K993801

FEB 7 2000

SECTION 7

## SUMMARY OF SAFETY AND EFFECTIVENESS

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

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: Gynecare Laparoscopic Morcellator

PREDICATE DEVICE NAME: Gynecare Laparoscopic Morcellator

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510(k) SUMMARY

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**Device Description**

The modified Laparoscopic Morcellator is comprised of two major components: the Laparoscopic Morcellator and the Motor Drive Unit (MDU). The Gynecare Laparoscopic Morcellator is a disposable device which is provided sterile. It is essentially a rotating, cylindrical (tubular) razor blade, with a blade guard, which allows tissue to be grasped with a standard grasper type instrument extending through the central lumen of the device and then drawn up inside the rotating cutter as the cutter cuts with a coring action. The cutting is powered by the Gynecare Laparoscopic Motor Drive Unit (MDU) via a flexible drive cable (see drawing). The physician can turn the Gynecare Laparoscopic Morcellator on and off via a foot pedal. The direction and speed of rotation are controlled on the face of the MDU by a nurse outside the sterile field.

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| **Device Description, Continued** | The variable-speed, reversible MDU is an integral part of the Gynecare Laparoscopic Morcellator since it drives the rotation of the cutter/Morcellator at a controlled speed and torque. The Gynecare Motor Drive Unit provides a user-selectable speed range at which to drive (rotate) the cutter/Morcellator. The torsional output of the motor is sufficient at all speeds to drive the cutter while cutting tough tissue. The direction of rotation of the motor is user-selectable. |
| **Indications For Use** | Indicated for cutting, coring and extracting tissue in operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures such as nephrectomy, and laparoscopic gynecologic procedures such as myomectomy and hysterectomy. |
| **Intended Use** | The Gynecare Laparoscopic Morcellator is intended for gynecologic, urologic, and general surgical endoscopic use by trained professionals in hospital environments. |
| **Technological Characteristics** | The modified device has identical technological characteristics to the predicate device. |
| **Performance Data** | Nonclinical laboratory was deemed unnecessary. |
| **Clinical Data** | No clinical data was deemed necessary to support this premarket notification; however, published literature is available to support the use of a laparoscopic morcellation device for laparoscopic hysterectomies. |

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**Conclusions**

Based on 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 Device under the Federal Food, Drug, and Cosmetic Act.

**Contact**

Gregory R. Jones
Director, Regulatory Affairs
ETHICON, Inc.
Rt. #22, West
Somerville, NJ 08876-0151

**Date**

November 8, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2000

Mr. Gregory R. Jones
Director, Regulatory Affairs
Ethicon, Inc., a Johnson & Johnson Co.
P.O. Box 151
Somerville, NJ 08876-0151

Re: K993801
Gynecare Laparoscopic Morcellator
Dated: November 8, 1999
Received: November 9, 1999
Regulatory Class: II
21CFR §884.1720/Procode: 85 HET

Dear Mr. Jones:

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

## INDICATION FOR USE

510(k) Number (if known): K993801

Device Name: Laparoscopic Morcellator

Indications For Use:

Indicated for cutting, coring and extracting tissue in operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures such as nephrectomy, and laparoscopic gynecologic procedures such as myomectomy and hysterectomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993801