



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

August 25, 2016

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

Re: K161355  
Trade/Device Name: invendoscopy E200 System  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: FDF  
Dated: July 15, 2016  
Received: July 18, 2016

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.

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

## Indications for Use

510(k) Number (if known)  
K161355

Device Name  
invendoscopy E200 System

### Indications for Use (Describe)

The invendoscopy E200 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 E200 System, the invendoscope SC200, is a sterile single use disposable device. The invendoscope SC200 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.

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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) Premarket Notification Invendoscopy E200 System	<b>Section 8</b> <b>510k Summary</b>	 <b>invendo medical</b> STERILE SINGLE-USE ENDOSCOPY
---	---	---

### Applicant Information

Name: invendo medical GmbH  
Address: Peterhofstr. 3b  
86438 Kissing  
Germany  
Contact: Oliver v. Ruepprecht  
Head of QA/RA  
Phone : +49 – 8233 – 744 98 16  
Fax : +49 – 8233 – 744 98 15  
Mail : [oliver.ruepprecht@invendo-medical.de](mailto:oliver.ruepprecht@invendo-medical.de)  
Date Prepared: 13.May 2016

### Identification of the proposed device

Device Name invendoscopy E200 System  
Components invendoscope SC200 (SC200 colonoscope)  
invendo SPU E200  
invendo ScopeController  
invendo E200 Drying Adapter  
Common Name Colonoscopy System  
Classification/name Class II (876.1500) / Colonoscope and Accessories, flexible/rigid  
Product Code FDF  
Review Panel Gastroenterology/Urology

### Predicate Devices

K100624 invendo C20 Colonoscopy System  
K121582 invendo C25 Colonoscopy System  
K100584 Olympus EVIS EXERA II 180 SYSTEM

### Intended Use

The invendoscopy E200 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 E200 System, the invendoscope SC200, is a sterile single-use disposable device. The invendoscope SC200 cannot be reprocessed.

### Device Description

The invendoscopy E200 System consists of an invendoscope SC200, an invendo SPU E200, an invendo ScopeController and an invendo E200 Drying Adapter.

The invendoscope SC200 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 SC200 is furthermore equipped with insufflation, irrigation and suction functions.

The invendo SPU E200 contains the video signal processing technology which enables the endoscope to illuminate, view, record and transmit video data of endoscopic images. The invendo SPU E200 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 E200 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 E200 Drying Adapter is intended to support drying of the inner parts of the invendo SPU E200. It is used to connect a waste container to the invendo SPU E200.

<b>Technology/Specification</b>	<b>Comparison to predicate devices</b>
Deflection technology and deflecting capability	Same technology as invendo SC20 colonoscope (K121582); both devices work with water-filled bellows and are pressure controlled
Irrigation	Same performance as invendo SC20 colonoscope (K121582); irrigation control via peristaltic pump instead of pressure chamber as by the invendo SC20 colonoscope

Technology/Specification	Comparison to predicate devices
Insufflation	Same performance and control technology as invendo SC20 colonoscope (K121582)
Suction	Identical to the invendo SC20 colonoscope (K121582)
Light Source	Identical to the invendo SC20 colonoscope (K121582)
Camera	Same technology (CMOS) as SC20 colonoscope (K121582); Both the camera of the SC20 colonoscope and the invendoscope SC200 works with standard resolution.
Diameter	Identical to the invendo SC20 colonoscope (K121582)
Working Length	Similar length as Olympus colonoscope (K100584); The working length of the invendoscope SC200 is longer than the working length of the Olympus colonoscope. The difference has no impact on safety or efficiency because the introduction deep depends from operator's decision.
Working channel	Identical to the invendo SC20 colonoscope (K121582)
Insertion	Manually pushed as the Olympus colonoscope (K100584)
Sterility	The invendoscope SC200 is sterile delivered, the predicate devices are unsterile delivered  The invendo SPU E200, the invendo ScopeController and the invendo E200 Drying Adapter is unsterile delivered as the predicate devices.
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 F1929 “Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration”
- ASTM F1886 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- 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 E200 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 E200 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 E200 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 E200 System is substantially equivalent to its predicate devices.