K100280
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ETHICON, INC.
a Johnson & Johnson company

MAR 24 2010

510k Summary

510(k) Owner	ETHICON, Inc.
Contact Information	Bryan A. Lisa Associate Director, Regulatory Affairs ETHICON Inc. PO Box 151 Route 22 West Somerville, NJ 08876 Telephone: 908.218.3392 Facsimile: 908.218.2595 Email: blisa@its.jnj.com
Date of Preparation	29 January 2010
Device Classification	Trade Name: GYNECARE MORCELLEX™ Tissue Morcellator Common Name: Laparoscope, gynecologic (and accessories) Classification Name/Number: Gynecologic laparoscope and accessories Regulation Number: 884.1720 Product code: HET
Predicate Device	GYNECARE MORCELLEX™ Tissue Morcellator: **K061050**
Device Description	The GYNECARE MORCELLEX™ Tissue Morcellator is a single-use device. The device is inserted into the patient with the use of the provided single-use obturator. The device allows tissue to be grasped with a standard grasping instrument extended through its central lumen. The tissue can be drawn up inside the device's central lumen into the inner stationary sheath as the exposed blade cuts the tissue. The physician can activate the GYNECARE MORCELLEX™ Tissue Morcellator via a foot pedal or via the dual-function Blade Guard / Activation Trigger on the device's detachable handle. The device can operate in either coring or peeling mode based on the degree of exposure of the blade and placement of the rotatable coreguard. The device is packaged with a single-use reducer cap to allow the optional use of a 5mm instrument.

Intended Use	The GYNECARE MORCELLEX™ Tissue Morcellator is intended for gynecologic, urologic and general surgical endoscopic use by trained professionals in hospital environments and ambulatory surgery centers.
Indications for Use	The GYNECARE MORCELLEX™ Tissue Morcellator is indicated for cutting, coring, and extracting tissue during operative laparoscopy including laparoscopic general surgical procedures, laparoscopic urologic procedures, and laparoscopic gynecologic procedures.
Technological Characteristics	The technological characteristics of GYNECARE MORCELLEX™, including design and materials, are identical to the predicate device, GYNECARE MORCELLEX™.
Performance Data	The bench testing data, including insertion and extraction forces, provided in this 510(k) demonstrates that the corrective action on the device design addresses the root cause of device failure.
Clinical Data	This 510(k) does not rely on clinical data to demonstrate substantial equivalence.
Conclusion	Based on the 510(k) summary and the information provided herein, we conclude that the subject device is substantially equivalent to the predicate devices under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAR 24 2010

Brian A. Lisa
Associate Director, Regulatory Affairs
ETHICON, Inc.
Route 22 West, P.O. Box 151
SOMERVILLE NJ 08876

Re: K100280
Trade/Device Name: GYNECARE MORCELLEX™ Tissue Morcellator
Regulation Number: 21 CFR §884.1720
Regulation Name: Gynecologic laparascope and accessories
Regulatory Class: II
Product Code: HET
Dated: January 29, 2010
Received: February 1, 2010

Dear Mr. Lisa:

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K100280

Device Name: GYNECARE MORCELLEX™ Tissue Morcellator

Indications for Use:

The GYNECARE MORCELLEX Tissue Morcellator is indicated for cutting, coring and extracting tissue during operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures, and laparoscopic gynecologic procedures.

Prescription Use X. (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K100280