June 29, 2020

Ethicon Endo-Surgery, LLC
% Ruth James
Senior Regulatory Affairs Program Lead
Ethicon Endo-Surgery, Inc.
4545 Creek Rd
Cincinnati, Ohio 45252

Re: K200420
Trade/Device Name: Echelon Contour Curved Cutter with blue reload, Echelon Contour Curved Cutter with green reload, Echelon Contour Curved Cutter reload, Blue, Echelon Contour Curved Cutter reload, Green
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: February 18, 2020
Received: February 20, 2020

Dear Ruth 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,

For Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200420

Device Name
Echelon Contour™ Curved Cutter Stapler with Reload

Indications for Use *(Describe)*
The Echelon Contour™ Curved Cutter with Reload is intended for transection and resection in colorectal surgical 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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ETHICON
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510(k) Summary

Submitter Information: Ethicon Endo-Surgery, LLC
475 Calle Street
Guaynabo, PR 00969

Application Correspondent
Ruth James MSc, RAC
Sr. Regulatory Affairs Program Lead
Ethicon Endo-Surgery, LLC.
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Date Prepared February 18, 2020

Device Trade Name:	Echelon Contour™ Curved Cutter Stapler with Reload
Models:	GCS40B, GCS40G, GCR40B, GCR40G
Device Common Name:	Cutter/Stapler
Classification Regulation:	21 CFR 878.4750; Implantable Staple
Device Class:	II
Panel:	79, General & Plastic Surgery
Classification (Product) Code:	GDW

Legally Marketed Predicate Device: CONTOUR™ Curved Cutter Stapler and Reload (cleared under K091322, K062869, K040038)

This predicate has not been subject to a design-related recall.
Echelon Endoscopic Linear Cutter Reload, Black (K131663, K112056) was used as reference device in this submission for MRI Compatibility.

Device Description
The Echelon Contour™ Curved Cutter Stapler with reload is a multifire, single patient use device with a curved head that cuts and staples. The device will provide ligation of colorectal structures when permanent ligation is required.

The device delivers four staggered rows of titanium staples, with a knife between the second and third row of staples, and staples and creates a 40 mm curved transection. The device is designed with a feature which prevents closing if a used reload or no reload is in the instrument.

Another feature is provided to prevent firing unless the closure trigger is latched in the closed position. A retaining pin holds tissue in place and can be positioned either manually or by squeezing the closure trigger.

The instrument is preloaded with a either a blue or green reload. The instrument may be further loaded for a maximum of six firings per instrument during a single procedure.

Each reload includes a knife blade with two staggered rows of staples on each side, an anvil, a yellow cutting washer, a retaining pin, and a staple retainer.

Indications for Use

The Echelon Contour™ Curved Cutter with Reload is intended for transection and resection in colorectal surgical procedures.

The Indications for Use statement for the new device is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.

Comparison of technological characteristics with the predicate device

At a high level, the subject and predicate devices are based on the following same technological elements:

- Intended Use
- Indications for use are within the already cleared indications for predicate device
- Device design and operation is the same
- Same open staple is used in both devices

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

- The reloads are designed with new Gripping Surface (GST) features and a new 3D final staple shape

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

Bench testing included the following tests:

- Leak Onset Pressure Equivalency
- Formed Staple Height (FSH) Equivalency
- Staple Line Integrity and Staple Form Quality Equivalency
- Force to Close
- Force to Fire
- Handle Performance Characterization

The new device was shown to have equivalent performance to the predicate device in all the bench tests conducted. The data generated by each test supports a finding of substantial equivalence of the new device to the predicate device.

Biocompatibility testing

The biocompatibility of materials used in the Echelon Contour™ Curved Cutter Stapler with Reload was evaluated based on ISO 10993-1:2018, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing", and on FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", issued on June 16, 2016.

All in vitro and in vivo testing performed on materials was conducted in accordance with applicable requirements in the FDA's Good Laboratory Practice Standard (21 CFR 58).

The battery of testing included the following tests:

- ISO Cytotoxicity
- ISO Sensitization
- ISO Irritation (Intracutaneous Reactivity)
- ISO Acute Systemic Toxicity
- USP Material Mediated Pyrogenicity

There were no findings of toxicological concern, for the new devices, with testing conducted per ISO 10993-1:2018.

Accelerated Aging Stability

Testing was performed on new devices that have been exposed to environmental and accelerated aging preconditioning. Device performance was maintained for the entirety of the proposed shelf life.

Sterilization

Pyrogen testing was conducted. The pyrogen testing and the risk assessment showed there is minimal to no risk for the staples with respect to the presence of endotoxins.

Animal Study

The following studies were included in this submission:

- Hemostasis study
- Survival study

Both studies were conducted in accordance with applicable requirements in the FDA's Good Laboratory Practice Standard (21 CFR 58).

The new device was shown to have equivalent performance to the predicate device in the pre-clinical tests conducted. The data generated by each test supports a finding of substantial equivalence of the new device to the predicate device.

Clinical Studies

This submission does not include data from Clinical Studies.

MR Safety Information

Non-clinical testing demonstrated the staples in the device are MR conditional.

Performance Data summary

The conclusions of the testing demonstrate that the new device performs substantially equivalent to the predicate device and does not raise new questions of safety and effectiveness.

Overall Conclusions

The non-clinical data included in this submission support the stapler is as safe as the predicate device and demonstrate that the Echelon Contour™ Curved Cutter Stapler with Reload should perform as intended in the specified use conditions and perform comparably to the predicate device that is currently marketed for the same intended use