3/1/99

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SECTION 7

510(k) Summary of Safety and Effectiveness

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 G-VAP Electrode Accessory PREDICATE DEVICE NAME: Scuba Electrosurgical System
Device Description	The G-VAP Electrode is an Bipolar Electrosurgical Electrode. It is used in conjunction with the Scuba Electrosurgical Generator.
Intended Use	The G-VAP 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, and septa. Excision of intrauterine myomas Excision of intrauterine polyps Lysis of intrauterine adhesions Incision of uterine septa
Technological characteristics	The modified device has the same technological characteristics as the predicate devices. The form, fit, function and method of operation are similar.

Continued on next page

510(k) Summary of Safety and Effectiveness, Continued

Performance Data	Pre-clinical as well as bench top 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	Susan Aloyan Director of Regulatory Affairs and Quality Assurance Gynecare/Ethicon, Inc. 235 Constitution Drive, Menlo Park, California 94025-1108
Date	July 31, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1999

Ms. Susan M. Aloyan
GYNECARE, INC.
235 Constitution Drive
Menlo Park, CA 94025

Re: K982738
G-VAP Electrodes for Gynecare Scuba System
Dated: December 2, 1998
Received: December 3, 1998
Regulatory Class: II
21 CFR 884.1690/Procode: 85HIH
21 CFR 884.4160/Procode: 85 HFG

Dear Ms. Aloyan:

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): K982738

Device Name: G-VAP Electrode for use with the SCUBA Hysteroscopic Electrosurgery System

Indications for Use: Tissue cutting, removal, and dessication as required or encountered in gynecologic hysteroscopic electrosurgical procedures for the treatment of intrauterine myomas, polyps, adhesions, and septa.

Excision of intrauterine myomas
Excision of intrauterine polyps
Lysis of intrauterine adhesions
Incision of uterine septa

(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 _____

(Optional Format 1-2-9G)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982738/S001