DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 7, 2016

Symmetry Surgical Inc.
% Ms. Michele Lucey
Regulatory Consultant
Lakeshore Medical Device Consulting LLC
128 Blye Hill Landing
Newbury, New Hampshire 03255

Re: K161744
Trade/Device Name: Symmetry Sharp Kerrison® Rongeur
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: August 6, 2016
Received: August 8, 2016

Dear Ms. Lucey:

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" (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.

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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K161744

Device Name
Symmetry Sharp Kerrison® Rongeur

Indications for Use *(Describe)*
The Symmetry Sharp Kerrison Rongeur is indicated for cutting bony tissue of the spine. The Symmetry Sharp Kerrison Rongeur is a manually operated instrument that consists of a Handle and Tips (available in single use or reusable).

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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K161744

Symmetry Surgical Inc

Special

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c)

Submitter Information:

Submitter's Name:	Symmetry Surgical Inc.
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Submitter Regulatory Contact:	Michele Lucey Lakeshore Medical Device Consulting, LLC 128 Blye Hill Landing Newbury, NH 03255 603-763-3455
Date Prepared:	September 7, 2016
Device Trade Name:	Symmetry Sharp Kerrison® Rongeur
Common/Usual Name:	Manual Rongeur
Regulation Name:	Manual Rongeur
Regulation Number:	21 CFR 882.4840

Class	2
Product Code	HAE
Predicate Device	K130541 Kerrison Disposable Tip Rongeur
Intended Use	The Symmetry Sharp Kerrison® Rongeur is indicated for cutting bony tissue of the spine. The Symmetry Sharp Kerrison® Rongeur is a manually operated instrument that consists of a Handle and Tips (available in single use or reusable).
Device Description	The Symmetry Sharp Kerrison Rongeur is designed to have detachable tips that are disposable. The detachable tips are provided as either sterile single use or as nonsterile reusable tips. The reusable tips must be cleaned and sterilized before use. The sterile, disposable tips are available in 4 cup sizes: (1, 2, 3, and 4 mm); which are identifiable by etchings on each device. The Reusable Tips for the Symmetry Sharp Kerrison® Rongeur Handle are available in 3 cup sizes: (2, 3, and 4 mm); which are identifiable by etchings on each device. The reusable tips have a mating code etched on each pair to ensure that only matched pairs are used. Each tip is designed with a shaft key that fits into its mating slot on the detachable instrument handle. The tip has cups, one within the stationary footplate and the other within the upper sliding shaft, performing the cutting of the bony tissue in the spine area. The various cup sizes within the working tips provide the surgeon various cutting configurations needed for the different characteristics of the bony tissue within the spine. The Symmetry Sharp Kerrison® Rongeur Handle operates with a cup and ball assembly for smooth motion of the footplate when the handle is squeezed. The detachable, reusable instrument handles of this device are provided non-sterile and must be cleaned and sterilized prior to use. The instrument handles are available in three shaft lengths: (5, 6, and 7 inches).

Technological Characteristics of the Device Compared to the Predicate Device:

Feature/Specification	Subject Device Symmetry Sharp Kerrison® Rongeur	Predicate Device Symmetry Kerrison Disposable Tip Rongeurs K130541	Comparison Of Subject Device to Predicate Device
General Description	Manual Rongeur	Manual Rongeur	Same
Intended Use	The Symmetry Sharp Kerrison® Rongeur is indicated for cutting bony tissue of the spine. The Symmetry Sharp Kerrison® Rongeur is a manually operated instrument that consists of a Handle and Tips (available in single use or reusable).	The Rongeur (handle and tip) is indicated for cutting bony tissue of the spine. The Symmetry Kerrison Disposable Tip Rongeur is a manually operated instrument that consists of handle and disposable detachable tips.	Same, except for the removal of "disposable" to allow for a general tip description
Device Size and Geometry	Tips are provided in 4 cup sizes, 1,2, 3, and 4 mm. Handle is provided in three shaft lengths, 5, 6, and 7 inches	Tips are provided in 4 cup sizes, 1,2, 3, and 4 mm. Handle is provided in three shaft lengths, 5, 6, and 7 inches	Same, except for the 1mm tip will not be marketed as a reusable device
Materials	Tips are 420 stainless steel Handle is primarily 420 stainless steel with mating component parts made from Mating components are manufactured with German Stainless Steel 1.4301, 1.4310 (equivalent to 304 SS, 303 SS, and 301 SS, respectively)	Tips are 420 stainless steel with an ABS insert Handle is primarily 420 stainless steel with mating component parts made from German Stainless Steel 1.4301, 1.4310 (equivalent to 304 SS, 303 SS, and 301 SS)	Same except for the removal of the ABS insert which had no mechanical or performance function, no longer present in the current disposable tip design
Mechanism of action	Cutting shaft and footplate	Cutting shaft and footplate	Same

Feature/Specification	Subject Device Symmetry Sharp Kerrison® Rongeur	Predicate Device Symmetry Kerrison Disposable Tip Rongeurs K130541	Comparison Of Subject Device to Predicate Device
	closed on tissue through mechanical handle compression	closed on tissue through mechanical handle compression	
Limits of use	Reusable handle, disposable tips, and reusable tips	Reusable handle and disposable tips	Similar, both devices have reusable and disposable components
How Supplied	Disposable tips are sterile Reusable tips and reusable handle are nonsterile and must be cleaned and sterilized before first use	Disposable tips are sterile Reusable handle is nonsterile and must be cleaned and sterilized before first use	Same, only difference is inclusion of the reusable tips
SAL	10^{-6}	10^{-6}	Same
Sterilization Method	Gamma for the disposable tips Steam for the reusable handle and disposable tips	Gamma for the disposable tips Steam for the reusable handle	Same except for adding steam for reusable tips

Principles of Operation: Each tip has cups, one within the stationary footplate and the other within the upper sliding shaft, performing the cutting of the bony tissue in the patient's spinal area when the instrument handles are compressed by the surgeon.

Performance Data: Design verification and validation testing including sterilization for both the reusable and disposable components, cleaning for the reusable components, cutting performance, durability, shelf life (disposable tips), and corrosion resistance. The following table provides details relative to the device performance testing used to support substantial equivalence:

Summary of Performance Testing Conducted to Establish Substantial Equivalence				
Performance Test	Verification and Validation Activities	Acceptance Criteria	Results	Device used for Testing
Validation of the recommended cleaning process for reusable components	Cleaning challenge for reuse to confirm the device can be effectively cleaned.	Cleaning validation results must meet the following criteria acceptance criteria: residual proteins residual hemoglobin and residual carbohydrates	For substantial equivalence the device must be able to be adequately cleaned for reuse Pass	Symmetry Sharp Kerrison® Rongeur Handle (worst case)
Validation of the recommended steam sterilization cycles for reusable components	Sterilization validation	Must meet the requirements as defined in the applicable ISO Standard for the overkill method to achieve an SAL of 10^{-6}	For substantial equivalence the reusable components must be able to be effectively sterilized with steam sterilization Pass	Symmetry Sharp Kerrison® Rongeur Handle (worst case)
Validation of gamma sterilization cycle for single use components	Sterilization validation to confirm 10^{-6} SAL for gamma sterilzation	Must meet the requirements as defined in the Applicable ISO standard for VD_{Max} to achieve an SAL of 10^{-6}	For substantial equivalence the single use component must be able to be sterilized using gamma sterilization Pass	Symmetry Sharp Kerrison® Rongeur Tip
Confirmation of multiple use for the reusable components	Verification testing confirming performance for multiple uses	The detachable tips must maintain acceptable cutting performance for up to 100 cuts. Reusable handle must maintain performance for 50 reuse cycles	For substantial equivalence the reusable must be sufficiently robust to support reuse Pass	Detachable Tips for the Symmetry Sharp Kerrison® Rongeur Handle And the Symmetry Sharp Kerrison® Rongeur Handle

Summary of Performance Testing Conducted to Establish Substantial Equivalence				
Performance Test	Verification and Validation Activities	Acceptance Criteria	Results	Device used for Testing
Resistance to corrosion for the reusable components	Corrosion testing	Must not corrode when exposed to a corrosion challenge	For Substantial Equivalence device must be resistant to corrosion Pass	Symmetry Sharp Kerrison® Rongeur Handle (same material as the reusable tips)
Packaging validation/shelf life for single use components	Shelf Life studies per ASTM standards	Package and product must demonstrate package and product stability over the claimed shelf life period	Package and product performance evaluations conducted on the single use component for shelf life confirm a two year shelf life Pass	Symmetry Sharp Kerrison® Rongeur Tip

Conclusion: Based on the performance testing and comparison the subject device is substantially equivalent to the predicate.