K100624
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FEB 2 3 2012

510(k) Summary
invendo medical C20 Colonoscopy System

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Device Name, 21 CFR807.92(a)(2).

Trade Name: invendo C20 Colonoscopy System; includes SC20 Colonoscope and the C20 Base System (base unit, drive, and handheld)
Common Name: Colonoscope
Classification Name: Endoscope and accessories, 21CFR 876.1500, product code: FDF

Predicate Devices, 21 CFR 807.92(a)(3):

Predicate Device	510(k) No.
Olympus CF-Q160AL/I	K001241
Fujinon EN 450P5/20 Double Balloon	K040048
ColonoSight 510B	K032688
NeoGuideEndoscopy System	K052930; K070622
Avantis 3rd Eye Retroscope	K070330
Softscope CAD 12	K092156
Medela Dominat 35c/i suction pump	K043544
Medela Basic 30	K021368
PROTOC02LTM Colon Insufflator with Performance Improvements	K030854
EndoGatorEndoscopy Irrigation Pump	K060962
Olympus Exera 160A videoprocessor	K051645

Device Description, 21 CFR 807.92(a)(4):

The invendo C20 Colonoscopy System has many features in common with currently marked colonoscopes. The invendo C20 Colonoscopy System consists of two separate components: a single use disposable colonoscope and a base system that supplies and controls the colonoscope according to user commands via a handheld control unit. 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 invendo C20 Colonoscopy System is equipped with insufflation, irrigation and suction functions. Deflection, rinsing, insufflation and suction are activated and controlled by the base unit, according to user commands.

Unlike other colonoscopes, the invendo C20 Colonoscopy System is not manually pushed or otherwise manually manipulated by the operator, but instead, moves under the operator's direction through use of a handheld controller that controls, among other things, the device's drive unit. The colonoscope uses a lubricated inverted sleeve technology for advancement and retraction. Unlike other colonoscopes, the invendo C20 Colonoscopy System uses pressure controlled bellows for the deflecting function. The endoscope deflects in any direction depending on the pressure in the bellows. The handheld control is connected to the base unit. Depending on the user commands, the base unit activates and controls the functions of the invendo SC20 Colonoscope.

The colonoscope component of the system is a single-use disposable device. The SC20 colonoscope cannot be reprocessed. The main materials with direct contact with the patient are silicone and polycarbonate. The whole colonoscope, including the lubricant, were demonstrated to be biocompatible per ISO 10993.

Specification Chart:

Viewing direction	Forward
Field ofview	114°
Chip	CMOS, 250.000 Pixels
Max. Diameter Device	18mm
Working length	2100mm
Total length	3600mm
Bending capacity	180° in each direction at 37°C
Diameter working channel	3.1mm
Max. speed colonoscope via drive unit	500mm/min
Power supply baseunit	100 – 240V 50/60Hz
Max. internal pressure bas eunit	600kPa
Max. internal vacuum base unit	-75kPa

Intended Use / Indications for Use, 21 CFR 807.92(a)(5):

The invendo C20 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 endoscopy surgery.

The colonoscope component of the invendo C20 Colonoscopy System, the SC20 Colonoscope, is a single use disposable device. The SC20 Colonoscope cannot be reprocessed.

The device is contraindicated in patients with fulminant colitis; acute diverticulitis; severe cardiopulmonary illness; or where there is a lack of cooperation on the part of the patient.

Predicate Comparison, 21 CFR 807.92(a)(6):

The invendo C20 Colonoscopy System has the same intended use and indications for use as the predicate devices. The C20 Colonoscopy System has similar technological characteristics, however, the principles of operation with respect to advancing and retracting the endoscope in the colon are different from the predicate devices. The invendo SC20 Colonoscope is not manually pushed or otherwise manually manipulated by the operator, but instead, moves under the operator's control and direction with the help of the drive unit and user selected commands. The colonoscope uses an inverted sleeve technology for advancing and retracting.

Like the predicate devices, the invendo SC20 Colonoscope is a long, flexible endoscope that features a working channel, deflectable tip, and optics at the tip of the device. The working length of the predicate devices is somewhat less since those devices adjust the length and conformation of the colon to the device, this minor difference does not raise new questions of safety and effectiveness.

The invendo SC20 Colonoscope uses an overtube mechanism for the transmission of advanced power like the SoftScope CAD12. In both cases the sleeve systems are disposable.

The deflecting tip of the invendo C20 Colonoscopy System is electrohydraulically controlled via fluid-filled bellows while the deflecting tips of the predicate devices are controlled by Bowden wires. The performance bench and clinical testing demonstrate that these differences do not raise new questions of safety or effectiveness as compared

to the cleared predicate devices and that the device is as safe and effective as its predicates.

The invendo C20 Colonoscopy System is capable of performing rinsing, suction and insufflation like the predicate devices.

The invendo C20 Colonoscopy System uses the same basic technology for visualization and illumination as the predicate devices.

The materials used in the invendo C20 Colonoscopy System are somewhat different from those of the predicate devices, the company has provided complete biocompatibility data demonstrating that the materials used are biocompatible and thus as safe as those used in the predicate devices.

Performance data demonstrate that the device is as safe and effective as the predicate devices. Thus, the invendo C20 Colonoscopy System is substantially equivalent.

Clinical data confirms that the device can successfully navigate the colon and perform polyp/lesion removals.

Nonclinical performance data, 21 CFR 807.92(b)(1):

To assess the performance of the invendo C20 Colonoscopy System, invendo conducted bench tests to measure forces encountered during device use, product stability, biocompatibility of device components (according ISO Standard ISO-10993 and FDA Guidance G959-1), and constructive safety (IEC 60601-1/60601-2-18). In all instances, the SC20 Colonoscope and the invendo C20 base system functioned as intended and met individual test specifications.

Forces: The forces exerted by the colonoscope while moving through small curves with and without deflection were measured. The maximum forces exerted by the deflection, and advancement of the colonoscope were less than the force necessary to cause a perforation as determined by Thomas, K. Wu; Gastrointest. Endosc. 1978 Volume 24.

Biocompatibility: The tested materials met the biocompatibility requirements as per ISO 10993.

Product stability: The invendo SC20 Colonoscope has been demonstrated to be stable over the labeled 6 month shelf life of the product.

Constructive safety: The system met the general requirements of safety and the particular safety requirements of endoscopic equipment per IEC 60601.

The results of the tests demonstrate that the device is as safe and effective as the predicate devices.

Clinical Study Summary, 21 CFR 807.92(b)(2):

Groth et al., "High Cecal Intubation Rates with a New Computer-Assisted Colonoscope: A Feasibility Study," **The American Journal of Gastroenterology**, vol. 106, pp. 1075-1080, June 2011.

A study was conducted in Germany to measure the rate of successful cecal intubation for the assessment of the safety and effectiveness of the invendo C20 Colonoscopy System. The study was a prospective single arm study of 61 asymptomatic subjects (between 50 and 75 years of age) that were willing to undergo screening colonoscopy and were at average risk for colorectal cancer. Exclusion criteria included (but were not limited to) subjects with:

- history of colorectal neoplasia including familial adenomatous polyposis (FAP) or hereditary non-polyposis colorectal cancer;
- suspected diagnosis of inflammatory bowel disease, bowel obstruction, acute diverticulitis, known severe diverticulosis or any known large bowel disease
- GI-related symptoms, complaints or diseases;
- previous abdominal surgery except for uncomplicated cholecystectomy, appendectomy or minor pelvic surgery (e.g., hernia repair, oophorectomy).

Investigators underwent "pre-study" training where 2-4 training cases were needed to gain proficiency. The investigators were experienced endoscopists that insufflated the colon with either CO_2 or water. The subjects were examined in the left lateral position, with shifting to the supine position in most cases.

Cecal intubation was achieved in 98.4% (60/61) of the subjects (95% CI: 91.2 - 99.9%). Two device malfunctions and no device-related adverse events were reported. Thirty-nine lesions in 26 subjects (42.6%) were detected. Of those lesions, 36 were polyps in 23 subjects (37.7%), ranging in size from 2mm to 18mm (average 4.8mm). The remaining 3 lesions consisted of one abnormally large ileocecal valve which underwent biopsy, one varicose knot (no intervention) and one lipoma (no intervention). Thirty-two polyps (88.9%) were removed by either forceps (22) or snare (10). There were two cases where a second conventional colonoscope was used for the removal of a 12mm flat lesion and for the treatment of post-polypectomy bleeding.

Therapeutic maneuvers other than biopsy and polypectomy were not evaluated because cecal intubation was the primary endpoint. Although not required by the

protocol, investigators performed retroflexions as needed to ensure thoroughness of examination; retroflexion did not pose a problem and was well tolerated.

This study demonstrates that the invendo C20 Colonoscopy System can successfully 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 endoscopy surgery.

Summary, 21 CFR 807.92(b)(3)

The laboratory studies, which include determinations of exerted forces, product stability, biocompatibility and constructive safety, demonstrate that the invendo C20 Colonoscopy System performs as well as the predicate devices. The clinical data demonstrate that the invendo C20 Colonoscopy System can successfully 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 endoscopy surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 23 2012

Mr. Oliver V. Ruepprecht
Manager QA/RA
Invendo Medical GmbH
Peterhofstr. 3b
KISSING 86438
GERMANY

Re: K100624
Trade/Device Name: Invendo C20 Colonoscopy System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: February 15, 2012
Received: February 15, 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, 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 Statement

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510(k) Number (if known): K100624

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Indications for Use:

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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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K100624