510(k) Summary

Submitter Information

Company:	Ethicon, Inc. Route 22 West Somerville, NJ 08876
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Date Prepared:	June 6, 2011

Identification of the Device

Common Name:	Electrosurgery System
Device Name:	GYNECARE VERSAPOINT™ II Bipolar Electrosurgery System
Classification Name:	Bipolar endoscopic coagulator cutter and accessories Hysteroscope and accessories
Device Classification:	Regulation Number: 21 CFR 884.4150 Regulatory Class: Class II Product Code: HIN
	Regulation Number: 21 CFR 884.1690 Regulatory Class: Class II Product Code: HIH

Predicate Devices

- GYNECARE VERSAPOINT Bipolar Electrocautery System (K962482)
- VERSAPOINT VRS 2.5mm Angled Loop Electrode (K994418)

Description of the Device

The GYNECARE VERSAPOINT™ II Bipolar Electrosurgery System (VERSAPOINT II System) is the next generation of the currently-marketed GYNECARE VERSAPOINT™ Bipolar Electrosurgery System (VERSAPOINT System). This electrosurgical system utilizes bipolar technology specifically designed to provide a range of gynecological surgical treatments, including vaporization to ablate and excise tissue, thermal coagulation of tissue and hemostasis of blood vessels. The VERSAPOINT II System is comprised of four main elements:

- the VERSAPOINT II Generator,

Continued on next page

510(k) Summary, Continued

Description of the Device, continued

- the VERSAPOINT II 4mm Angled Loop Electrode,
- the VERSAPOINT II Footswitch, and
- the VERSAPOINT II Connector Cable.

The VERSAPOINT II System offers five bipolar output modes:

1. Ablation (VC [VaporCut]) – for tissue removal and cutting
2. Enhanced Ablation (VP [VersaPulse]) – an enhanced version of the Ablation (VC) output mode attained by use of short-duration high power pulses
3. Blended Ablation (BL) – simultaneous ablation and coagulation (the generator rapidly switches between ablation and coagulation output modes)
4. Enhanced Blended Ablation (VBL) – a variant of the VP output mode that rapidly switches the output ON and OFF to deliver blended ablation/coagulation
5. Coagulation (DES [Desiccate]) – for thermal coagulation and hemostasis

Indications for Use

The GYNECARE VERSAPOINT™ II Bipolar Electrosurgery System is intended for use in 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. Procedures include:

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

Contra-indications for Use

The GYNECARE VERSAPOINT™ II Bipolar Electrosurgery System is NOT intended for use in tubal sterilization procedures.

The use of this device is contraindicated in patients with the following conditions:

- Acute cervicitis
- Pregnancy
- Cervical or uterine malignancy
- Active pelvic inflammatory disease
- Unaddressed adnexal pathology

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510(k) Summary, Continued

Technological Characteristics

This electrosurgical system utilizes bipolar technology specifically designed to provide a range of gynecological surgical treatments, identical to the predicate device.

This premarket notification is for modifications to the currently-marketed GYNECARE VERSAPOINT™ Bipolar Electrosurgery System (generator, connector cable, foot switch and loop electrode). Modifications to the generator include hardware and software updates to accommodate a new 4mm loop electrode. A new connector cable is provided to enable connection of the new 4mm loop electrode and existing electrodes to the generator. In addition, a new heavier weight footswitch has been added to the system which allows the clinician to change power and mode settings.

Performance Testing

Two bench studies and one animal study (conducted in compliance with the Good Laboratory Practices regulation, 21 CFR Part 58) demonstrate the substantial equivalence of the performance of the GYNECARE VERSAPOINT™ II Bipolar Electrosurgery System to the predicate GYNECARE VERSAPOINT™ Bipolar Electrosurgery System with regards to:

- maximum thermal margin and depth of tissue necrosis,
- mean volume of gas generated,
- mean tissue removal rate, and
- hemostasis performance.

Conclusions Drawn from Studies

Validity of Scientific Data:
The bench studies followed scientific protocols with pre-determined acceptance criteria. The animal study was conducted in compliance with Good Laboratory Practices (GLPs). The data were scientifically valid in accordance with 21 CFR 860.7.

Substantial Equivalence:
Information presented in this premarket notification establishes that the GYNECARE VERSAPOINT™ II Bipolar Electrosurgery System is as safe and effective as the predicate device when used in accordance with the labeled directions for use for the stated indication.

Risk and Benefits:
The risks of the subject device are the same as those of the predicate device. The benefits to the patient are the same as those for the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

DEC - 2 2011

Mr. Brian A. Kanerviko
Director, WW Regulatory Affairs
Ethicon, Inc.
Route 22 West
SOMERVILLE NJ 08876

Re: K111751
Trade/Device Name: GYNECARE VERSAPOINT™ II Bipolar Electrosurgery System
Regulation Number: 21 CFR§ 884.4150
Regulation Name: Bipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: HIN, HIH
Dated: November 11, 2011
Received: November 17, 2011

Dear Mr. Kanerviko:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111751

Device Name: GYNECARE VERSAPOINT™ II Bipolar Electrosurgery System

Indications for Use:

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- Lysis of intrauterine adhesions
- Incision of uterine septa
- Endometrial ablation

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111751

Prescription Use √ and/or Over-the-Counter Use ___
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)