May 21, 2021

Ethicon Endo-Surgery, LLC
% Ms. Ruth James, MSc, RAC
Senior Regulatory Affairs Program Lead
Ethicon Endo-Surgery, LLC.
4545 Creek Road
Cincinnati, OHIO 45242

Re: K211273
Trade/Device Name: Harmonic Hand Piece, Blue, Harmonic Hand Piece, Gray
Regulatory Class: Unclassified
Product Code: LFL
Dated: April 26, 2021
Received: April 27, 2021

Dear Ms. James:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211273

Device Name
HARMONIC® Blue Hand Piece
HARMONIC® Gray Hand Piece

Indications for Use *(Describe)*
The HARMONIC® Blue Hand Piece, when used in conjunction with the HARMONIC® Instruments, 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.

The HARMONIC® Gray Hand Piece, when used in conjunction with the HARMONIC® Instruments, 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Ethicon Endo-Surgery, LLC
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USA

K211273

510(k) Summary

Submitter Information: Ethicon Endo-Surgery, LLC
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Date Prepared May 20, 2021

Device Trade Name:	HARMONIC® Blue Hand Piece HARMONIC® Gray Hand Piece
Models:	HARHPBL, HARHPBLCN (Blue) HARHPGR, HARHPGRCN (Gray)
Device Class:	Unclassified
Panel:	II
Classification (Product) Code:	79, General & Plastic Surgery LFL

Legally Marketed Predicate Devices:

- HARMONIC® Hand Piece, Blue (K063192)
- HARMONIC® Hand Piece, Gray (K002906)

This predicate has not been subject to a design-related recall.

Device Description

HARMONIC® Blue Hand Piece

The HARMONIC® Blue Hand Piece is designed to convert electrical energy from a compatible Ethicon Generator to mechanical motion for the instrument blade. The Blue Hand Piece is intended for use exclusively with a compatible HARMONIC Generator. The Blue Hand Piece is permanently attached to a blue cord which connects to the front of the Generator.

The Blue Hand Piece is a re-useable instrument with a limited service life. The Blue Hand Piece is programmed with a counter to limit the service life to 100 procedures. The generator will give a Hand Piece error after 100 procedures are completed. The number of activations during a procedure is not limited, and the counter will not log a procedure until the Hand Piece is unplugged from the generator or the generator is powered down. The number of remaining procedures is indicated on the display of the generator in the Systems Settings screen. The Hand Piece is compatible with generator software 2018-1 or later.

HARMONIC® Gray Hand Piece

The HARMONIC® Gray Hand Piece is designed to convert electrical energy from a compatible Ethicon Generator to mechanical motion for the instrument blades. This Hand Piece is intended for use with a compatible Ethicon Generator.

The Hand Piece is permanently attached to a cord which connects to the front of the Generator.

The Hand Piece is a re-useable instrument with a limited service life. The Hand Piece is programmed with a counter to limit the service life to 95 procedures. The generator will give a Hand Piece error after 95 procedures are completed. The number of activations during a procedure is not limited, and the counter will not log a procedure until the Hand Piece is unplugged from the generator or the generator is powered down. The number of remaining procedures is indicated on the display of the generator in the Systems Settings screen. The Hand Piece is compatible with generator software 2018-1 or later.

The Hand Piece is packaged with a Blade Wrench and Test Tip. The Blade Wrench is used to secure instrument blades to the Hand Piece. The Hand Piece, Blade Wrench, and Test Tip are packaged non-sterile and must be sterilized per their insert instructions prior to use.

Indications for Use for new devices (identical to predicates)

The HARMONIC® Blue Hand Piece, when used in conjunction with the HARMONIC® Instruments, 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.

The HARMONIC® Gray Hand Piece, when used in conjunction with the HARMONIC® Instruments, 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.

Comparison of technological characteristics with the predicate device
At a high level, the new and predicate devices are based on the following same technological elements:

Characteristic	**New Devices**	**Legally marketed Predicate Devices K063192, K002906**
Indications for Use	Identical	Identical
Contraindications	Identical	Identical
Non-Sterile, Single Patient Use	Yes	Identical
Bio-Compatibility of Materials: All tissue-contacting materials comply with ISO 10993-1.	Yes	Yes
Packaging Method	Identical	Identical
Device Operation	Identical	Identical

The following technological differences exist between the new and predicate devices:

- The new Hand Pieces have a standard connector (tear-drop) interface to GEN11 generators.
- The new Hand Pieces are only compatible with GEN11 operating 2018-1 software and later generators.
- The Electrically erasable programmable read-only memory (EEPROM) in the Hand Pieces has been upgraded with cybersecurity improvements.
- The cable design has been harmonized for both Blue and Gray Hand Pieces.
- The cable components have been modified to improve hand activation durability
- There is a new protective end cap, used in packaging, for the Gray Hand Piece.

Performance Data

Risk analyses for each device modification are provided. Verification testing, Biocompatibility evaluation and Electrical testing were conducted to confirm device modifications do not raise new issues of safety or effectiveness.

Clinical studies were not required to demonstrate substantial equivalence.

Conclusions

Risk analyses show that the risk profile of the new devices has not changed as a result of the described changes while having the same intended use as the predicate devices. Verification testing, Biocompatibility evaluation and Electrical testing conducted, confirm the performance of the new devices is consistent with the predicate devices and does not raise any new questions of safety and effectiveness.