DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 3, 2017

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

Re: K172036
Trade/Device Name: Medrobotics Flex Robotic System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: July 5, 2017
Received: July 5, 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 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172036

Device Name
Medrobotics Flex Robotic System

Indications for Use *(Describe)*
The Medrobotics Flex Robotic System is intended to provide robot-assisted control of the Flex Colorectal Drive during visualization of and surgical site access to the anus, rectum and distal colon. The Flex Robotic System is intended for use in adults (≥22 years of age).

The Flex Colorectal Drive is intended for robot-assisted visualization of and surgical site access to the anus, rectum, and distal colon in adults (≥22 years of age). The Flex Colorectal Drive 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.

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510(k) Summary
Medrobotics Flex Robotic System

Submitter's Name:	**Medrobotics Corporation**
Submitter's Address:	**475 Paramount Drive Raynham, MA 02767**
Contact Person:	**John D. Bonasera**
Phone Number:	**508-692-6460**
Fax Number:	**508-823-1703**
Date Prepared:	**July 5, 2017**
Device Trade Name:	**Medrobotics Flex® Robotic System**
Device Common Name:	**Endoscope/Endoscope and Accessories**
Product Code:	**FDF**
Classification:	**The Medrobotics Flex Robotic System is classified as Class II per 21 CFR § 876.1500**
Predicate Device:	**Medrobotics Flex Robotic System (K162330)**
Device Description:	**The Medrobotics Flex Robotic System is an operator controlled flexible scope that include the benefits of both a rigid scope and a computer assisted controller. This allows for the Flex Colorectal Drive to be introduced via an operator controlled user interface, easily providing transanal access to the anus, rectum and distal colon. Visualization is provided by a user selectable 2D or 3D HD camera incorporated in distal end of the scope. The Flex Robotic System's scope also provides accessory channels for the use of varied flexible surgical instruments.**
Intended Use:	**The Medrobotics Flex Robotic System is intended to provide robot-assisted control of the Flex Colorectal Drive during visualization of and surgical site access to the anus, rectum and distal colon. The Flex Robotic System is intended for use in adults (≥22 years of age). The Flex Colorectal Drive is intended for robot-assisted visualization of and surgical site access to the anus, rectum, and distal colon in adults (≥22 years of age). The Flex Colorectal Drive also provides accessory channels for compatible flexible instruments used in surgery.**
Performance Data:	**The Flex Robotic system has been successfully tested for function, performance, and safety as per FDA recognized Standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18, and Biocompatibility and Toxicity testing of the patient contacting materials to ISO 10993-1. It has been tested and met acceptance criteria per FDA recognized standards for the establishment of labeled shelf life and shipping, and validated for sterility by ETO and Steam to a SAL of 10^{-6}.**
Substantial Equivalence:	**The Medrobotics Flex Robotic System is substantially equivalent to and has the intended use as the predicate device.**