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# 510(k) SUMMARY
# FOR THE US ENDOSCOPY
# COLONIC SPLINTING OVERTUBE

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

**Applicant:** United States Endoscopy Group, Inc.
5976 Heisley Road
Mentor, Ohio 44060

**Contact Persons:** Craig L. Moore, General Counsel
Bob Bishui, Regulatory Affairs Manager
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Mentor, Ohio 44060
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**Device Common Name:** Colonic Splinting Overtube

**Trade Name:** None at this time.

**Classification Name:** Endoscope and Accessories

**Device Classification:** Class II, per 21 CFR 876.1500

**Product Code:** 78 (FDF)

**Predicate Devices:**

K023259 Soft Sleeve Colonoscope Splint
(International Healthcare Technologies, a division of Helix Medical, Inc.)

K052084 Endo-Ease™ Advantage Endoscopic Overtube
(Spirus Medical, Inc.)

K040836 Guardus® Overtube
(US Endoscopy)

**Product Description:**
The US Endoscopy Colonic Splinting Overtube is an overtube that includes a soft distal tip, an irrigation line, proximal seal at the handle, a hydrophilic coating, and an optional adhesive anchor.

**Indication For Use:**
The Colonic Splinting Overtube is indicated for use with an endoscope to prevent the reformation of the sigmoid loop subsequent to the reduction of the curvature of the sigmoid colon by the endoscope during the colonoscopy procedure. The Colonic Splinting Overtube is intended to provide for easy advancement of the scope while minimizing mucosal pinching.

**Safety and 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 Colonic Splinting Overtube has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Mr. Craig L. Moore
General Counsel
United States Endoscopy Group, Inc.
5976 Heisley Road
MENTOR OH 44060

OCT 20 2009

Re: K092221
Trade/Device Name: Colonic Splinting Overtube
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: July 17, 2009
Received: July 22, 2009

Dear Mr. Moore:

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.

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):** K092221

**Device Name:** Colonic Splinting Overtube

**Indications for Use:**

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092221