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Attachment IV – 510(k) Summary

K040302

Statement:

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the reviewer, this summary is formatted in accordance with the Agency's final rule.

Modified Device Name: VERSAPOINT* Resectoscopic System

Predicate Device Name: VERSAPOINT* Electrosurgery System (SCUBA)

Device Description:

The telescopic clip is a component of the VRS resectoscopic electrodes, and is designed to support, guide, and secure the distal portion of the electrode within the resectoscope. The telescopic clip is currently manufactured with Polypropylene (PP). It is proposed to change the material to Polybutyleneterephthalate (PBT).

Indications for Use:

Tissue cutting, removal, and desiccation as required or encountered in gynecologic hysteroscopic electrosurgical procedures for the treatment of intrauterine myomas, polyps, adhesions, and septa, and benign conditions requiring endometrial ablation.

- Excision of intrauterine myomas
- Excision of intrauterine polyps
- Lysis of intrauterine adhesions
- Incision of uterine septa
- Endometrial ablation

Technological Characteristics:

The modified device has the same technological characteristics as the predicate device. The only change to the device is to the material of the telescopic clip. The telescopic clip is currently manufactured with Polypropylene (PP). It is proposed to change the material to Polybutyleneterephthalate (PBT).

Performance Data:

Biocompatibility and bench testing have been performed to verify that the product meets the performance requirements described.

Conclusion:

Based upon the 510(k) summaries and 510(k) statements and the information provided herein, we conclude that the new device is substantially equivalent to the predicate device under the Federal Food, Drug, and Cosmetic Act.

Contact:

Patricia M. Hojnoski
Sr. Project Manager
Regulatory Affairs
Gynecare, A Division of Ethicon, Inc.
P.O. Box 151, Route 22 West
Somerville, NJ 08876

Date:

February 6, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

Ms. Patricia M. Hojnoski
Sr. Project Manager Regulatory Affairs
Gynecare Worldwide
A Division of ETHICON, Inc.
U.S. Route 22 West
P.O. Box 151
SOMERVILLE NJ 08876

Re: K040302
Trade/Device Name: VERSAPOINT* Resectoscope System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulation Number: 21 CFR 884.4160
Regulation Name: Unipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: 85 HIH and HFI
Dated: February 6, 2004
Received: February 10, 2004

Dear Ms. Hojnoski:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

Indications for Use

510(k) Number (if known): K040302
Device Name: ____VERSAPOINT* Resectoscopic System __

Indications for Use:

Tissue cutting, removal, and desiccation as required or encountered in gynecologic hysteroscopic electrosurgical procedures for the treatment of intrauterine myomas, polyps, adhesions, and septa, and benign conditions requiring endometrial ablation.

- Excision of intrauterine myomas
- Excision of intrauterine polyps
- Lysis of intrauterine adhesions
- Incision of uterine septa
- Endometrial ablation

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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 K040302