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 15, 2014

Ethincon Endo-Surgery, LLC
Ms. Emily Kruetzkamp
Regulatory Affairs Associate
475 Calle C
Guaynabo, Puerto Rico 00969

Re: K141122
Trade/Device Name: Harmonic® Scallop Blade and Generator G11
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, HGI, LFL
Dated: August 19, 2014
Received: August 20, 2014

Dear Ms. Kruetzkamp:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141122

Device Name
Harmonic Scallop Blade

Indications for Use *(Describe)*
The Harmonic Scallop Blade is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141122

Device Name
Generator G11

Indications for Use *(Describe)*
The Generator G11 provides radiofrequency power to drive EnSeal electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive Harmonic ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. EnSeal and Harmonic instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Company
Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact
Emily Kruetzkamp, Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
Telephone: (513) 337-1546
Fax: (513) 337-2802
Email: ekruetzk@its.jnj.com

Date Prepared: April 25, 2014

Trade Name:	Harmonic® Scallop Blade
Common Name:	Instrument, ultrasonic surgical
Classification Name:	Instrument, ultrasonic surgical
Device Class:	Unclassified
Classification Regulation:	Unclassified
Panel:	79, General and Plastic Surgery
Classification Code:	LFL

Trade Name:	Generator G11
Common Name:	Electrosurgical & Ultrasonic Surgical Generator
Classification Names:	Electrosurgical, Cutting & Coagulation & Accessories; Electrocautery, Gynecologic (and Accessories); Instrument, Ultrasonic Surgical
Device Class:	Class II
Classification Regulations:	21 CFR 878.4400, 21 CFR 884.4120, and Unclassified (LFL)
Panel:	79, General and Plastic Surgery
Classification Codes:	GEI, HGI, LFL

Predicate Devices
Harmonic® 10cm Combination Hook Blade, K072203
Generator G11, K101990
Medtronic Integrated Power Console (IPS®) System, K081475
Codman® Cobb Spinal Elevator, Class I exempt per CFR 878.4800

Device Description:
The Harmonic® Scallop Blade is a sterile, single patient use device, consisting of a titanium blade with a non-removable gray sheath. The Harmonic® Scallop Blade instrument allows for the cutting of soft tissue and coagulation of vessels up to and including 2 mm in diameter. A soft grip pad on the handle housing facilitates grasping. The instrument is equipped with an integrated internal torque wrench, which is used for assembly to the Harmonic® Hand Piece.

The device system has four essential parts: the generator, the Footswitch, the Hand Piece, and the instrument. The Generator G11 supplies energy to Enseal® electrosurgical instruments and Harmonic® ultrasonic surgical instruments. The generator utilizes a touchscreen display interface and has a receptacle port that accepts either Enseal® or Harmonic® devices. Connectors (one for Harmonic® and one for Enseal® instruments) are used to enable the generator to power currently cleared surgical instruments. The Generator G11 hardware has not changed from the Predicate. The Harmonic® Scallop Blade instrument is designed for use exclusively with the Generator G11 software version 2013_1 or later, which has been updated to increase the maximum Power output to 60W required to power the Harmonic Scallop Blade.

Indications for Use:

Harmonic Scallop Blade

The Harmonic Scallop Blade is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Generator G11

The Generator G11 provides radiofrequency power to drive EnSeal electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive Harmonic ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. EnSeal and Harmonic instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

Technological Characteristics:

The Harmonic® Scallop Blade is similar in technological characteristics to the Predicate Device, the Harmonic® Combination Hook Blade HK105. The Harmonic Scallop Blade end effector design is different in that it incorporates a wide concave blade design.

The Subject Device Harmonic® Scallop Blade is similar to the Predicate Device Cobb Spinal Elevator in its ability to scrape soft tissue from orthopedic structures. The Subject Device Harmonic Scallop Blade is similar to the Predicate Device Medtronic IPC® System with Midas Rex® Legend® instruments in that the devices have the same durability when touching orthopedic structures in removing soft tissue from bone.

The Generator G11 supplies power to both the Enseal® electrosurgical and Harmonic® ultrasonic surgical devices. The Subject Device Generator G11 software version 2013_1 enables the maximum ultrasonic power output to 60W.

Performance Data:

Ex-vivo and in-vivo tests were performed to verify that the performance of the Harmonic Scallop Blade instrument meets the definition of substantial equivalence to the Predicate Devices, Harmonic® Blade HK105, Codman Cobb, and Medtronic Integrated Power Console (IPC®) System, Midas Rex® Legend® instruments. Device performance was assessed against design requirements, including bench and preclinical testing. Applicable software verification and validation testing was completed per FDA Guidance for industry and staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "General Principles of Software Validation; Final Guidance for Industry and FDA Staff." Bench testing includes device durability, acoustics, and reliability testing. Preclinical studies include acute and 30-day survival studies, and demonstrate device performance on spot coagulation, general

procedure capability, hemostasis following muscle transection, tissue effects and healing response, and blade strength to access orthopedic procedures. These testing criteria demonstrate that the Harmonic® Scallop Blade performs as intended and is substantially equivalent to the Predicate Devices.

This submission does not include data from Clinical Studies.