DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 12, 2016

Neos Surgery S.L.
% Mr. Marcos Velez-Duran
President
M Squared Associates, Inc.
575 Eighth Avenue, Suite 1212
New York, New York 10018

Re: K160739
Trade/Device Name: Cranial COVER
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: March 16, 2016
Received: March 17, 2016

Dear Mr. Velez-Duran:

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" (21 CFR 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. Pena -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)*
K160739

Device Name
Cranial COVER

Indications for Use *(Describe)*
The Cranial COVER is intended for use to cover burr holes resulting from cranial surgery. With the available sizes, burr holes with an epicranial diameter between 10 and 14 mm, made with standard perforators or with spherical drills, can be covered.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Cranial COVER Cranial Burr Hole Cover System 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor: Neos Surgery S.L.
Parc Tecnològic del Vallès
C/Ceramistes, 2 (08290)
Cerdanyola del Vallès
Barcelona, Spain

Contact: Marcos Velez-Duran
M Squared Associates, Inc.
575 Eighth Avenue, Suite 1212
New York, NY 10018
Ph: 703-562-9800 Ext 206
Fax: 702-562-9797
Email: MVelez-Duran@MSquaredAssociates,com

Date of Submission: March 16, 2016

Proprietary Name: Cranial COVER, Cranial Burr Hole Cover System

Common Name: Burr hole cover

Regulatory Class: 882.5250 Burr hole cover

Classification Panel: Neurology

Product Codes: GXR

Predicate Device(s): Leibinger Burr Hole Covers – K983885
Neuropace Burr Hole Cover – K123163
Cranial LOOP XL – K132044

Device Description

The Cranial COVER is a postoperative biocompatible cranial burr hole cover system. It fits into most common cranial burr holes, and its upper platform is in contact with the skull surface. It

avoids the anti-cosmetic postoperative skin concavities. It does not require any specific surgical instrument for its handling or implantation. It is provided sterile, for a single use.

Two different sizes are presented:

- FC050300, large size, for the most common burr holes, made with standard perforators (diameters 14/11 mm or 13/9 mm[1]).
- FC050400, small size, for small burr holes (diameters from 12 mm to 10 mm), made with spherical drills.

The device functions like a clamp. An upper (epicranial) and a lower (subcranial) platform, joined by two cable ties, are tightened together with the help of non-implantable elements (handle and applier) and cover the burr hole.

Indications for Use

The Cranial COVER is intended for use to cover burr holes resulting from cranial surgery. With the available sizes, burr holes with an epicranial diameter between 10 and 14 mm, made with standard perforators or with spherical drills, can be covered.

Technological characteristics and comparison to predicate devices

The Cranial COVER is substantially equivalent in its indications for use and anatomical implantation site to the Leibinger Burr Hole Covers (K983885), the NeuroPace Burr Hole Cover (K123163) and the Cranial LOOP XL (included in K132044). More specifically:

- The Cranial COVER has the same indications for use as the primary indications for use of the Leibinger Burr Hole Covers and the NeuroPace Burr Hole Cover.
- A part of the indications for use of the Cranial LOOP XL is the same indications for use of the Cranial COVER (covering burr holes resulting from cranial surgery).

[1] In burr holes made with perforators, epicranial and subcranial diameters are different. For instance, the 14/11 mm perforator generates burr holes with epicranial diameter 14 mm and subcranial diameter 11 mm.

Additionally, Cranial COVER is substantially equivalent in its technology to the Cranial LOOP XL, as their design features and manner of implantation are the same: they are both clamp-like devices.

Finally, the material of the implanted parts of the Cranial COVER is the same as the material of the implanted part of the Cranial LOOP XL and the NeuroPace Burr Hole Cover (PEEK).

A side-by-side comparison of the Cranial COVER to the predicate devices follows:

Device	**Cranial COVER (FC050300 / FC050400)**	**Cranial LOOP XL (FC050200)**	**NeuroPace Burr Hole Cover (model 8110)**	**Leibinger Burr Hole Covers**
Company	Neos Surgery S.L.	Neos Surgery S.L.	NeuroPace Inc.	Howmedica, Inc.
510(k) No.	Present submission	K132044	K123163	K983885
Product Code	GXR - burr hole cover	GXR - burr hole cover	GXR - burr hole cover	GXR - burr hole cover
Indications for Use	The Cranial COVER is intended for use to cover burr holes resulting from cranial surgery. With the available sizes, burr holes with an epicranial diameter between 10 and 14 mm, made with standard perforators or with spherical drills, can be covered.	The Cranial LOOP Cranial Bone Fixation Systems: Cranial LOOP, Cranial LOOP (L) and Cranial LOOP (XL), are long-term implantable devices indicated for post-craniotomy bone flap fixation. (…) **The Cranial LOOP (XL) (FC050200) is to be used for covering a standard 14 mm cranial burr hole** only.	**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 Leibinger Burr Hole Covers are designed to be used with fixation screws to cover burr holes of various diameters in the craniofacial skeleton in order to provide good cosmetic results and protection of the underlying soft tissues and brain.** This device can also be used to secure cranial bone flaps.
Device Design	Two platforms linked by two adjustable cable ties, which are joined to the lower platform and have a locking system that allows movement of the upper platform towards the lower platform but impedes backward movements. The surgeon tightens the upper platform to the bone by gently pressing with the applier and pulling on the handle. The device remains adjusted to the bone thickness and it	Two platforms linked by two adjustable cable ties, which are joined to the lower platform and have a locking system that allows movement of the upper platform towards the lower platform but impedes backward movements. The surgeon tightens the lower platform to the bone and bone flap by gently pressing with the applier and pulling on the handle. The device remains adjusted to the bone thickness and it achieves its	The NeuroPace® Burr Hole Cover (model 8110) includes a base 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 Burr Hole Cover has a segmented plate-like structure. These Burr Hole Covers are 0.5 rnm thick and are comprised of four different configurations

	covers the burr hole like a plug.	intended use by fixing the bone flap to the cranial bone and by covering the burr hole.		
Applier Instrument	Not necessary	Not necessary	Screwdriver (minimum)	Screwdriver (minimum)
Material Composition	Platforms and ties (implantable parts) - PEEK Handle and applier- biocompatible polymer	Platforms and ties (implantable parts) - PEEK Handle and applier- biocompatible polymer	Synthetic polymer (PEEK according to the IFUs) and silicone.	Titanium
Sizes	- FC050300: for burr holes of diameter 14/11 mm and 13/9 mm - FC050400: for burr holes of diameter from 10 to 12 mm	FC050200, only size applicable in burr holes.	One size (14 mm).	Four different configurations. (According to the Intended Use: to cover burr holes of various diameters)
Implant life	Long-term implant	Long-term implant	Long-term implant	Long-term implant
Biocompa-tible	Yes	Yes	Yes	Yes
Provided Sterile	Yes	Yes	Yes	No
MRI Compatibility	MR Safe	MR Safe	MR compatible	MR compatible (although no data is available in the IFUs or 510k summary).
Method of Fixation to Cranium	Like a clamp	Like a clamp	Titanium Screws	Titanium Screws

Some differences exist in the diameters of the holes that the subject and the predicate devices are able to cover. Despite these differences, it is important to consider that burr holes made with a 14/11 mm standard perforator are the ones most commonly used in cranial surgery, and these burr holes can be covered with all the mentioned devices. Additionally, for both Cranial COVER and Leibinger Burr Hole Covers different sizes of the device are available, to cover different diameters.

Once implanted, and despite being based in essentially two basic designs to keep their position (clamp-like in the case of Cranial COVER and Cranial LOOP XL; screwed to the bone in the case of NeuroPace and Leibinger Burr Hole Covers), all these devices remain adjusted on the burr holes and cover them properly in the long-term.

Sterility

The sterilization method of the device does not differ from that of the Cranial LOOP XL predicate device (included in K132044). The sterilization process specification, the sterilization validation method and the bioburden limits are the same for this product and the predicate device Cranial LOOP XL. The results for the Cranial COVER are comparable to those obtained with Cranial LOOP XL.

Biocompatibility

With respect to the materials used in their manufacturing, all devices are made of biocompatible materials. The Cranial COVER, as well as the predicate devices Cranial LOOP XL and NeuroPace Burr Hole Cover, are made of PEEK (this makes them radiolucent and prevents interference with CT scanning and MRI systems). The Leibinger Burr Hole Covers are made of titanium.

The implantable parts of the Cranial COVER are the upper and lower platforms, as well as the ties, all of which are made of PEEK. As already mentioned, this is the same material used in the same parts of the predicate device Cranial LOOP XL (K132044). PEEK is well established as an implantable thermoplastic material. The Cranial COVER handle and applier (the non-implantable parts of the device) are made of biocompatible polymers. Letters of Authorization to Masters Files for these polymers have been provided.

Discussion of mechanical and performance testing

Mechanical and performance testing confirms that Cranial COVER performs as intended and that it is substantially equivalent to the predicate devices.

Performance testing has demonstrated that the technological characteristics of Cranial COVER do not raise any new safety or effectiveness issues. A summary of the tests performed, including a discussion of the relevance of their results to determine the substantial equivalence of Cranial COVER to the predicate devices, follows:

Test	Test Method Summary	Results and Conclusion
A. Functional testing		
A.1. Functionality of implantable parts	Goal: Determine the breaking force of the ratchet mechanism of the device's upper platform. Method: Fully assembled devices were tested. A calibrated dynamometer was used to apply a traction force on the upper platform until its ratchets broke.	All tested samples meet the specifications. Functionality of the devices is demonstrated. Results are comparable to the Cranial LOOP XL predicate device.
A.2. Functionality of the handle	Goal: Determine the breaking force of the ratchet mechanism between the handle and the lower platform (and cable ties). Method: Fully assembled devices were tested. A calibrated dynamometer was used to apply a traction force on the handle until its ratchets	

	broke.	
B. Biomechanical testing		
B.1. Push-in	Goal: Simulate patient's pressure on the device and determine the force required to sink the devices up to a maximum of 2 mm. Method: Fully assembled devices were tested in holes equivalent to those in which they will be implanted. The implanted devices were placed under a calibrated dynamometer and a cylindrical tool used to apply force on the upper platform.	All tested samples meet the specifications. The devices have an adequate biomechanical behavior at push-in and pull-out. Results are better than those obtained with the Cranial LOOP XL predicate device. Both devices must be able to resist pull-out and push-in forces appropriately. However, the use of Cranial LOOP XL as a fixation element for the bone flap causes that these devices are subject to different force intensities. In general, it is reasonable to say that the Cranial COVER is subject to a less demanding situation than Cranial LOOP XL; the results obtained confirm this point.
B.2. Pull-out	Goal: Simulate pulling forces during implantation or caused by increased ICP, to determine the maximum force that 1) the device can withstand before sliding out from the burr hole, or 2) the handle can withstand before breaking. Method: Fully assembled devices were tested in holes equivalent to those in which they will be implanted. A calibrated dynamometer was used to apply a traction force on the handle until the lower platform slid out from the hole or the handle broke.	
C. Cadaver testing	Goal: Evaluation of the devices when simulating their implantation on the skull of patients in a clinical environment, following the procedures described in the products' Instructions for Use. Method: The test was performed on a cadaveric specimen with fully assembled devices. Some of the most relevant aspects analyzed include: - availability of space to place and position the device - absence of danger for the surgeon - fast and instrument-free implantation - epicranial and subcranial profiles - lateral and axial stability when the device is moved - completeness of burr hole covering - ease of device removal	Correct implantation is verified in a simulated real-life situation. The devices show adequate performance and safety. The results demonstrate that the Cranial COVER is equivalent, in terms of performance and safety and to the relevant extent, to the predicate device Cranial LOOP XL.

All the setups applied in the tests simulate clinical service conditions and, in some cases, the worst case scenario. The results of the testing confirmed that both sizes of the Cranial COVER will

perform as intended in the clinical setting, and that they are comparable to the predicate devices – particularly to the Cranial LOOP XL (included in K132044).

The following standards are applicable to the design and performance of the Cranial COVER:

- Recognition number 14-428: ISO 11137-1:2006, "Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013)]"
- Recognition number 14-409: ISO 11137-2:2013, "Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose"
- Recognition number 14-407: ISO 11737-1:2006, "Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products [Including: Technical Corrigendum 1 (2007)]"
- Recognition number 14-327: ISO 11737-2:2009, "Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process"
- Recognition number 2-220: ISO 10993-1:2009, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]"

Discussion of clinical testing

No clinical testing was deemed necessary to support substantial equivalence to predicate devices.

Conclusion

Based on the design features, the use of established well-known biocompatible materials, technological characteristics comparison, indications for use, and results of the mechanical and performance testing, the subject device has demonstrated substantial equivalence to the identified legally marketed predicate devices.