

SEP 14 2005

510(k) Premarket Notification: Traditional
Endo-Ease Endoscopic Overtube

K052084

510(k) Summary

Trade Name: Endo-Ease™

Sponsor: Spirus Medical, Inc.
1063 Turnpike Street
Stoughton, MA 02072
FDA Registration No. not yet assigned

Device Common Name: Endoscopic overtube

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices: K040048 – Balloon Overtube (Fujinon Corp.)
K973500 – Bard Endoscopic Overtube (C.R. Bard, Inc.)
K040836 – Disposable Overtube (U.S. Endoscopy)

Product Description:

The device described in this 510(k) consists of a sterile, single use, flexible overtube designed for use with currently marketed flexible endoscopes in the lower GI tract.

Indications for Use:

The Spirus Medical, Inc. Endo-Ease Endoscopic Overtube is indicated for use with a flexible endoscope to aid in endoscopic insertion and advancement during diagnostic and therapeutic lower GI flexible endoscopy.

Safety and Performance:

Substantial equivalence for the new device was based on design characteristics, comparison to legally marketed predicate devices, and performance testing. Performance testing consisted of destructive tensile testing of the helix and collars.

Conclusion:

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the proposed Spirus Medical, Inc. Endo-Ease Endoscopic Overtube has been shown to be safe and effective for its intended use.



SEP 14 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Spirus Medical, Inc.
c/o Ms. Pamela Papineau, RAC
Consultant
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
AYER MA 01432

Re: K052084
Trade/Device Name: Endo-Ease Endoscopic Overtube
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: July 29, 2005
Received: August 2, 2005

Dear Ms. Papineau:

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 (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Spirus Medical, Inc.
July 29, 2005

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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
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052084

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