January 8, 2018

invendo medical GmbH
Oliver v. Ruepprecht
Head of QA/RA
Peterhofstr. 3b
Kissing, Bavaria 86438
Germany

Re: K173085
Trade/Device Name: invendoscopy E210 System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: September 27, 2017
Received: September 29, 2017

Dear Oliver v. Ruepprecht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173085

Device Name
invendoscopy E210 System

Indications for Use *(Describe)*

The invendoscopy E210 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 colonoscope component of the invendoscopy E210 System, the invendoscope SC210, is a sterile single use disposable device. The invendoscope SC210 cannot be reprocessed.

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.

510(k) Premarket Notification invendoscopy E210 System	**Section D.1** **510k Summary**	invendo medical STERILE SINGLE-USE ENDOSCOPY

Applicant Information

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Germany

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Date Prepared: September 27,2017

Identification of the proposed device

Device Name	invendoscopy E210 System
Components	invendoscope SC210 (SC210 colonoscope) invendo E210 Processing Unit invendo E210 Power Unit invendo ScopeController invendo Drying Adapter
Common Name	Colonoscopy System
Classification/name	Class II (876.1500) / Endoscope and Accessories
Product Code	FDF
Review Panel	Gastroenterology/Urology

Predicate Devices

K161355	Invendoscopy E200 System
K100584	Olympus EVIS EXERA II 180 SYSTEM

Intended Use

The invendoscopy E210 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 colonoscope component of the invendoscopy E210 System, the invendoscope SC210, is a sterile single-use disposable device. The invendoscope SC210 cannot be reprocessed.

Device Description

The invendoscopy E210 System consists of an invendoscope SC210, an invendo E210 Processing Unit, an invendo E210 Power Unit, an invendo ScopeController and an invendo Drying Adapter. The invendo E210 Processing Unit and the invendo E210 Power Unit together form the invendo SPU E210.

The invendoscope SC210 is a sterile single-use disposable colonoscope. The distal tip of the colonoscope is deflectable and equipped with a CMOS camera and LEDs for illumination. A working channel is incorporated for biopsies and polypectomies. The invendoscope SC210 is furthermore equipped with insufflation, irrigation and suction functions.

The invendo E210 SPU (consisting of invendo E210 Processing Unit and invendo E210 Power Unit) contains the video signal processing technology which enables the endoscope to illuminate, view, record and transmit video data of endoscopic images. The invendo SPU E210 supplies the colonoscope and controls its functions according to the commands of the operator.

The operator uses the invendo ScopeController unit to control the invendoscopy E210 System. The invendo ScopeController allows the operator to control following functions of the colonoscope: deflection of the tip; insufflation; irrigation and suction. The invendo ScopeController also allows the user to record images.

The invendo Drying Adapter is intended to support drying of the inner parts of the invendo SPU E210. It is used to connect a waste container to the invendo SPU E210.

Technology/Specification	Comparison to predicate devices
Deflection technology and deflecting capability	Deflecting technology and capability are similar to the invendoscopy E200 System (K161355); the bending diameter of the deflecting of the invendoscope SC210 is between the bending diameters of the predicate devices; an additional passive deflecting part is integrated in the invendoscope SC210.

Technology/Specification	Comparison to predicate devices
Irrigation	Identical to the invendoscopy E200 System (K161355)
Insufflation	Identical to the invendoscopy E200 System (K161355)
Suction	As the invendoscopy E200 System (K161355) the invendoscopy E210 System uses a pinch valve to control the suction.
Light Source	Same technology as invendoscope SC200 (same LED) but different light control methodology.
Camera	Same technology (CMOS) as invendoscope SC200 (K161355); the invendoscope SC210 works with high definition (HD) resolution as the Olympus EVIS EXERA II 180 SYSTEM.
Diameter	Identical to the invendoscope SC200 (K161355)
Working Length	Identical to the invendoscope SC200 (K161355)
Working channel Ø	The working channel of the invendoscope SC210 is 3.2mm, the working channel of the invendoscope SC200 is 3.1mm.
Insertion technology	Identical to the invendoscope SC200 (K161355)
Sterility	Identical to the invendoscope SC200 (K161355)
Material	The materials of the invendoscope (synthetic plastics) and the predicate devices are different but the whole device is biocompatible as required by the ISO10993-1 Standard.

Performance testing

The following non-clinical testing was performed to validate the design and to assure conformity with the following design standards:

- IEC 60601-1 “Medical electrical equipment part 1 – General requirements for safety” incl. national deviations
- IEC 60601-2-18 “Medical electrical equipment part 2 - Particular requirements for the basic safety and essential performance of endoscopic equipment”
- IEC 60601-1-2 “Medical electrical equipment part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility –Requirements and tests”; including national deviations FCC CFR 47 part 15

- ISO 10993-5; -7; -10 "Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity"; Part 7: Ethylene Oxide Sterilization Residuals"; Part 10: Tests for irritation and skin sensitization"
- IEC 62366 "Medical devices: Application of usability engineering to medical devices"
- ASTM 4169 "Standard Practice for Performance Testing of Shipping Containers and Systems"
- ASTM F88 "Standard Test Method for Seal Strength of Flexible Barrier Materials"
- ASTM F1886 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1929 "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration"
- ASTM F2096 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ISO 11135 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices"
- Evaluation of insertion forces

In all instances, the invendoscopy E210 System functioned as intended, performed as well as or better than the predicate and met individual test specifications.

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

Substantial Equivalence

The invendoscopy E210 System has the same intended use and indications for use, and similar technological characteristics and principles of operation as the predicate devices.

The minor technological differences between the invendoscopy E210 System and its predicate devices raise no new issues of safety or effectiveness.

Performance data demonstrate that the device is as safe and effective as the predicate devices. Thus, the invendoscopy E210 System is substantially equivalent to its predicate devices.