February 9, 2018

Symmetry Surgical Inc.
Christopher Smith
Sr. Director of Regulatory Compliance
3034 Owen Drive
Antioch, Tennessee 37013

Re: K173272
Trade/Device Name: Ergonomic Handle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 9, 2017
Received: October 12, 2017

Dear Christopher Smith:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173272

Device Name
Ergonomic Handle

Indications for Use *(Describe)*
Laparoscopic surgical manual instruments are designed to be used endoscopically through cannula to perform cutting, grasping, dissecting, retracting, and manipulating functions.

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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Section 4: 510(k) SUMMARY

Submitter's Name: Symmetry Surgical Inc.
Address: 3034 Owen Drive, Antioch, TN 37013 USA
Telephone: 1-800-251-3000
Fax: 1-800-342-3272
Submitter: Christopher Smith
Date Prepared: February 8, 2018

Device Trade Name: Ergonomic Handle
Common Name: Ergonomic Handle
Device Classification: Class II
Classification Name: Endoscope and Accessories
Regulation: 21 CFR 876.1500
Device Regulation Panel: General and Plastic Surgery
Device Product Code: GCJ
Predicate Device: K150127 Laparoscopic Handles with PEEK Insulation

Device Description:
Symmetry® laparoscopic surgical manual instruments consist of a handle and a 5mm shaft, which hold various 5 mm inserts cleared under K973259. The shaft comes in two lengths: 33 cm and 45 cm. One handle can be used in combination with a variety of different 5 mm inserts. The handles have monopolar posts which allow them to be used for electrosurgery.

The ergonomic laparoscopic handles have an adjustable grip. They may be used in one of the three handle positions: pistol grip, hybrid, and inline. To change the handle position, retract the position adjustment button and lock the grip in the chosen position. The handle comes in two sizes.

Intended Use:
Laparoscopic surgical manual instruments are designed to be used endoscopically through cannula to perform cutting, grasping, dissecting, retracting, and manipulating functions. The Ergonomic handle is intended to be used with 5mm inserts available from K&W and previously cleared under K973259.

Indications For Use:
Laparoscopic surgical manual instruments are designed to be used endoscopically through cannula to perform cutting, grasping, dissecting, retracting, and manipulating functions.

Technological Characteristics of the Device Compared to the Predicate Device:
Indications between the predicate and subject device are equivalent. Both devices are intended to be used endoscopically to perform cutting, dissecting, retracting, and manipulating functions.

- The subject device has additional ability to adjust the handle position to allow for better surgeon comfort but this does not affect the function of the device.
- The subject device allows the devices to be disassembled for easier cleaning and sterilization.

- The subject device is only available in a 5mm option and does not introduce a new worst-case scenario.
- The subject device adjustable grip angle allows the surgeon to use the device in a more comfortable manner depending on the procedure and does not affect the performance of the device for its indicated uses.

There are no technological characteristics that raise new issues of safety or effectiveness. Based upon the similarities of the Ergonomic Handle and the predicate device studied, the safety and effectiveness of the Ergonomic Handle is substantially equivalent to the predicate device referenced.

Assessment of Performance Data:
Design verification and validation testing including biocompatibility, sterilization, cleaning, electrical safety, and mechanical testing was performed in support of the substantial equivalence determination.

Biocompatibility Testing
The Ergonomic handles are considered External Communicating Devices: Tissue/Bone/Dentin with limited contact duration (<24 hours). Cytotoxicity, Intracutaneous Reactivity, Sensitization and Acute Systemic Toxicity tested was performed on the finished devices. Biocompatibility testing was completed per ISO 10993-1, ISO 10993-5, ISO 10993-10, and ISO 10993-11. All acceptance criteria of the standards were met through testing or justified through risk assessment.

Sterilization Validation
The Ergonomic handles are provided to the user non-sterile and must be sterilized prior to the initial use and each subsequent use. Sterilization testing was conducted in accordance with ISO 17665-1. Testing was done to validate common Pre-vacuum steam sterilization cycles of 132°C for 4 minutes and 134° for 3 minutes to achieve a Sterility Assurance Level of 10^{-6}.

Electrical Safety
The proposed devices comply with the ANSI/AAMI ES60601-1 "Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance" standard for safety and the IEC 60601-2-2 "Medical Electrical Equipment – Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories" for high frequency devices.

Mechanical Testing
Reliability testing was conducted that included both shaft deflection and electrical safety testing after simulated use. There are additional tests performed for internal use to characterize surgeon satisfaction with the device over the lifetime of the product and those tests are not applicable to the safety or efficacy of the product for its intended use.

Based off the previously mentioned tests the subject device is substantially equivalent to the predicate device.

Conclusion:
The submitted information in this premarket notification is complete, and based on the indications for use, technological characteristics, performance testing and comparison to the predicate devices, the Ergonomic Handle raises no new questions of safety or effectiveness and can be considered to be substantially equivalent to the predicate device.