K131851

DEC - 6 2013

510(k) Summary

Submitter Information:

OsteoMed
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Contact Person: Mrs. Piedad Peña, MS

Date Prepared: October 26, 2013

Device Information:

Proprietary/Trade Name: OsteoMed Neuro Rongeur
Common Name: Manual Rongeur
Classification Name:
- Regulation Number: 21 CFR 882.4840
- Regulation Name: Manual Rongeur
- Product Code: HAE

Device Class: II

Predicate Devices:

Instrumed Micro Kerrison Rongeur (K081651)
Common Name: Manual Rongeur
Classification Name:
- Regulation Number: 21 CFR 882.4840
- Regulation Name: Manual Rongeur
- Product Code: HAE

Device Class: II

Integra Kerrison Rongeur (K09227)
Common Name: Manual Rongeur
Classification Name:
- Regulation Number: 21 CFR 882.4840
- Regulation Name: Manual Rongeur
- Product Code: HAE

Device Class: II

Device Description:

The OsteoMed Neuro Rongeur is a low profile instrument designed to cut bone 180° off the straight axis of the ronguer. It has a rectangular scoop-shaped tip which compresses and cuts cranial or spinal bone. The ronguer is a manually operated instrument used for cutting and biting soft tissue and bone during surgery involving the skull or spinal column.

The OsteoMed Neuro Rongeur is made from Medical Grade Stainless Steel per ASTM F-899.

Indications for Use/Intended Use:

The OsteoMed Neuro Rongeur is a manually operated instrument indicated for cutting or biting bone during surgery involving the skull or spinal column.

Target Population:

Adults and Pediatric population

Technological Characteristics:

The OsteoMed Neuro Rongeur, the Instrumed Micro Kerrison Rongeur (K081651) and the Integra Kerrison Rongeur (K092227) are predicate devices used for cutting bone and soft tissue during surgery of the skull and the spinal column. The predicates have a scoop-shaped cutting tip which also compress and cut bone. The difference between the predicate devices and the OsteoMed Neuro Rongeur is the cut. The cut is made at 180 degrees off the straight axis, as oppose to 90 degrees off the straight axis for the predicates. The change in the design does not affect the change in the overall cutting mechanics of the device.

Material used for the OsteoMed Neuro Rongeur and the predicates is medical grade stainless steel. The material used for the OsteoMed Neuro Rongeur and the predicates is biocompatible.

Performance / Clinical Data:

The OsteoMed Neuro Rongeur was compared to the Instrumed Micro Kerrison Rongeur (K081651) and the Integra Kerrison Rongeur (K092227). The testing consisted of force comparison of the Instrumed Micro Kerrison Rongeur (K081651), while making cuts in the same media. The data demonstrated that both instruments made effective cuts and performed equally. Therefore the OsteoMed Rongeur performed as well as the Instrumed Micro Kerrison Rongeur.

The indications for use of the OsteoMed Neuro Rongeur and the Integra Kerrison Rongeur are identical indications for both skull and spinal column bone cutting. The indications for use of the Instrumed Micro Kerrison Rongeur are also identical with the exception where cutting the skull is not included.

Clinical Testing is not required to support substantial equivalence.

In conclusion, the device is safe and effective and performs as well as the Instrumed Micro Kerrison Rongeur (K081651) and the Integra Kerrison Rongeur (K092227).

Substantial Equivalence:

Substantial equivalence for this device is based on similarities in intended use, function (design and technology), performance, and operational principle to the predicate devices, Integra Kerrison Rongeur (K092227) and Instrumed Micro Kerrison Rongeur (K081651) based on their promotional materials, labeling and clearance letter.

- The OsteoMed Neuro Rongeur intended use and indications for use is exactly like the Integra Kerrison Rongeur (K092227) for cranial and spine applications; Neuro Surgery.
- The material used for the OsteoMed Neuro Ronguer as is the same material used for both the Instrumed and Integra Rongeurs predicate rongeurs; stainless steel.
- The design, operational principle and technology of cutting the bone is similar to both the Instrumed and Integra predicate rongeurs. The material is captured and removed the same as the predicate devices. The down mechanical cut of the OsteoMed Neuro Ronguer is similar to the predicates, which have both down or up cuts as well. Therefore the differences in the direction of the mechanical cut do not add any safety or efficacy issues.

Due to the similarity of intended use, indications for use, function, materials, performance, and operational principle to the predicate devices, OsteoMed believes that the OsteoMed Neuro Rongeur does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

OsteoMed
c/o Mrs. Piedad Peña
Manager, Regulatory Affairs
3885 Arapaho Road
Addison, TX 75001

Re: K131851
Trade/Device Name: OsteoMed Neuro Rongeur
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: November 5, 2013
Received: November 6, 2013

Dear Mrs. Peña:

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" (21CFR 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,

Victor Krauthamer -A

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): K131851

Device Name: OsteoMed Neuro Rongeur

Indications For Use:

The OsteoMed Neuro Rongeur is a manually operated instrument indicated for cutting or biting bone during surgery involving the skull or spinal column.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Victor Krauthamer -A
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