

**Attachment 4 – 510(k) Summary**

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**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 “...510(k) Summaries and 510(k) Statements...” (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

**MODIFIED DEVICE NAME:** Versapoint Electrosurgery Loop Electrode Accessory

**PREDICATE DEVICE NAME:** Scuba Electrosurgical System and Versapoint Electrosurgery G-VAP Electrode Accessory

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**Device Description** The Loop Electrode is an Bipolar Electrosurgical Electrode. It is used in conjunction with the Scuba Electrosurgical Generator.

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**Intended Use** The Loop Electrode is intended for use in gynecologic hysteroscopic electrosurgical procedures.

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**Indications Statement** Tissue cutting, removal, and desiccation as required or encountered in gynecologic hysteroscopic electrosurgical procedures for the treatment of intrauterine myomas, polyps, adhesions, 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

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**Technological characteristics** The modified device has the same technological characteristics as the predicate device. The form, fit, function and method of operation are similar.

*Continued on next page*

**510(k) Summary of Safety and Effectiveness, Continued**

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<b>Performance Data</b>	Preclinical testing has been performed to verify that the product meets the performance requirements described. It was determined that the device performs safely and effectively.
<b>Conclusion</b>	Based upon the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.
<b>Contact</b>	Gregory Jones Director Regulatory Affairs – Domestic Gynecare/Ethicon, Inc. Route 22 Somerville New Jersey
<b>Date</b>	November 4, 1999

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JAN 24 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Gynecare, Inc.  
c/o Mr. William Goeller  
Sr. Project Manger  
ETHICON, Inc.  
P.O. Box 151  
Somerville, NJ 08876-0151Re: K994418  
SCUBA System Hysteroscopic Electrosurgery  
System VRS Angled Loop Electrode  
Dated: December 28, 1999  
Received: December 29, 1999  
Regulatory Class: II  
21 CFR §884.1690/Procode: 85 HIH  
21 CFR §884.4160/Procode: 85 KNF

Dear Mr. Goeller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K994418

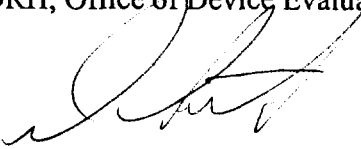
Device Name: Scuba Hysteroscopic Electrosurgery System

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

(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~~

(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K994418 (Optional Format 1-2-96)

Scuba System Hysteroscopic Electrosurgery System Loop Electrode  
Gynecare/Ethicon, Inc.