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JAN 18 2013

Premarket Notification [510(k)] Summary

Category	Comments
Date Summary Prepared:	October 8, 2012
Applicant:	NeuroPace Inc. 455 N. Bernardo Avenue Mountain View, CA 94043 USA Tel: 650-237-2700 FAX: 815-352-0788 www.neuropace.com
Applicant's Contact Information:	Isabella Abati VP, Regulatory Affairs
Device Trade/ Proprietary Name:	NeuroPace® Burr Hole Cover model 8110
Device Common Name:	Cover, Burr Hole
Device Classification:	II
Device Classification Name:	Burr Hole Cover (21 CFR 882.5250, Product Code GXR)

Substantial Equivalence Device Information

510(k) Summary – Predicate Device Information

Predicate Device(s):	Burr Hole Cover
Predicate Device Manufacturers:	Image-Guided Neurologics, Inc. (Medtronic)
510(k) Number:	K001096
Predicate Device Common Name:	Cover, Burr Hole
Predicate Device Classification Name & Citation:	Burr Hole Cover (21 CFR 882.5250, Product Code GXR)

Description of the Device

The NeuroPace® Burr Hole Cover (model 8110) (also referred to as "the device") includes a base (also referred to as a "retainer") that is screwed to the cranium (skull) using bone screws. The cap is an assembly comprised of a cap and a gasket. The cap is pressed into the base covering the opening in the base and securing a single 1.3 mm lead. The Burr Hole Cover requires three bone screws (1.5 to 1.8 mm).

The screws and driver are not included in the device's packaging. The contents of the unopened, undamaged package are sterile and non-pyrogenic.

Device Characteristics

The Burr Hole Cover is provided sterile (for single-use only) and consists of one model / size. The device is meant to be a permanent implant.

The Burr Hole Cover incorporates materials commonly found in medical devices that are known to be biocompatible. The cap and base are made from a synthetic polymer and the gasket is made from silicone.

The Burr Hole Cover is MR/CT scanning compatible and is sterilized using ethylene oxide gas (EtO).

The Burr Hole Cover does not include any software, incorporate any medicinal substances or contain any color additives.

Intended Use

The NeuroPace® Burr Hole Cover is intended for use following cranial surgery to cover a 14 mm burr hole. Secondarily, the NeuroPace Burr Hole Cover also can be used to support a 1.3 mm indwelling lead.

The predicate device is also intended for use as an implantable 14 mm burr hole cover following cranial surgery and can also be used to support indwelling catheters and electrodes (leads). (The intended use of the subject Burr Hole Cover is encompassed within the intended use of the predicate device and is narrower in scope than the intended use of the predicate device. Therefore, no safety or efficacy issues are presented by the difference between the intended use of the subject Burr Hole Cover and the intended use of the predicate device.

Comparison to Predicate Device

The Burr Hole Cover is substantially equivalent in its intended use, technology, target population, materials, and anatomical site to the Image-Guided Neurologics Burr Hole Cover (K001096). Image-Guided Neurologics (a.k.a. IGN) was acquired by Medtronic, Inc. in 2005. A side-by-side comparison of the NeuroPace Burr Hole Cover to the predicate device follows.

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510(k) Summary – Device Comparison

Description	Subject Device: NeuroPace, Inc. Burr Hole Cover	Predicate Device: Image-Guided Neurologics, Inc. Burr Hole Cover
Intended Use	Intended to cover a 14 mm burr hole following cranial surgery. Secondarily, the NeuroPace Burr Hole Cover can be used to support 1.3 mm indwelling leads.	Intended to be used as an implantable 14 mm burr hole cover following cranial surgery. The device can also be used to support indwelling catheters and electrodes. The device is MR/CT scanning compatible, and is provided sterile, and is for one time use only.
Device Classification Name and Product Code	Burr Hole Cover (21 CFR 882.5250, Product Code GXR)	Same
Environment of Use and Principal Operator	Hospital/Healthcare Facility Neurosurgeon	Same
Target Population	To be used following cranial surgery in patients to cover a hole drilled into the cranium and to support a lead (electrode)	To be used following cranial surgery in patients to cover a hole drilled into the cranium and to support electrodes or catheters
Anatomical Site	Permanent implant in cranium (skull)	Same
Method of Sterilization	EtO (Ethylene Oxide)	Same
Labeled as non-pyrogenic?	Yes	Same
Single Use?	Yes	Same
Biocompatible?	Yes	Same
Performance Testing:		
Method of Fixation to Cranium	Titanium Screws	Same
Lead (Electrode) Support?	Yes	Same
MR/CT Compatible?	Yes	Same

The NeuroPace® Burr Hole Cover materials differ from the predicate device. The NeuroPace device is composed of a synthetic polymer and silicone material. The synthetic polymer material is used to make a commercially available cranial permanent implant [Kelyniam Custom Skull Implant (K103582)]. The silicone material has a long standing history of use in implantable medical devices. Furthermore, biocompatibility of the Burr Hole Cover has been demonstrated in accordance with ISO 10993-1.

Technological characteristics, such as materials and design (for example dimensions) are demonstrated by performance testing to not raise new issues of safety or effectiveness; thus demonstrating that the NeuroPace® Burr Hole Cover is substantially equivalent to the legally marketed predicate device.

Summary of Supporting Data

Performance testing was conducted on the Burr Hole Cover to demonstrate compliance with the product requirements specification either by design analysis or functional testing. The following product requirements are supported: dimensional / geometry, device usability, lead compatibility, lead movement, fixation / retention, cranial rigidity, biocompatibility, sterility, pyrogenicity, MR/CT scanning compatibility and packaging / shelf life. The following guidances and standards were used for testing.

- ANSI/AAMI/ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing.
- ANSI/AAMI/ISO 10993-7:2008, Biological evaluation of medical devices, Part 7: Ethylene oxide sterilization residuals
- ANSI/AAMI/ISO 11607-1: 2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging
- ANSI/AAMI/ISO 11135:2007, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ASTM F88 - Standard Test Methods for Seal Strength of Flexible Barrier Materials
- ASTM F-1980, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F2096-04, Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)
- ASTM D 4169-09, Standard Practice for Performance Testing of Shipping Containers and Systems
- ST67:2003/(R) 2008, Sterilization of health care products – Requirements for products labeled 'sterile', 1st Ed.
- United States Pharmacopoeia 28 & NF 23, Bacterial Endotoxins Test <85>
- United States Pharmacopoeia 28 & NF 23, Transfusion and Infusion Assemblies and Similar Medical Devices <161>
- FDA Guidance, A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems, Draft Document: 1997.
- AAMI TIR 28:2009 Product adoption and process equivalence for ethylene oxide sterilization

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- Guidance for Industry – Medical Device Tracking; Guidance for Industry and FDA Staff – Labeling
- ASTM D-4332-01, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- FDA Guideline On Validation Of The Limulus Amebocyte Lysate Test As An End-Product Endotoxin Test For Human And Animal Parenteral Drugs, Biological Products, And Medical Devices, December 1987

No clinical testing was deemed necessary to support substantial equivalence.

This 510(k) notification for the Burr Hole Cover concludes that the device is considered to be substantially equivalent to the legally-marketed predicate device (as shown in the **510(k) Summary – Device Comparison Table**). The successful completion of the performance testing further supports the subject NeuroPace® Burr Hole Cover's substantial equivalence to the predicate device. No issues of safety or effectiveness are raised by the NeuroPace ® Burr Hole Cover.

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

January 18, 2013

NeuroPace, Inc
Ms. Isabella Abati
Vice President of Regulatory Affairs
455 N. Bernardo Avenue
Mountain View, CA 94043

Re: K123163
Trade Name: NeuroPace® Burr Hole Cover (Model 8110)
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Covers
Regulatory Class: Class II
Product Code: GXR
Dated: December 5, 2012
Received: December 6, 2012

Dear Ms. Abati:

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,

Kesia Y. Alexander

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

Enclosure

Indications for Use Statement

510(k) Number (if known): Not Known

Device Name: NeuroPace® Burr Hole Cover

Indications for Use:

The NeuroPace® Burr Hole Cover is intended for use following cranial surgery to cover a 14 mm burr hole. Secondarily, the NeuroPace Burr Hole Cover also can be used to support a 1.3 mm indwelling lead.

Prescription Use __X__ (21 CRF 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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