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510K Summary
Enteroscopy Overtube

APR 12 2010

Submitter Information

Contact: Bob Bishui
Regulatory Affairs Manager
Craig Moore
General Counsel

Address: 5976 Heisley Road
Mentor, Ohio
44060

Telephone: 440-639-4494

Device Name

Trade Name: None at this time

Common/usual Name: Enteroscopy Overtube
Classification Name: Endoscopic access overtube, gastroenterology-urology

Device Classification: Class II, per 21 CFR 876.1500

Product Code: 78 (FED)

Predicate Device

Disposable Overtube (Guardus® overtube disposable)	510(k) 040836
Endo-Ease Endoscopic Overtube	510(k) 080050
St-E1 Overtube	510(k) 903842
Colonic Splinting Overtube	510(k) 092221

Description of Device

The device is an endoscopic accessory designed to provide external support to and maintain a path for an endoscope to minimize the formation of gastric looping by the endoscope and to minimize mucosal pinching, while inserting, advancing, and removing the endoscope during endoscopic procedures in the upper gastrointestinal tract, including the small intestine. The device is intended for prescription use, is non-sterile, is intended for single use, and is not intended for reprocessing.

Indications for Use

The Enteroscopy Overtube is indicated for use to aid the insertion, advancement and removal of appropriately sized endoscopes and endoscopic devices during diagnostic and therapeutic endoscopic procedures in the upper gastrointestinal tract, including the small intestine.

Summary Of Safety Performance

Substantial equivalence for the new device was based on design characteristics, a comparison to legally marketed predicate devices, and performance testing. Performance testing consisted of functional bench testing. All components that come into direct contact with the patient have a long history of use in medical devices and are biocompatible.

Conclusion:

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the proposed US Endoscopy Enteroscopy Overtube has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Bob Bishui
Regulatory Affairs Manager
United States Endoscopy
5976 Heisley Road
MENTOR OH 44060

APR 12 2010

Re: K100081
Trade/Device Name: Enteroscopy Overtube
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: January 11, 2010
Received: January 12, 2010

Dear Mr. Bishui:

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.

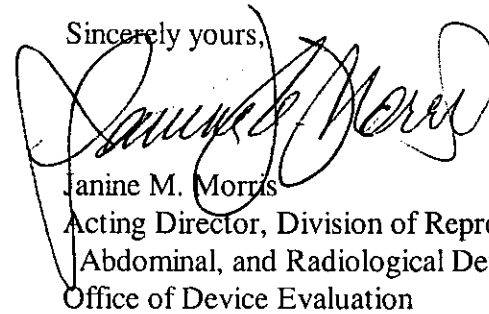
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K100081

Device Name: Enteroscopy Overtube

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100081