JAN 24 2000

Attachment 4 – 510(k) Summary

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

Device Description

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

Intended Use

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

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

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

Performance Data	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.
Conclusion	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.
Contact	Gregory Jones Director Regulatory Affairs – Domestic Gynecare/Ethicon, Inc. Route 22 Somerville New Jersey
Date	November 4, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2000

Gynecare, Inc.
c/o Mr. William Goeller
Sr. Project Manger
ETHICON, Inc.
P.O. Box 151
Somerville, NJ 08876-0151

Re: 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)