November 8, 2018

RJR Surgical, Inc.
% Karen Warden
Representative/Consultant
BackRoads Consulting, Inc.
PO Box 566
Chesterland, Ohio 44026-0566

Re: K180949
Trade/Device Name: Steribite®
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: October 4, 2018
Received: October 9, 2018

Dear Karen Warden:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Matthew C. Krueger -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180949

Device Name
Steribite®

Indications for Use *(Describe)*
The Steribite® Rongeur is a manually operated instrument indicated for cutting or biting bone during surgery involving the skull or spinal column.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K180949 510(k) Summary

Date	November 6, 2018
Sponsor **Sponsor Telephone**	RJR Surgical, Inc. 2530 Superior Avenue, STE 703 Cleveland, OH 44114 (216)241-2804
510(k) Contact	Karen E. Warden, PhD BackRoads Consulting PO Box 566 Chesterland, OH 44026 Office: (440)729-8457
Subject Device	
Trade Name	Steribite®
Common Name	Kerrison Rongeur
Regulatory Class	Class II
Classification **Product Code**	21 CFR 882.4840 Manual Rongeur HAE
Predicate Device	
K150428	Integra® Kerrison Rongeurs 21 CFR 882.4840 Manual Rongeur HAE
Reference Device	
K140927	Universal Navigation Instruments for EXPEDIUM® and VIPER® MIS Spine Systems was used to justify the device material (420 stainless steel) in this anatomic location (spine). This reference device was used in addition to the processing of the materials, manufacturing method, and manufacturing residual testing were provided for the subject device.
Subject Device	
Device Description	Steribite® is a system of disposable manual surgical Kerrison rongeurs. The instruments are offered in a 40° up configuration having shaft lengths of 8 and 11 inches and bite sizes 1mm to 5mm to accommodate variations in surgical need. The devices are sold sterile and single use only.
Intended Use	The Steribite® Kerrison rongeur is a manually operated instrument indicated for cutting or biting bone during surgery involving the skull or spinal column.
Materials of Use	The shaft portion of the device is manufactured from stainless steels (420 and 17-4PH for patient contacting; 302 and 316 for rivet pins and springs). The handles are manufactured from polyarylamide resin (type IXEF PARA GS-1022, Solvay).

Table: Technological Characteristics as Compared to the Predicate Device

Steribite® possesses similar technological characteristics as compared to the predicate device K150428. Different characteristics do not raise different questions of safety and effectiveness, and scientific methods were applied to evaluate different characteristics' effects on safety and effectiveness.

	Subject Device K180949	**Predicate Device K150428**
Trade Name	Steribite®	Integra® Kerrison Rongeurs
Indications for Use	The Steribite® Rongeur is a manually operated instrument indicated for cutting or biting bone during surgery involving the skull or spinal column (Rx).	Integra® Kerrison Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column (Rx).
Manufacturer	RJR Surgical, Inc.	Integra York PA, Inc.
Anatomic location	Skull and spine	Skull and spine
Patient contacting Material	Stainless steel (types 420 and 17-4PH)	Stainless steel (type 420)
Basic design	Scissor action grip with translational slide of the punch shaft to the angled footplate	Scissor action grip with translational slide of the punch shaft to the angled footplate
Dimensions		
Shaft length	8 and 11 inches	4.75 to 15 inches
Footplate	40°, up	40° and 90°, up/down
Bite width	1 to 5mm, 1mm increments	1 to 6mm, 1mm increments
Sterilization	Provided sterile, single use	End user sterilized, reusable

Non-Clinical Performance Testing Submitted to Demonstrate Substantial Equivalence

Mechanical testing was performed to assess the performance of the subject device models, 1-5 mm bite sizes and 8-11 in handles, as compared to a similar reference device, K150468, K2 Manual Rongeur:

- Cut performance: Steris IMS test standard was applied to demonstrate full profile cut in simulated use.
- Cut force: a controlled load ranging from 10-35 pounds was applied to the handles of each device under test in a stepwise fashion (5 pounds) to assess cut force for a 2mm thick bone analog compared to the reference device.
- Handle strength: A continuous load to failure was applied to the devices to demonstrate that the force to cause failure was least twice the required cutting force.

Sterilization
Sterilization validation was conducted in accordance with ISO 11137-1:2006, *Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices and ISO 11137-2:2006, Sterilization of health care products—Radiation— Part 2: Establishing the sterilization dose.*

Bacterial endotoxin testing was conducted in accordance with AAMI ST72:2011/(R)2016, *Bacterial Endotoxins Test methods, routine monitoring, and alternatives to batch testing.*

The packaging performance and stability testing were conducted in accordance with ANSI/AAMI/ISO 11607-1:2006/(R)2010 *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems.*

Biocompatibility

The Steribite Rongeur is categorized as an external communicating device with limited contact (≤24 h) with tissue/bone, cerebrospinal fluid (CSF), and blood (indirect contact with blood through CSF as CSF is reabsorbed into the venous system). The appropriate biocompatibility endpoints that were assessed include:

1. Cytotoxicity
2. Sensitization
3. Irritation/intracutaneous reactivity
4. Acute systemic toxicity
5. Material-mediated pyrogenicity
6. Hemolysis

ISO 10993-5 Third Edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Third Edition 1020-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ASTM F2459 was applied to demonstrate residual manufacturing material cleanliness

Clinical performance testing was not submitted in this 510(k).

Conclusion

Steribite® possesses indications for use and technological characteristics similar to the predicate devices. The performance testing demonstrated that the device is as safe and effective as the predicate and performs as well as the predicate. Therefore, Steribite® is substantially equivalent to the predicate.