7 Special 510k Summary

DEC 2 0 2012

Applicant Information

Name: invendo medical GmbH

Address: Peterhofstr. 3b
86438 Kissing
Germany

Contact: Oliver v. Ruepprecht
Manager QA/RA
Phone : +49 – 8233 – 744 98 16
Fax : +49 – 8233 – 744 98 15
Mail : oliver.ruepprecht@invendo-medical.de

Device Information

Device Name: invendo C25 Colonoscopy System

Components: invendoscope SC20 (SC20 colonoscope)
invendo C25 Base System (base unit, drive, cleaner, handheld)

Common Name: Colonoscope

Classification: Class II, FDF 876.1500

Predicate device: invendo C20 colonoscopy system (K100624)

Intended use: The invendo C25 Colonoscopy 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 invendo C25 Colonoscopy System, the SC20 colonoscope, is a single-use disposable device. The SC20 colonoscope cannot be reprocessed.

Description	The invendo C25 Colonoscopy System is a modified version of the invendo C20 Colonoscopy System. Like the predicate device, the invendo C25 Colonoscopy System is steered and controlled by the operator. The distal tip of the colonoscope is deflectable and includes a CMOS camera and LEDs for illumination. A working channel is incorporated to enable biopsies and polypectomies. The invendo C25 Colonoscopy System includes insufflation, irrigation and suction functions. The invendo C25 Colonoscopy System consists of two components: (1) the invendo C25 base system; and (2) a single-use, disposable colonoscope, the SC20 colonoscope. The invendo C25 base system provides the SC20 colonoscope with the above mentioned functions and transfers user commands to the colonoscope. To control the colonoscope, the operator uses a handheld control unit. All colonoscope functions are solely activated by the user. The invendo C25 base system consists of the Supply and Processing Unit (SPU or base unit), the handheld control and the drive unit.
Description of the differences	The main differences between the C25 Colonoscopy System and the predicate are check valves integrated into the single use colonoscope, an additional decompression line for the rinse tube and the reprocessing regimen for the base unit that eliminates the need to clean and high-level disinfect after each patient. In addition, the C25 colonoscopy system includes minor technology, material, accessory (lubricant), and cosmetic changes compared to the predicate. These minor changes include, for example, an increased deflecting length of the colonoscope; changes to the internal power supply system; additional settings in the graphical user interface that allow the user to change the settings for rinsing function, deflection speed and insufflation gas during, and not only prior to, an examination; a reduction of the safety current of the light source; and the integration of an additional level sensor in the lubrication chambers of the system.
Performance and safety Tests	The following non-clinical testing was performed to validate the design and to assure conformity with 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"
- ISO 10993-5 "Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity"
- ISO 10993-10 "Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization"
- Test of the check valve under worst case conditions
- Evaluation of the decompression line and the corresponding system tests
- Evaluation of the backflow into the system without any check valves
- Evaluation of the reprocessing performance
- Evaluation of the performance compared to the predicate device

In all instances, the SC20 colonoscope and the C25 base system functioned as intended, performed as well as or better than the predicate, and met individual test specifications.

Substantial equivalence

The invendo C25 Colonoscopy System has the same intended use, indications for use, functions, operational principles and components as the predicate device.

As a result, the C25 is substantially equivalent to its predicate.

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

December 20, 2012

invendo medical GmbH
% Mr. Oliver v. Ruepprecht
Manager QA/RA
Peterhofstr. 3b
86438 KISSING
GERMANY

Re: K121582
Trade/Device Name: invendo C25 Colonoscopy System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: November 21, 2012
Received: November 26, 2012

Dear Mr. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

13 Indications for Use Statement

510(k) Number (if known): K121582

Device Name: invendo C25Colonoscopy System

Indications for Use:

The invendo C25 Colonoscopy 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 invendo C25 Colonoscopy System, the SC20 Colonoscope, is a single use disposable device. The SC20 colonoscope cannot be reprocessed.

Prescription Use X
(Part 21 CFR 801 Subpart D)

~~AND~~ / ~~OR~~

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2012.12.20 13:11:03 -05'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121582