510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Sponsor:	ETHICON Women's Health and Urology ETHICON, Inc. P.O. Box 151 Route 22 West Somerville, New Jersey 08876
Contact:	Sarah McManus ETHICON Women's Health and Urology ETHICON, Inc. P.O. Box 151 Route 22 West Somerville, New Jersey 08876 Phone: 908-218-2954 Fax: 908-218-2595 Email: smcmanu3@its.jnj.com
Date of Submission:	5 June 2013
Proprietary Name:	MORCELLEX SIGMA™ Generator
Common Name:	Laparoscope, gynecologic (and accessories)
Regulation:	21 CFR 884.1720
Regulatory Class:	II
Product Codes:	HET, Gynecologic laparoscope and accessories.
Predicate Device:	GYNECARE X-TRACT Motor Drive Unit (FEMRX OPERASTAR SYSTEM) - K954648
Device Description:	The MORCELLEX SIGMA™ Generator provides mechanical power to the ETHICON laparoscopic tissue morcellators via the morcellator's Flexible Drive Cable which connects the morcellator to the MORCELLEX SIGMA™ Generator. The MORCELLEX SIGMA™ Generator is equipped with a bi-directional motor that has a user-selectable speed range at which to rotate the ETHICON

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laparoscopic tissue morcellator. Activation buttons located on the Front Panel of the device allow the user to select the motor rotation direction and the speed of rotation.

Indications for Use

The MORCELLEX SIGMA™ Generator is used with the following ETHICON Morcellation Devices: GYNECARE X-TRACT™, GYNECARE MORCELLEX™, and MORCELLEX SIGMA™. The MORCELLEX SIGMA™ Generator is used in conjunction with the ETHICON Morcellation Devices for gynecologic, urologic, and general surgical endoscopic use by trained professionals in hospital environments and ambulatory surgery centers. The MORCELLEX SIGMA™ Generator is used in conjunction with ETHICON Morcellation Devices for cutting, coring, and extracting tissue during operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures, and laparoscopic gynecologic procedures.

Technological Characteristics

The MORCELLEX SIGMA™ Generator and the predicate device, the GYNECARE X-TRACT Motor Drive Unit, have the same fundamental technology, the same basic design, and use the same principle of operation.

The MORCELLEX SIGMA™ Generator and the predicate device, the GYNECARE X-TRACT Motor Drive Unit, provide mechanical power to the ETHICON laparoscopic tissue morcellators. This pre-market notification is for modifications to the currently-marketed GYNECARE X-TRACT Motor Drive Unit. Minor modifications were made to the Front Panel user interface to identify the purpose of the activation buttons and to add Motor Status indicator LED's. Internal component changes include a new Power Supply component, a new Printed Circuit Board Assembly and the addition of an audible alert buzzer to alert the user of the motor status.

MORCELLEX SIGMA™ Generator and the predicate device, the GYNECARE X-TRACT Motor Drive Unit, both provide bi-directional motor rotation (clockwise/counter-clockwise) and the same operational speed. The rated voltage is essentially the same for both devices. The rated frequency is identical. Both devices are the same dimensions and same approximate weight. The proposed device, the MORCELLEX SIGMA™ Generator, provides greater maximum power draw and greater maximum torque output compared to the predicate device, GYNECARE X-TRACT Motor Drive Unit.

Performance Data

Bench studies were conducted to demonstrate the performance of the MORCELLEX SIGMA™ Generator. The bench studies consisted of evaluating the following device characteristics: device weight, speed, torque output, and activation/de-activation pressure. Bench testing was also conducted to evaluate the compatibility of the MORCELLEX SIGMA™ Generator with the ETHICON laparoscopic tissue morcellators.

Electrical safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1:1988 + A1:1991 + A2:1995 *Medical Electrical Equipment - Part 1: General requirements for safety* and IEC60601-1-2:2007 *Medical electrical equipment – Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility – Requirements and tests.*

Conclusions

The data provided in this premarket notification demonstrate that the MORCELLEX SIGMA™ Generator is substantially equivalent to the predicate device, the GYNECARE X-TRACT Motor Drive Unit. Both devices have the same intended use, the same fundamental technology and the same principle of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 27, 2013

ETHICON, Inc.
% Sarah McManus
Manager, Regulatory Affairs
P.O. Box 151, Route 22 West
Somerville, NJ 08876

Re: K131656
Trade/Device Name: MORCELLEX SIGMA™ Generator
Regulation Number: 21 CFR§ 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET
Dated: August 28, 2013
Received: August 29, 2013

Dear Sarah McManus,

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 -S

for
Benjamin R. Fisher, Ph.D.
Director
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): K131656

Device Name: MORCELLEX SIGMA™ Generator

Indications for Use:

The MORCELLEX SIGMA™ Generator is used with the following ETHICON Morcellation Devices: GYNECARE X-TRACT™, GYNECARE MORCELLEX™, and MORCELLEX SIGMA™. The MORCELLEX SIGMA™ Generator is used in conjunction with the ETHICON Morcellation Devices for gynecologic, urologic, and general surgical endoscopic use by trained professionals in hospital environments and ambulatory surgery centers. The MORCELLEX SIGMA™ Generator is used in conjunction with ETHICON Morcellation Devices for cutting, coring, and extracting tissue during operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures, and laparoscopic gynecologic procedures.

Prescription Use___V_____ 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)

Herbert P. Lerner -S