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

May 4, 2017

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

Re: K162330
Trade/Device Name: Flex Robotic System and Flex Colorectal Drive
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: April 7, 2017
Received: April 7, 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 yours,

Benjamin R. Fisher -S

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)*
K162330

Device Name
Flex Robotic System and Flex Colorectal Drive

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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TRADITIONAL 510(K) SUMMARY

Flex® Robotic System and Flex® Colorectal Drive

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.

510(k) Number	K162330
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	April 6, 2017
Device Trade Name	Flex® Robotic System and Flex® Colorectal Drive
Device Common Name	Flexible Colonoscope and Accessories
Device Classification Name	Endoscope and accessories
Product Code	FDF
Classification	Class II
Predicate Device	The NeoGuide Navigator Endoscopy System, K070622
Reference Device	The Flex® Robotic System and Flex® Colorectal Drive were also compared to the Medrobotics Flex® System, K150776 and the Storz TEO System, K945209. The proposed system is a modified version of the cleared Flex System, K150776. The proposed system includes the Flex® Rectoscope, which, like the Storz reference device facilitates access to the colorectal anatomy and allows sealing of the anatomy for insufflation.
Device Description	The Flex® Robotic System and Flex® Colorectal Drive make up the Flex Robotic Colorectal System. The Flex Robotic Colorectal

	System is an operator-controlled flexible endoscope that provides the benefits of both a rigid endoscope and a computer assisted controller. The Flex Robotic Colorectal System is a software-controlled device. The Flex® Robotic Colorectal System allows for the endoscope to be introduced via an operator-controlled user interface easily providing visualization and access of structures in the anus, rectum, and distal colon. Visualization is provided by a digital camera attached at the distal end of the endoscope. The Flex Robotic Colorectal System's endoscope also provides two accessory channels for use of varied flexible instruments. The Flex Robotic Colorectal System is intended for professional use only in a hospital setting. The Flex Robotic System is provided non-sterile and reusable. The Flex Robotic Colorectal 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.
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.
Substantial Equivalence	The Flex® Robotic System and Flex® Colorectal Drive are substantially equivalent to the NeoGuide Navigator Endoscopy System (NeoGuide System). As shown in the comparison table at the end of this section, the Flex® Robotic System and Flex® Colorectal Drive have very similar functionality and intended use as the predicate device.
Summary of Performance Testing	The Flex® Robotic System and Flex® Colorectal Drive have 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 Colorectal 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 Colorectal 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 Colorectal System could withstand anticipated shipping conditions.

Usability/Human Factors Testing

Medrobotics performed usability and human factors testing of the Flex Colorectal 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 and Flex® Colorectal Drive 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 and Flex® Colorectal Drive design meets the intended user requirements and facilitates safe and effective user interactions with little chance of committing dangerous user errors.

Animal and Cadaver Testing

Medrobotics performed three animal studies to evaluate the safety of the Flex® Robotic System and Flex® Colorectal Drive for transanal access to the colorectal anatomy. The studies were conducted in accordance with Good Laboratory Practice (GLP).

One study evaluated abrasion caused by the Flex® Colorectal Drive (the patient contacting portion of the Flex® Robotic System). The study concluded that the Flex® Colorectal Drive does not cause an increased level of abrasion during visualization and access of the anus and rectum in a porcine model when compared to a colonoscope control.

The other study demonstrated that the Flex® Robotic System and Flex® Colorectal Drive provided acceptable visualization of and access to the colorectal space and served as a stable platform that enabled the surgeon to perform full thickness surgical procedures (excision, suturing, and bleeding control) on live (porcine) rectal tissue.

The third study demonstrated that the Flex® Robotic System and Flex® Colorectal Drive provided acceptable visualization of and access to the colorectal space and served as a stable platform that enabled the surgeon to perform submucosal surgical procedures (excision, suturing, and bleeding control) on live (porcine) rectal tissue.

Finally, a study of the use of the Flex® Robotic System and Flex® Colorectal Drive was conducted in six human cadaveric specimens. The results of the study demonstrated that the Flex Robotic System and Flex Colorectal Drive enabled trans-anal entry, maintained insufflation of the colon, and provided visualization and access to perform trans-anal tissue resection and resection closure in human anatomy with a high degree of success.

Electrical Safety

The Flex® Robotic System and Flex® Colorectal Drive have 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 and Flex® Colorectal Drive were 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
- Common emitter immunity testing, for cell phones, Wi-Fi, Bluetooth, and some RFID frequencies was performed per the latest edition 60601-1-2:2014 (4th Ed.) Table 9, Section 8.10. Some of the frequencies in Table 9 are tested per 60601-1-2:2007, but power levels are higher and dwell times are longer in Table 9 testing.
- RFID immunity ad hoc testing was performed for two common RFID emitters not included in Table 9 testing, 125kHz (low frequency RFID, or LF RFID) and 13.56MHz (high frequency RFID, or HF RFID). The testing was based on standard 60601-1-2 conducted EMI testing (modulation) conditions at these frequencies, with increased field strength and longer dwell times.
- Electro-Surgical Unit (ESU) immunity testing was based on IEC 60601-2-27:2011 Particular Requirements for ECG, Section 202.6.2.101.

Biocompatibility

The Flex® Colorectal Drive, including Flex Camera and Flex Rectoscope, contains the patient contacting portions of the Flex® Colorectal 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 Colorectal Drive 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. The results of these tests demonstrate that the patient contacting portions of the device, as intended for use, are biocompatible and non-toxic.

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

The Flex® Colorectal Drive is supplied sterile and is a single use device. The Flex® Colorectal 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 Colorectal Drive is stable over the labeled shelf life.

Cleaning and Sterilization of Reusable System Components

The Flex Colorectal System includes reusable components, the Flex® Camera, Flex® Colorectal Instrument Support and Flex® Rectoscope, 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

The Flex 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 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

Conclusion

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

Table 1 Comparison of Proposed, Predicate, and Reference Devices

Device Name	**PROPOSED** **Flex Robotic Colorectal System** **[K162330]**	**PREDICATE NeoGuide System [K070622]**	**REFERENCE** **Flex System [K150776]**	**REFERENCE** **Karl Storz Proctoscope/ TEO System [K945209]**
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.	For endoscopic access and visualization of patient anatomy through a natural orifice.
Indications for 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.	The NeoGuide 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.	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 Karl Storz Endoscopy Proctoscopes, Sigmoidoscopes, Accessories, and Proctosigmoidoscopy Instruments are manually operated, reusable devices which are designed for use by qualified surgeons during gastroenterological endoscopic procedures. The instruments are designed to facilitate the introduction or removal of instruments, telescopes, and light during gastroenterological endoscopic surgery.

Device Name	**PROPOSED** **Flex Robotic Colorectal System** **[K162330]**	**PREDICATE NeoGuide System [K070622]**	**REFERENCE** **Flex System [K150776]**	**REFERENCE** **Karl Storz Proctoscope/ TEO System [K945209]**
Operational Principles	Cable steered CMOS based video endoscope using electromechanical controls driven from a console based computer controlled physician handle	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.	Cable steered CMOS based video endoscope using electromechanical controls driven from a console based computer controlled physician handle	
Energy Source	AC powered	AC powered	AC powered	
Software	Yes. Software-driven endoscope.	Yes. Software-driven endoscope.	Yes. Software-driven endoscope.	

Device Name	**PROPOSED** **Flex Robotic Colorectal System** **[K162330]**	**PREDICATE NeoGuide System [K070622]**	**REFERENCE** **Flex System [K150776]**	**REFERENCE** **Karl Storz Proctoscope/ TEO System [K945209]**
Hardware	Major hardware system components: - Flex Drive (endoscope) - Flex Console (including video monitor and joystick) - Flex Base - Flex Cart - Flex Camera (with light source) - Flex Rectoscope - Instrument Support Arm	Major hardware system components: - NeoGuide Colonoscope (with integrated camera) - Actuation Control Unit - External Position Sensor - Cart - Colonoscope Support Arm - Isolation Transformer - Video Monitor - Light source/insufflation Unit	Major hardware system components: - Flex Scope (endoscope), including camera and light source - Flex Console (including video monitor and joystick) - Flex Base - Flex Cart - Instrument Support Arm	Major hardware system components: - Proctoscope - Sigmoidoscope - Accessories - Proctosigmoidoscopy Instruments
Operating Environment – Temperature	50° - 86° F (10° - 30° C)	50° - 104° F (10° - 40° C)	50° - 86° F (10° - 30° C)	
Operating Environment – Relative Humidity	15 – 75% relative humidity, non-condensing	30 – 85% relative humidity	15 – 75% relative humidity, non-condensing	
Operating Environment – Air pressure	700 – 1060 hPA	700 – 1060 hPA	700 – 1060 hPA	

Device Name	**PROPOSED** **Flex Robotic Colorectal System** **[K162330]**	**PREDICATE NeoGuide System [K070622]**	**REFERENCE** **Flex System [K150776]**	**REFERENCE** **Karl Storz Proctoscope/ TEO System [K945209]**
Lubrication	Yes. Lubricate using sterile petroleum jelly.	Yes. Lubricate using medical grade water-soluble lubricant.	No.	
Insufflation	Insufflation is necessary for procedure.	Insufflation is necessary for procedure.	Not applicable. Insufflation not used in ENT procedures.	Insufflation is necessary for procedure.
Insufflation maintenance	Rectoscope seals the flexible scope and anatomy to maintain insufflation.	Rigid scope exterior is self-sealing against the anus to maintain insufflation	Not applicable. Insufflation not used in ENT procedures.	Rectoscope seals the flexible scope and anatomy to maintain insufflation.
Anatomical Access	Scope gains access through entry of the Flex Rectoscope Obturator dilates the anus as the rectoscope is inserted	No access tools required	Scope gains access through use of a retractor	Rigid scope gains entry to the anatomy through this rectoscope Obturator dilates the anus as the rectoscope is inserted

Device Name	**PROPOSED** **Flex Robotic Colorectal System** **[K162330]**	**PREDICATE NeoGuide System [K070622]**	**REFERENCE** **Flex System [K150776]**	**REFERENCE** **Karl Storz Proctoscope/ TEO System [K945209]**
Rectoscope Ports for Compatible Instruments	Yes. The system has both left (1) and right (1) instrument ports which seal against specialized compatible rigid laparoscopic instruments to facilitate two handed surgery. Also contains a third auxiliary port to accept a variety of laparoscopic instruments.	Not applicable – does not use a rectoscope	Not applicable – does not use a rectoscope	Yes. The system has both left (1) and right (1) instrument ports which seal against specialized compatible rigid laparoscopic instruments to facilitate two handed surgery. Also contains a third auxiliary port to accept a variety of laparoscopic instruments.
CO_2 Port	Yes. 2 leur lock ports to provide CO_2 gas to the surgical field for insufflation.	Yes	Not applicable. Insufflation not used in ENT procedures.	Yes. 2 leur lock ports to provide CO_2 gas to the surgical field for insufflation.
Rectoscope Working Length	51.8 mm 109 mm	Not applicable – does not use a rectoscope	Not applicable – does not use a rectoscope	Ranging from 75 mm to 200 mm
Rectoscope Diameter	40 mm	Not applicable – does not use a rectoscope	Not applicable – does not use a rectoscope	40 mm

Device Name	**PROPOSED** **Flex Robotic Colorectal System** **[K162330]**	**PREDICATE NeoGuide System [K070622]**	**REFERENCE** **Flex System [K150776]**	**REFERENCE** **Karl Storz Proctoscope/ TEO System [K945209]**
Access for Compatible Instruments	• Compatible flexible instruments through accessory channels on the Flex Drive • Compatible laparoscopic instruments through the auxiliary port on the Flex Rectoscope	Compatible flexible instrument through instrument channel of the scope	Compatible flexible instruments through accessory channels on the Flex Drive	Compatible laparoscopic instruments through the ports on the rectoscope
Scope Rigidity	Flexible / Semi-Rigid endoscope	Flexible / Semi-Rigid endoscope	Flexible / Semi-Rigid endoscope	
Scope Overall Diameter	28mm (18mm scope + 2, 5mm instrument channels)	14.5mm	28mm (18mm scope + 2, 5mm instrument channels)	
Scope Working Diameter	18mm	14.5mm	18mm	
Scope Working Length	19.2cm (17cm working length + 2.2cm to traverse the rectoscope to enter the patient)	161 cm (132 cm under active control)	17cm	

Device Name	**PROPOSED** **Flex Robotic Colorectal System** **[K162330]**	**PREDICATE NeoGuide System [K070622]**	**REFERENCE** **Flex System [K150776]**	**REFERENCE** **Karl Storz Proctoscope/ TEO System [K945209]**
Advance/retract	Electromechanically 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 The links of the endoscope are locked in a rigid state prior to initiation of a surgical procedure.	Electromechanically 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.	
Maximum Allowable Speed	Linear: 22mm/s Articulation: 22mm/s	Linear: Not applicable. Directly controlled by the physician inserting and withdrawing the device Articulation: Not published	Linear: 22mm/s Articulation: 22mm/s	
Tip Articulation	0° - 110°	Unknown – redacted from K070622	0° - 110°	
Steering	Electromechanical joystick controls (the Physician Controller) on a console aid steering	Electromechanical joystick controls on the handle of the scope aid steering	Electromechanical joystick controls (the Physician Controller) on a console aid steering	
Direct Visualization	Yes, during entire procedure	Yes, during entire procedure	Yes, during entire procedure	
Multi-Segmented Endoscope Structure	Yes	Yes	Yes	

Device Name	**PROPOSED** **Flex Robotic Colorectal System** **[K162330]**	**PREDICATE NeoGuide System [K070622]**	**REFERENCE** **Flex System [K150776]**	**REFERENCE** **Karl Storz Proctoscope/ TEO System [K945209]**
Semi-rigid follow the leader / guiding function	Yes	Yes	Yes	
Electromechanically cable driven / controlled segments	Yes	Yes	Yes	
3D flexible movements and tip orientation	Yes	Yes	Yes	
Haptic feedback to user	Based on mechanical scope limits – Yes Based on patient anatomy – No	Based on mechanical scope limits – No Based on patient anatomy – No	Based on mechanical scope limits – Yes Based on patient anatomy – No	
Fluid Lumen	Yes	Yes	Yes	
Working Channel(s)	Yes 4.7 mm in diameter	Yes, 3.2 mm in diameter	Yes 4.7 mm in diameter	
View optics / Optical Sensor	Lens / Solid State Camera (CMOS)	Lens / Solid State Camera (CCD)	Lens / Solid State Camera (CMOS)	
Optics – Pixels	1280 x 720	768 x 490	800 x 800	
Optics – CCD Type	Color	Color	Color	
Optics – Field of View	> 80° (actual measurement approx.. 86°)	140° +/- 10°	> 80° (actual measurement approx.. 86°)	

Device Name	**PROPOSED** **Flex Robotic Colorectal System** **[K162330]**	**PREDICATE NeoGuide System [K070622]**	**REFERENCE** **Flex System [K150776]**	**REFERENCE** **Karl Storz Proctoscope/ TEO System [K945209]**
Optics – Direction of View	Forward / 0°	Forward	Forward / 0°	
Optics – Depth of Field	25 – 60 mm	3 – 80 mm	25 – 60 mm	
Optics – F-stop	5.6	7.2	5.6	
Optics – Signal-to-Noise Ratio	39 dB	Unknown – not published or included in K070622	39 dB	
Optics – Sensitivity	3300 nV/lux-sec	Unknown – not published or included in K070622	3300 nV/lux-sec	
Light Source	LED	LED	LED	
Video Image Processing	Video Data Display	Video Data Display	Video Data Display	
Video Display	Standard color video display	Standard color video display	Standard color video 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	Flex Colorectal Drive is provided Sterile	Endoscope is provided Clean / Non-Sterile	Flex Scope is provided Sterile	

Device Name	**PROPOSED** **Flex Robotic Colorectal System** **[K162330]**	**PREDICATE NeoGuide System [K070622]**	**REFERENCE** **Flex System [K150776]**	**REFERENCE** **Karl Storz Proctoscope/ TEO System [K945209]**
Electrical Safety & EMC	Passed the applicable electromagnetic compliance (EMC) and electrical safety requirements of IEC 60601-1-2 and IEC 60601-1	Passed	Passed	