K080050

## Section 5 – 510(k) Summary

MAY - 6 2008

### General Information

| | |
|---|---|
| **Owner's Name:** | Spirus Medical, Inc. |
| Address: | 1063 Turnpike Street<br>Stoughton, MA 02072 |
| Telephone Number: | (781) 297-5042 |
| Fax Number: | (781) 297-5059 |
| Contact Person: | Robert Ailinger |
| **Subject Device Name:** | Endo-Ease Endoscopic Overtube |
| Trade Name: | Endo-Ease Endoscopic Overtube |
| Common/Usual Name: | Endoscopic Overtube |
| Product Code: | FDA |
| FDA Regulation: | 21 CFR 876.1500 – Endoscope & accessories |
| Device Classification: | Class II |

**Predicate Device Name:**

| | |
|---|---|
| Trade Name: | Endo-Ease Endoscopic Overtube (Spirus Medical, Inc.) |
| Common/Usual Name: | Endoscopic Overtube |
| Product Code: | FDA |
| FDA Regulation: | 21 CFR 876.1500 – Endoscope & accessories |
| Device Classification: | Class II |
| Premarket Notification: | K060235 |

**Product Description:**
The device described in this 510(k) consists of a modified 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 to aid endoscopic insertion and advancement to the mid-ileum using during diagnostic and therapeutic upper GI endoscopy and enteroscopy. The Endo-Ease is used with an endoscope of appropriate diameter and length (such as an enteroscope or pediatric colonoscope).

**Substantial Equivalence**
Substantial Equivalence for the Spirus Medical, Inc. Endo-Ease Overtube is based upon physical comparison to the predicate device as well as a clinical study demonstrating the device's effectiveness in reaching the ileum. In a study involving the treatment of 101 patients, the user successfully reached the ileum in 48% of patients; the mid-ileum was reached in 6% of cases.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY - 6 2008

Spirus Medical, Incorporated
% Ms. Pamela Papineau, RAC
Consultant
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
AYER MA 01432

Re: K080050
Trade/Device Name: Endo-Ease™ Endoscopic Overtube
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: April 29, 2008
Received: May 2, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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|---|---|---|
| 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

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

Enclosure

## Section 4 – Indications for Use Statement

510(k) Number (if known): K080050

Device Name: Endo-Ease™ Endoscopic Overtube

Indications for Use:

The Spirus Medical, Inc. Endo-Ease Endoscopic Overtube is indicated to aid endoscopic insertion and advancement to the mid-ileum during diagnostic and therapeutic upper GI endoscopy and enteroscopy. The Endo-Ease is used with an endoscope of appropriate diameter and length (such as an enteroscope or pediatric colonoscope).

Prescription Use __X___ OR Over-the -Counter Use ____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080050