K121253

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510(k) Summary

JUL 17 2012

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Preparation Date: April 16th, 2012

Trade Name: Meridian™ Cranial Perforator

Common Name: Cranial Perforator

Classification Name: Neurological surgical devices

Device Description:

The Meridian™ Cranial Perforator is a sterile packed, single-use cutting device intended to perform cranial burr-hole trephination in neurosurgery, driven by powered sources having a standardized and commonly used Hudson fitting clutch. The device automatically releases and stops perforating at cranial bone thickness of at least 3 mm. The Meridian™ pediatric perforators automatically release and stop perforating at cranial bone thickness of at least 1.5 mm. Both versions are available for burr-hole diameters of Ø6, Ø7 and Ø11 mm.

The Meridian™ Cranial Perforator per CFR, Part 882.4305, is a bone cutting and drilling instrument driven by a pneumatic or electric surgical motor in order to drill burr-holes through the skull of a patient. An integrated clutch mechanism prevents plunging of the perforator tip into the underlying dura and parenchyma tissue. The device is a Class II (USA) device and classified IIa in Europe (EEC).

The Meridian™ Cranial Perforator is a device similar in design and construction to other cranial perforators currently on the market; (e.g.: Acra-Cut models DGR-I and DGR-II and Codman Disposable Perforators etc...)

The Meridian™ Cranial Perforator requires a motor and an attached or integrated speed reducer in order to run the perforators at a speed range of 800 ... 1200 RPM.

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Intended Use:
The adeor® Meridian™ Cranial Perforator is a sterile, single-use cutting accessory intended for cranial burr-hole trephination in neurological surgery

Indications for Use:
The Meridian™ Perforator is a single-use surgical device for cranium perforation. The device automatically releases and stops perforating at cranial bone thickness of at least 3 mm. The Meridian™ pediatric perforator version automatically releases and stops perforating at cranial bone thickness of at least 1.5 mm.

Predicate Devices:

K933894, K071931	2	Disposable Perforators	2	Codman & Shurtleff, Inc.
K833266	3	Automatic Cranial Drill (Perforator)	3	Acra Cut, Inc.

Substantial Equivalence:
The Meridian™ Cranial Perforator is substantially equivalent to the currently marketed Acra-Cut DGR-II and Codman 26-1221 based on the device's similarity to the predicate devices in indications, principle of operations, materials and design. The predicate and subject devices are marketed in the European Union as substantially equivalent.

Technological Characteristics Comparison:

Parameters:	Acra-Cut Inc. DGR-II	Codman 26-1221	Adeor Meridian
Class	II	II	II
Indications for Use:	The Acra-Cut DGR-I is designed to automatically release and stop upon penetration of bone that is at least 3 mm thick. The DGR-II perforator is for use on thin skull/skull areas such as pediatric, temporal and suboccipital areas. They are designed to automatically release and stop upon penetration of bone as thin as 1 mm.	The Codman Disposable Perforator is for use in perforating the cranium. When properly used, it is designed to automatically disengage once perforation is accomplished and when pressure is removed from the drill point.	The Meridian™ Perforator is a single-use surgical device for cranium perforation. The device automatically releases and stops perforating at cranial bone thickness of at least 3 mm. The Meridian™ pediatric perforators automatically release and stop perforating at cranial bone thickness of at least 1.5 mm.
Dimensions and design:	similar	similar	similar
Materials	Plastic/ stainless steel	Plastic/stainless steel	Plastic/stainless steel
Fitting	Hudson	Hudson	Hudson
Principle of operation	similar	similar	similar
Cutting Performance	similar	similar	similar

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Burr hole diameters Ø	Ø 5/8,7/11,11/14 mm	Ø 6/9, 7/11, 11/14 mm	Ø 6/9, 7/11, 11/14 mm
Release mechanism	automatic	automatic	automatic
Rotation speed	800 RPM	Not-known	800-1200 RPM
Cutting performance	similar	similar	similar
Single-use supply	Gamma sterile	Gamma sterile	Gamma sterile

The technological characteristics of the subject device are based on the same cranial perforator technology as the predicate devices. Substantial equivalence of the Meridian™ Adeor cranial perforator is based upon the comparison to predicate device's characteristics.

Performance Standards:
Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug and Cosmetic Act.

Performance testing:
Substantial equivalence of the Meridian™ Adeor cranial perforator is based upon the comparison to predicate device's technical characteristics, indications, principle of operations, materials, design, and sterile supply as a single-use medical device.

Performance Bench Testing:
Samples of each model were used to drill holes in wood and animal bone to verify its mechanical functionality similar to predicate devices. The release mechanism worked reliable on both materials and stopped cutting as soon as the thin remaining pad of material became elastic.

On animal cadavers (pig head and calf shoulder) the release mechanism worked reliable and a clear bone pad has been formed which can easily be removed from the bur-hole. All tests have been performed satisfactory with the following positive remarks: The release mechanism worked reliable on several bur-holes. There was no friction observed between the rotating cutting parts. There has been no skidding of the subject device on the animal cadaver bone. A firm axial rotation and no wobbling of the subject device have been observed. A plain and even surface of the perforated bone and on the bone flap was observed. (See "Performance Bench testing protocol" for details in Chapter 18)

Sterilzation Process Validation:
The sterilization process is based on international Standards ISO 11137-1:2006, ISO 11137-2:2006 and ISO 11137-3:2006 which are recognized by FDA, as well.

The sterilization dose of 25 kGy has been validated according to ISO 11137-1:2006, ISO 11137-2:2006 (see Validation Report: Radiation Sterilization for product family "Perforators" n. PR/7-5-0-331). Latest revalidation has been performed 05-24-2012.

The sterilization process according to standards ISO 11137-1:2006, ISO 11137-2:2006 and ISO 11137-3:2006 has been validated (see Validation Report: Radiation Sterilization "HiCut & Perforators" n. V 7-5-0-235 R).

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The Test Report no. 100239-10 (see annex) investigation indicates that any microbial contamination of the device (average bioburden of three independent lots < 2 cfu/sample) was inactive by the irradiation of 4.8 kGy (according to prEN ISO 111137-2) Therefore, the Gamma irradiation method ensures effective conditions (sterility assurance level (SAL) $\leq 10^{-6}$) for the sterilization of the product by application of a minimum dose of 25 kGy.

Final Sterilization Process Assessment:
It can be confirmed that the requirements of the standards ISO 11137-1:2006, ISO 11137-2:2006 and ISO 11137-3:2006 and the validation protocol V 7-5-0-235 P with regard to the validation of the sterilization procedure for the product group "Perforators" are met. It could be shown that the documented procedure of a routine sterilization with $\geq$25 kGy ensures a SAL $\leq 10^{-6}$.

Conclusion:
Substantial equivalence of the Meridian™ Adeor cranial perforator in comparison to predicate device's the currently marketed Acra Cut DGR-I/II and Codman 26-1221 is demonstrated with regard to the similarity of device characteristics, described functionality, for the same indications of use, and sterile supply as a single-use medical device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Adeor Medical Technologies GmbH
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JUL 17 2012

Re: K121253
Trade/Device Name: Meridian™ Cranial Perforator
Regulation Number: 21 CFR 882.4305
Regulation Name: Powered Compound Cranial Drills, Burrs, Trephines, and their Accessories
Regulatory Class: Class II
Product Code: HBF
Dated: April 19, 2012
Received: April 27, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K121253

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The Meridian™ pediatric perforators automatically release and stop perforating at cranial bone thickness of at least 1.5 mm.

The perforators are available in three sizes: for burr-hole diameters of 6 mm, 7 mm and 11 mm.

Pediatric: for bone thickness of at least 1.5 mm:	For bone thickness of at least 3.0 mm:
PER 6-9-**SP**	PER 6-9-**S**
PER 7-11-**SP**	PER 7-11-**S**
PER 11-14-**SP**	PER 11-14-**S**

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

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