K130541

510(k) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

General Company Information

Company Name:	Symmetry Surgical
Company Address:	3034 Owen Drive Nashville, TN 37013
Company Telephone:	615-964-5558
Contact:	Dalene T. Binkley, MS, RAC
Contact Address and Telephone:	1927 N. Arthur Drive Columbia City, IN 46725 260-244-4189
Date:	February 24, 2013
Device Trade Name:	Symmetry Kerrison Disposable Tip Rongeurs
Common Name:	Manual Rongeurs
Classification Name and Reference:	HAE - Class II (21 CFR 882.4840)
Predicate Device:	Codman Kerrison Laminectomy Rongeurs, Preamendment Integra Kerrison Rongeurs, K092227, cleared 2/17/10

AUG 05 2013

Device Description: The Symmetry Kerrison Disposable Tip Rongeurs are manually operated instruments, provided with a non-sterile reusable handle and a set of sterile, disposable tips, indicated for cutting bony tissue of the spine. They represent a design modification to the predicate devices, the Codman Kerrison Laminectomy Rongeurs and the Integra Kerrison Rongeurs, introducing disposable tips to the device.

The Symmetry Kerrison Disposable Tip Rongeurs handles are comprised of stainless steel, and operate with a cup and ball assembly for smooth motion of the footplate when the handle is squeezed. The handles and disposable tips are provided in various sizes to help provide the surgeons with more options.

Intended Use: The Symmetry Kerrison Disposable Tip Rongeurs are indicated for cutting bony tissue in the area of the spine. This intended use is similar to that of our predicate devices.

Technological Characteristics: The technological characteristics of the proposed device are similar or the same as those of the predicate devices. The design modification introduces disposable tips to the device providing the surgeon with a disposable option while assuring the sterility and sharpness of the tips. This design modification does not impact the safety and effectiveness of the device. The Symmetry Kerrison Disposable Tip Rongeurs are substantially equivalent to their predicate devices Codman Kerrison Laminectomy Rongeurs and Integra Kerrison Rongeurs. Substantial equivalence is based on intended use, performance characteristics, materials, and principle of operation.

Performance Data (Nonclinical and/or Clinical): Performance testing consisting of cut testing, foot load plate testing, cycle testing and corrosion resistance demonstrates the proposed devices perform according to its description and intended use and supports the safety and effectiveness of the device. The Symmetry Surgical Disposable Tip Rongeurs conform to their design specifications and are substantially equivalent to the commercially distributed devices for the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 5, 2013

Symmetry Surgical
% Dalene T. Binkley, MS, RAC
Regulatory Affairs Consultant
1927 N. Arthur Drive
Columbia City, IN 46725

Re: K130541
Trade/Device Name: Symmetry Kerrison Disposable Tip Rongeurs
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: June 18, 2013
Received: June 25, 2013

Dear Ms. Binkley:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130541

Device Name: Symmetry Kerrison Disposable Tip Rongeurs

Indications For Use:

The Symmetry Kerrison Disposable Tip Rongeurs are indicated for cutting bony tissue of the spine.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K130541