February 16, 2024

Neos Surgery S.L.
Eduard Garcia
QA & RA Manager
Ceramistes 2
Cerdanyola, Spain 08290

Re: K240137
Trade/Device Name: Cranial LOOP, Cranial LOOP L and Cranial LOOP XL Cranial Bone Fixation System
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr hole cover
Regulatory Class: Class II
Product Code: GXR
Dated: January 17, 2024
Received: January 18, 2024

Dear Eduard Garcia:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2024.02.16 12:20:35 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K240137

Device Name

Cranial LOOP, Cranial LOOP L and Cranial LOOP XL Cranial Bone Fixation System

Indications for Use *(Describe)*

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.

In cranial bone fixation procedures, the Cranial LOOP (FC050000) and Cranial LOOP (L) (FC050100) are for use within the osteotomy line (calvarial gap) while the Cranial LOOP (XL) (FC050200) is to be used for covering a standard 14 mm cranial burr hole only.

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 LOOP, Cranial LOOP L and Cranial LOOP XL Cranial Bone Fixation System Special 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the 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: Cherita James
M Squared Associates, Inc.
127 West 30th Street, 9th Floor
New York, New York 10001 Ph:
347-954-0624
Fax: 703-562-9797
Email: Cjames@MSquaredAssociates.com

Date: February 16, 2024

Proprietary Name: Cranial LOOP, Cranial LOOP L and Cranial LOOP XL Cranial Bone Fixation System

Common Name: Cover, Burr Hole

Regulatory Class: II

Regulation: 882.5250 Burr hole cover

Product Codes: GXR

Predicate Device(s): Cranial LOOP, Cranial LOOP L and Cranial LOOP XL Cranial Bone Fixation System – K132044

Device Description: The Cranial LOOP, Cranial LOOP L and Cranial LOOP XL Cranial Bone Fixation System is a biocompatible, postoperative cranial bone fixation system that fixes the bone flap to the skull, without any specific surgical instrument for its handling or implantation. It is provided sterile, for single use. Cranial LOOP and Cranial LOOP L are applied in the craniotomy gap. They can fix cranial thicknesses ranging from 1.5 mm to 24 mm and

gaps ranging between 1.7 mm and those made using a craniotome standard cranial router. Cranial LOOP XL is applied in a burr hole made using a standard drill 14 mm. They can fix cranial thicknesses ranging from 4mm to 24 mm.

Indications for Use: 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.

In cranial bone fixation procedures, the Cranial LOOP (FC050000) and Cranial LOOP (L) (FC050100) are for use within the osteotomy line (calvarial gap) while the Cranial LOOP (XL) (FC050200) is to be used for covering a standard 14 mm cranial burr hole only.

Technological characteristics, comparison to predicate device

The device under evaluation has the same technical characteristics as the predicate device. Both designs consist of two platforms linked by two adjustable cable ties. These cable ties are joined to the lower platform and have a locking system that allows the movement of the upper platform towards the lower platform but impedes backward movements. The upper platform is tightened to the cranial bone and bone flap by the surgeon with the aid of the applier by a simple pressure on the applier and pulling on the handle. Device remains adjusted to the bone thickness, and it fixes the bone flap to the cranial bone, like a clamp.

Performance testing

Biomechanical and functional testing (displacement force when fixated to a synthetic and cadaveric cranium and tensile load to device failure) were performed to evaluate the impact of the changes to Cranial LOOP with respect to its previously cleared version (identified as the predicate device). The acceptance criteria were met in both tests. The performance testing showed that the Cranial LOOP had equivalent or better performance compared to its predicate, thus demonstrating that the device is as safe and effective as it does not raise different questions of safety and effectiveness than the predicate.

Discussion of clinical testing

No clinical testing was performed to support this submission.

Substantial Equivalence/ Conclusion

Based on the comparison of the indications for use, product technical characteristics, principles of operation and performance, the modified Cranial LOOP has demonstrated to be substantial equivalence to the previously cleared version of Cranial LOOP (identified as the predicate). The differences do not raise new issues of safety or effectiveness, based on the risk assessment performed and on the results of the verification / validation activities that have been conducted. The results of the performance testing demonstrate that the subject device meets its specifications.