flex System Components, Mechanical Engineering Verification– Base Cleaning Survivability
- Flex System Hi-Res Camera Verification
- Flex Cart Verification
- Flex System Electrical Design Requirements Electrical Design Verification
- Flex Console Safety PCA Verification

- Electrical Design Verification
- Overall Flex System Functionality (Simulated Use Re-Verification)
- Surgical Instrument Compatibility Verification

Transportation Testing

Testing was performed to demonstrate that all components of the Flex System could withstand anticipated shipping conditions.

Usability/Human Factors Testing

Medrobotics performed usability and human factors testing of the Flex System. Such testing was performed in accordance with FDA Draft Guidance Document "Applying Human Factors and Usability Engineering to Optimize Medical Device Design" (June 22, 2011). In addition, Wiklund's Usability Testing of Medical Devices was used as a reference.

This testing assessed the performance of the Flex System when used by representative end users (i.e., head and neck surgeons and nurses/surgical technicians) in accordance with the IFU after having been trained on how to use the system. The testing demonstrated that the Flex System design meets the intended user requirements and facilitates safe and effective user interactions with little chance of committing dangerous user errors.

Animal Testing

Medrobotics performed two animal studies to evaluate the safety of the Flex System. Both studies evaluated abrasion and blunt force trauma caused by the Flex Scope (the patient contacting portion of the Flex System) compared to intubation control. The studies were conducted in accordance with Good Laboratory Practice (GLP). Both studies concluded that the Flex Scope does not cause an increased level of abrasion and/or blunt force trauma during visualization and access of the oropharynx and hypopharynx/laryngopharynx when compared to intubation control.

Electrical Safety

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

- UL 60601-1 (1) Issued: 2003/04/25 Ed: 1 Rev: 2006/04/26 Medical Electrical Equipment, Part 1:General Req. for Safety
- CSA C22.2#601.1 Issued: 1990/01/01 (R2005) Medical Electrical Equipment - Part 1: General Requirements for Safety General Instruction No. 1: 1990, Supplement 1: 1994, Amendment 2:1998; General Instruction No. 2: 2003
- ANSI/AAMI ES60601-1:2005/(R)2012 Issued: 2012/01/17 Medical electrical equipment – Part1: General requirements for basic safety and essential performance with C1:2009/(R)2012 and A2:2010/(R)2012

- CAN/CSA-C22.2 No. 60601-1: 08(R2013) Issued: 2011/06/01 Medical Electrical Equipment -Part 1: General Req. for Basic Safety & Essential Perf.; Cor. 2: 2011
- 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 60601-1-6: 2004, First Edition Issued: 2004/06/24 Medical electrical systems – Part 1- 6:General requirements for safety – Collateral standard: Usability
- 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 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 Scope contains the patient contacting portions of the Flex System. In accordance with *ANSI/AAMI/ISO 10993-1:2009*, and *FDA 510(k) Memorandum - #G95-1 Table 1 Initial Evaluation Tests for Consideration*, the Flex Scope is classified as "external communicating device", in contact with "tissue/bone/dentin" and "limited exposure" (≤24 hours). Table 1, below, provides a summary of the biocompatibility and toxicity testing performed on the Flex System.

Table 1. Summary of Biocompatibility and Toxicity Testing

Test	Outcome of Evaluation
Cytotoxicity Study	Pass
ISO Systemic Toxicity Study in Mice	Pass
ISO Systemic Toxicity Study in Mice	Pass
ISO -Intracutaneous Study	Pass
ISO -Intracutaneous Study	Pass
ISO - Maximization Sensitization Study	Pass
ISO - Maximization Sensitization Study	Pass
ISO - Oral Mucosal Irritation Test	Pass

Sterilization, Packaging and Shelf Life for Single Use Flex Scope

The Flex Scope is supplied sterile and is a single use device. The Flex Scope 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

The Flex Scope sterile packaging was validated in accordance with the following standards as part of a study demonstrating that the packaging system is stable over its labeled shelf life:

- ISO 11607-1:2006 (R) 2010, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ASTM F1886M-09, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1929-12, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F190-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Cleaning and Sterilization of Reusable System Components

The Flex System consists of reusable capital equipment supplied non-sterile, with the exception of the Flex Scope, as discussed above.

The Flex Instrument Support is provided non-sterile. The Flex Instrument Support is intended to be cleaned and sterilized before each use. The Flex Instrument Support cleaning instructions were validated in accordance with the following standards:

- ANSI/AAMI ST79:2010, Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- 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

The Flex Instrument Support sterilization process was validated in accordance with the following standards:

- ANSI/AAMI/ISO 17665-1:2006, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices
- ANSI/AAMI ST79:2010, Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI TIR12:2010, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

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 cleaning instructions for the Flex Base, Flex Cart, Stand, Flex Console, and Monitor 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

The disinfection instructions for the Flex Base, Flex Cart, Stand and Flex Console (excluding the Monitor) 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

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 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.

Clinical Study

A European post-market clinical follow up study with 45 subjects was performed using the Flex System. The study protocol required that clinical study subjects undergo two separate procedures. The first was a five-point visualization and access procedure, in which the

investigator visualized and accessed (1) the palatine tonsil area; (2) the base of tongue area; (3) the epiglottis; (4) the posterior pharyngeal wall; and (5) the false vocal cords. The second was a surgical procedure to treat the patient's previously diagnosed condition with surgical site access and visualization being provided by the Flex System. Forty five (45) subjects were treated in a total of 46 surgical procedures.

Five-Point Visualization & Access Procedure

As shown in Table 2, below, the Flex System was effective (>90%) in providing visualization and access in the oropharynx, hypopharynx and larynx during the Five-Point Visualization & Access Procedure.

Table 2. Five Points Visualization and Access

Anatomical Location	**Visualization Achieved (N=45)**	**Access Gained (N=45)**
Palatine tonsil area	45 (100%)	44 (98%)
Base of tongue area	45 (100%)	44 (98%)
Epiglottis	45 (100%)	44 (98%)
Posterior pharyngeal wall	45 (100%)	44 (98%)
False vocal cords[1, 2]	42 (93%)	41 (91%)

[1] The study investigators reported total inability to visualize and access the false vocal cords in 3 and 4 out of 45 subjects, respectively.

[2] The study investigators reported difficulty in visualization and/or access in 7 out of 42 visualization-achieved/41 access-gained patients.

Surgical Procedures

A variety of surgical procedures were successfully completed (89%) in the oropharynx, hypopharynx and larynx with surgical site access and visualization provided by the Flex System. A wide variety of anatomical locations in the oropharynx, hypopharynx and larynx were visualized and accessed during the surgical procedures. The safety and effectiveness of the Flex System for providing visualization and access to the true vocal cords was not assessed in the study.

Conclusion

Based on the indications for use, technological characteristics, and performance testing, Medrobotics has demonstrated that the Flex System is as safe and effective as the predicate

devices for the stated intended use, and the Flex System is, as a result, substantially equivalent to the predicate devices.

Table 3. Proposed and Predicate Device Comparison

	Flex System [K150776]	**Vision-Sciences System [K072073]**	**Vision-Sciences System [K102733]**	**NeoGuide System [K052930, K070622]**
Intended Use	For endoscopic access and visualization of patient anatomy through a natural orifice.	For endoscopic access and visualization of patient anatomy through a natural orifice.		For endoscopic access and visualization of patient anatomy through a natural orifice.
Indications for 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.	The flexible ENT videoscope with the EndoSheath System is intended for use in flexible endoscopic examination of the upper airway, vocal cords, and/or nasal passages. The digital video processor is intended for use with the VSI flexible video scope.	The flexible ENT-500 Video ENT Scope with EndoSheath Technology is intended for use in flexible endoscopic examination of the upper airway, vocal cords and/or nasal passages; and for use in diagnostic arthroscopic and endoscopic procedures to provide illumination and visualization of the interior cavity of the body through either a natural or surgical opening.	The NeoGuide Navigator Endoscopy System is intended to provide visualization and diagnostic/therapeutic access to the adult lower gastrointestinal tract (including, but not limited to, the anus, rectum, sigmoid colon, colon, cecum, and ileocecal valve) for endoscopy and endoscopic surgery.

	Flex System [K150776]	**Vision-Sciences System [K072073]**	**Vision-Sciences System [K102733]**	**NeoGuide System [K052930, K070622]**
Operational Principles	Cable-steered CMOS-based video endoscope using electromechanical controls driven from a console-based, computer-controlled physician handle.	A cable-steered flexible video laryngoscope with CCD-based imaging allowing for high resolution picture quality.		Cable-steered endoscope using electromechanical controls on the handle distal tip CCD camera and tool channels for instrument-based therapeutic procedures, valves for air insufflation, water irrigation, and suction.
Rigidity	Flexible/semi-rigid endoscope.	Continuously flexible endoscope.		Flexible/semi-rigid endoscope.
Advance/Retract	Electromechanically aided with physician controller on console.	Manual.		Manual.
Steering	Electromechanical joystick controls (the Physician Controller) on a console aid steering.	Manual control.		Electromechanical joystick controls on the handle of the scope aid steering.
Direct Visualization	Yes, during the entire procedure.	Yes, during the entire procedure.		Yes, during the entire procedure.

	Flex System [K150776]	**Vision-Sciences System [K072073]**	**Vision-Sciences System [K102733]**	**NeoGuide System [K052930, K070622]**
Multi-Segmented Endoscope Structure	Yes.	One continuously extruded flexible structure.		Yes.
Semi-Rigid Follow the Leader/Guiding Function	Yes.	No, manual.		Yes.
Electromechanically Cable-Driven/Controlled Segments	Yes.	No, manual.		Yes.
3D Flexible Movements and Tip Orientation	Yes.	Yes.		Yes.
Haptic Feedback to User	Yes.	No.		No.
Fluid Lumen	Yes.	Yes.		Yes.
Working Channel(s)	Yes, 4.7 mm in diameter.	Yes.		Yes, 3.2 mm in diameter.

	Flex System [K150776]	**Vision-Sciences System [K072073]**	**Vision-Sciences System [K102733]**	**NeoGuide System [K052930, K070622]**
View Optics/Optical Sensor	Lens/solid state camera (CMOS).	Lens/solid state camera (CCD).		Lens/solid state camera (CCD).
Light Source	LED.	LED.		LED.
Video Image Processing	Video data display,	Video data display,		Video data display,
Biocompatibility	Patient contacting materials have been shown to be biocompatible after testing to ISO 10993.	Patient contacting materials have been shown to be biocompatible after testing to ISO 10993.		Patient contacting materials have been shown to be biocompatible after testing to ISO 10993.
Sterilization	The Flex Scope is provided sterile. The reusable components of the Flex System are provided clean/non-sterile.	Sheath for scope provided sterile.		Provided clean/non-sterile.
Electrical Safety and EMC	Passed the applicable electrical safety requirements of IEC 60601-1-2 and IEC 60601-1.	Passed.		Passed.