K141368

JUL 11 2014

Premarket Notification [510(k)] Summary

Category	Comments
Date Summary Prepared:	May 22, 2014
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 R. 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):	NeuroPace® Burr Hole Cover
510(k) Number:	K123163
Device Trade/ Proprietary Name:	NeuroPace® Burr Hole Cover model 8110
Predicate Device Common Name:	Cover, Burr Hole
Device Classification:	II
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 predicate device") includes a base (also referred to as a "retainer") that is screwed to the cranium (skull) using bone screws. 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 NeuroPace® 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 base is made from a synthetic polymer and the cap 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.

Indications for Use / Intended Uses

The intended use of the NeuroPace® Burr Hole Cover, as described in its labeling, has not changed as a result of the modifications to the device.

The indication for use/ intended uses are as follows:

> 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.

Summary of Technological Characteristics

The modified Burr Hole Cover (subject device) is substantially equivalent to NeuroPace's Burr Hole Cover (predicate device, FDA 510(k) K123163). Modifications were made to the predicate device to both the cap assembly and the base (or retainer) of the cleared Burr Hole Cover. The modifications do not affect the intended use and do not constitute a significant change compared to the predicate device in terms of the design, the materials, the fundamental scientific technology, the target population, or the anatomical site.

A side-by-side comparison of the modified device and the predicate device is provided in the following table.

510(k) Summary – Device Comparison

Description	Modified Device: NeuroPace® Burr Hole Cover	Predicate Device: NeuroPace® Burr Hole Cover (K123163)
Intended Use	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.	Same
Device Classification Name and Product Code	Burr Hole Cover (21 CFR 882.5250, Product Code GXR)	Same
Materials	Synthetic Polymer and Silicone	Same

510(k) Summary – Device Comparison

Description	Modified Device: NeuroPace® Burr Hole Cover	Predicate Device: NeuroPace® Burr Hole Cover (K123163)
Environment of Use and Principal Operator	Hospital / Healthcare Facility Neurosurgeon	Same
Target Population / principles of operation	To be used following cranial surgery in patients to cover a hole drilled into the cranium and to support a lead (electrode)	Same
Anatomical Site	Permanent implant in cranium (skull)	Same
Biocompatible?	Yes	Same
Method of Fixation to Cranium	Titanium Screws	Same
Lead (Electrode) Support?	Yes	Same
MR/CT Compatible?	Yes	Same
Method of Sterilization	EtO (Ethylene Oxide)	Same
Packaging materials	Device packaged within double Tyvek pouch	Same
How Supplied?	Sterile (SAL 1 x 10^{-6})	Same
Labeled as non-pyrogenic?	Yes	Same
Single Use?	Yes	Same
Shelf Life	1 year	Same

Summary of Supporting Data

The results of testing conducted on the modified Burr Hole Cover demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device. Specifically, the following evaluations were successfully performed on the proposed device such as: dimensional / geometry, functionality at operating temperature, lead compatibility, lead movement, retention and cranial rigidity. Materials used in the modified device are biocompatible and are the same as used in the predicate device. Sterility evaluations were performed on the modified device confirming non-pyrogenicity and product sterility, and that bioburden and residual levels demonstrated compliance with recognized performance standards. The modified Burr Hole Cover does not require clinical or animal testing to support substantial equivalence. The clearance of the predicate device also did not require these types of testing.

Conclusions

The modified NeuroPace® Burr Hole Cover is substantially equivalent to the legally marketed predicate NeuroPace® Burr Hole Cover (as shown in **510(k) Summary – Device Comparison**). The successful completion of performance evaluations further supports that the modified device is substantially equivalent to the predicate device (K123163). No new issues of safety or effectiveness are raised by the modifications made to the predicate device.

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

July 11, 2014

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

Re: K141368
Trade/Device Name: NeuroPace® Burr Hole Cover, Model 8110
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: June 9, 2014
Received: June 11, 2014

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 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,

Carlos L. Peña-S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141368

Device Name
NeuroPace® Burr Hole Cover, Model 8110

Indications for Use *(Describe)*
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.

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)*

Carlos L. Pena -S

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