JUL 1 1 2005

K051068

510(k) Summary

(1) Contact Information

This 510(k) premarket notification is being submitted by Joseph Azary on behalf of Zutron Medical. The device is manufactured by Specialty Medical Systems, Inc.

Submitter / Regulatory Consultant: Joseph Azary, Azary Technologies LLC, 543 Long Hill Avenue, Shelton, CT 06484, Tel: 203-944-9320, Fax: 203-944-9317

Device Owner: Zutron Medical, 1911 Broadway, Kansas City, MO 64108

Manufacturer: Specialty Medical Systems, Inc (SMS), 1911 Broadway, Kansas City, MO 64108, FDA Establishment Registration# 9010172

Establishment Registration for Zutron Medical is pending.

(2) Device Information

(3) **Trade or Proprietary Name:** Zutron Colonoscope Stiffening Device

Common Name: Stiffening Wire or Stiffening Device

Classified Name: Endoscope Accessories

(4) Predicate Devices:

- Steel Wire – PreAmendment Device (medical articles dated as early as 1972 reference the use of steel wires for the stiffening of colonoscopes)
- Guide Wires and Cables
  - Sullivan Variable Stiffness Cable, K901610, Wilson Cook Medical, Product Code KOG
  - GIP / Medi-Globe Guide Wires, K941973, Medi-Globe Corp, Product Code FGE
  - GIP / Medi-Globe, Stiffy Variable Stiffness Guide Wire, 510(k) Unknown, Medi-Globe Corp, Product Code not specified
  - Endo-Glide Guidewire, K023603, Endo-Therapeutics Inc., Product Code KOG
- Colonoscopes with Stiffness Controls
  - Olympus PCF-160AL/I, K001241, Olympus Optical, Product Code FDF

(5) **Intended Use:** The intended use of the device is to allow the physician to increase the stiffness of the colonoscope when extra rigidity is required.

(6) Technological Characteristics: The Zutron Colonoscope Stiffening Device performs the same functions as several other devices on the market. Additionally, the subject device is composed of the same materials and has similar dimensions to some of the predicate devices.

(7) Conclusion: We believe the differences are minor and conclude that the subject device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2005

Zutron Medical
c/o Mr. Joseph M. Azary
Regulatory Consultant
Azary Technologies, LLC
543 Long Hill Avenue
SHELTON CT 06484

Re: K051068
Trade/Device Name: Zutron Colonoscope Stiffening Device
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: June 15, 2005
Received: June 20, 2005

Dear Mr. Azary:

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

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

Enclosure

K051068

Indications for Use

510(k) Number ~~(if known)~~: K051068

Device Name: Zutron Colonoscope Stiffening Device

Indications For Use:

The intended use of the device is to allow the physician to increase the stiffness of the colonoscope when extra rigidity is required.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051068

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