JUN 27 2014

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Traditional 510(k) Summary

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Preparation Date: May 9th, 2014

Trade Name: HiCut™ Highspeed Instrument

Common Name: Bur

Classification Name: Neurological surgical devices

Device Description:

The HiCut™ Highspeed Instrument is a sterile packed, single-use cutting device with numerous tip designs and various lengths. The rear end is designed to fit in various commonly marketed surgical motor drill systems. The tip designs are similar to the commonly used tip designs.

The HiCut™ Highspeed Instrument is classified Class II (USA) (Class IIa in EU) per CFR, Part 882.4310. The HiCut™ Highspeed Instruments are simple powered burs to be inserted in pneumatic or electric powered motor drill devices.

Indications for Use:

HiCut™ Highspeed Instruments are surgical burs indicated for trephination, incision, cutting, removal, shaping, sawing of soft and hard tissue, bone and biomaterials in Orthopedic Surgery, Neurological and Spinal Surgery, ENT Surgery, Plastic and Maxillofacial Surgery, Arthroscopy, Sternotomy and General Surgery.

Intended Use:

The HiCut® Highspeed Instruments are intended to be single-used with a compatible surgical drill system for surgical bone work.

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Predicate Devices:

K113476	Drills, Burrs, Trephines & Accessories (Simple, Powered) (HBE)	The Anspach Effort, Inc.
K922299 / K013091	Drills, Burrs, Trephines & Accessories (Simple, Powered) (HBE)	Von Zeppelin Chirurgische Instrumente GmbH
K081475	Drills, Burrs, Trephines & Accessories (Simple, Powered) (HBE)	Medtronic Xomed, Inc.

Substantial Equivalence:

The HiCut™ Highspeed Instrument is substantially equivalent to the predicate devices. The equivalence is based on the device similarity to the predicate devices in indications of use, functionality and technological characteristics. The predicate devices K113476 and K081475 and the subject device are marketed in the European Union as substantially equivalent.

Technological Characteristics Comparison:

The technological characteristics of the subject device are based on the same HiCut™ Highspeed Instrument technology as the predicate devices. The material of both the HiCut™ Highspeed Instruments and of the predicate devices is surgical steel and some have a layer of diamonds. Similar to the other legally marketed burs used for surgical bone trephination (predicate devices) the Hicut™ devices are sterilized, individually packed devices and are used in conjunction with a surgical motor drive either pneumatic or electric.

Performance data testing:

This submissions includes the following non-clinical performance testing:

1) Biocompatibility: evaluated in compliance with ISO 10993.
Conclusion: Based on the selected materials and the provided evaluation, sufficient biocompatibility can be assumed.

2) Sterility: The method of radiation complies with the norms ISO 11137-1, 2 and 3.
Conclusion: The sterilization process is validated and ensures the sterility of the device throughout the shelf life and transport.

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The following sterility and shelf life testing is included in the submission:

Procedure/Criteria
Validation and Revalidation of the Radiation Sterilization Method
Establishment of the sterilization dose
Sterility assurance level (SAL)
Testing to ensure that packaging maintains device sterility (tested: integrity of the sealed seam according to ISO 11607) and is not adversely affected by aging (10-year of artificial aging test in accordance with ASTM F 1980) or transport (drop and vibration test based on ISO13355 and ASTM D 5276-98). The compliance with these criteria is ensured for at least the duration of shelf life.

3) Parameter comparison: Substantial equivalence to the predicate devices is based on the comparison of geometrical conditions and their critical values. Samples for each system of both the subject and predicate devices were compared. As a result, it can be stated that the subject devices have an equivalent rear end design, which ensures a secure fit into the corresponding drill chucks. Further qualification criteria of the subject device such as materials, design and mechanical constitution exceed the same results as the predicate devices. Thus, the substantial equivalence and therefore, the safety and effectiveness of the subject device can be established.

Considering the conclusions of the non-clinical tests, it can be stated that the subject device is as safe, as effective, and performs as well as the predicate devices.

Conclusions

Based upon the comparison of their functionality, intended use and technological characteristics to the predicate devices and the conclusions drawn from the non-clinical performance testing, the HiCut™ Highspeed Instruments proved to be substantially equivalent. The subject device described in this submission performs as intended and raises no 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

June 27, 2014

Adeor Medical AG
Mr. Fabio von Zeppelin
Chief Operating Officer
Kirchplatz 1
Pullach, 82049 Germany

Re: K130755
Trade/Device Name: HiCut™ Highspeed Instrument
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered simple cranial drills, burrs, trephines, and their accessories
Regulatory Class: Class II
Product Code: HBE
Dated: May 9, 2014
Received: May 27, 2014

Dear Mr. Zeppelin:

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" (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 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,

Binita S. Ashar -S
2014.06.27 10:50:49 -04'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K130755

Device Name
HiCut™ Highspeed Instrument

Indications for Use *(Describe)*
HiCut™ Highspeed Instruments are surgical burs indicated for trephination, incision, cutting, removal, shaping, sawing of soft and hard tissue, bone, and biomaterials in Orthopedic Surgery, Neurological and Spinal Surgery, ENT Surgery, Plastic and Maxillofacial Surgery, Arthroscopy, Sternotomy and General Surgery.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

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

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