Osteonic Co., Ltd
% Sanglok Lee
Manager
Wise Company Inc.
#507, #508, 166 Gasan digital 2-ro, Geumcheon-gu
Seoul, 08507
Korea, South

Re: K210360

Trade/Device Name: Neuro Plating System, Neuro Plating System Plates(NST304M02A and 61 Models), Neuro Plating System-Packaging unit(NSP-001 and 10 models), Neuro Plating System-Sterile Kit(TCN-011 and 69 models), Neuro Plating System-Screws(N15A03 and 11 models)
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: December 9, 2021
Received: December 17, 2021

Dear Sanglok Lee:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

for Adam Pierce
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)*
K210360

Device Name
Neuro Plating System

Indications for Use *(Describe)*
Neuro Plating System is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedure.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date: November 9, 2021

1. Applicant / Submitter:

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2. Submission Correspondent

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3. Device:

- Proprietary Name – Neuro Plating System
- Common Name – Neuro Plating System
- Classification Name – Preformed Alterable Cranioplasty Plate; Burr hole cover; Cranioplasty plate fastener

4. Predicate devices:

- Primary Predicate devices: K190811- Neuro Plating System by Osteonic Co., Ltd.

5. Product Code & Regulation Number:

GWO, GXR, HBW (21CFR§882.5320, 21CFR§882.5250, 21CFR§882.5360)

6. Device Description:

The Neuro Plating System is comprised of plates and screws. The range of plate sizes is from 0.3mm to 0.6mm thick. It is made of commercially pure titanium of Gr 1, 2 and 3 (ASTM F67) and in 3 colors (silver, blue and gold) by anodizing. The range of screw diameter is from 0.8mm to 1.95mm in lengths of 3.0 to 6.0mm. It is made of Ti-6Al-4V ELI titanium alloy (ASTM F136) and in 3 colors (silver, green and gold) by anodizing.

Neuro Plating System consists of plates and screws to provide fixation and aid in the alignment and stabilization of fractures in reconstructive processes. The plate is placed on the fractured bone and the screw is inserted into the bone through a plate hole to fix. If necessary, the plate may be bent or cut to meet the anatomical needs of patient.

The Neuro Plating System has two types of sterilization method; Neuro Plating System is non-sterile state packed in PE bag which must be sterilized before use and Neuro Plating System - Sterile Kit is provide sterile state with gamma sterilization packed in Tyvek and PET. Both are single use only.

7. Indication for use:

Neuro Plating System is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedure.

8. Non-clinical tests:

There are a number of differences between the predicate devices and the subject devices as presented in this submission, however, the differences were evaluated through design control, risk analysis and verification & validation activities, and test results demonstrated that the subject devices and predicate devices are substantially equivalent.

The following tests were performed:

- 4 Point Bending Test
- Torsion Test & Axial Pullout Strength Test
- Packaging Process Validation Test (only Neuro Plating System - Sterile Kit)
- Gamma Sterilization Validation (only Neuro Plating System - Sterile Kit)
- Shelf life (only Neuro Plating System - Sterile Kit)

The subject device's titanium grade is the same as the predicate device's, but the subject device is thicker than the predicate device. Therefore, the performance testing of the subject device is expected to be substantially equivalent to the predicate device.

Validation of sterilization parameters and biocompatibility of the subject device are supported by sterilization validation and biocompatibility testing as provided in the primary predicate K190811.

9. Substantial Equivalence:

The subject device is similar to the predicate devices in terms of indications, materials, use and design. All of the technical characteristics are substantially equivalent to the corresponding characteristics of the predicate devices. There might be slight differences in dimensions, shapes between the subject device and each predicate device, however, the information and the data of non-clinical testing such as mechanical testing and sterilization testing provided in this submission supports substantial equivalence to the predicate devices in safety and performance.

	Subject device	Predicate Device	Reference Device	Equivalence
Manufacturer	OSTEONIC Co., Ltd.	OSTEONIC Co., Ltd.	Stryker	-
Device Name	NEURO PLATING SYSTEM	NEURO PLATING SYSTEM	Stryker Universal Neuro 3 System	-
510(K) #	K210360	K190811	K131775	-
Class	2	2	2	Equivalent
Product Code	GWO, GXR, HBW	GWO, GXR, HBW	GWO, GXR, HBW	Equivalent
Intended Use	Neuro Plating System is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedure.	Neuro Plating System is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedure.	The Stryker Universal Neuro 3 System is intended for reconstruction, stabilization and/or rigid fixation of non load-bearing areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and higher).	Equivalent
Material (Chemical composition)	▪Plate- Pure Titanium ASTM F67 ▪Screw- Titanium Alloy ASTM F136	▪Plate- Pure Titanium ASTM F67 ▪Screw- Titanium Alloy ASTM F136	▪Plate- Pure Titanium ASTM F67 ▪Screw- Titanium Alloy ASTM F136	Equivalent
Surface Treatment	▪ Plate: Anodizing ▪ Screw: Anodizing	▪ Plate: Anodizing ▪ Screw: Anodizing	▪ Plate: Anodizing ▪ Screw: Anodizing	Equivalent
Shape and Dimension	Straight, angle, Y-shape, X-shape, D-Y shape, burr hole, square, matrix and mesh plate with various lengths and thickness (0.1 to 0.6mm). The screws range in diameters of 0.8 to 1.95mm and lengths from 3.0 to 6.0mm.	Straight, angle, Y-shape, X-shape, D-Y shape, burr hole, square, matrix and mesh plate with various lengths and thickness (0.1 to 0.6mm). The screws range in diameters of 0.8 to 1.95mm and lengths from 3.0 to 6.0mm.	Performed alterable cranioplasty plate, burr hole cover, cranioplasty plate fastener.	- The safety and performance of plates and screws were shown to be equivalent to predicate device. - Most of components (plates and screws) of the model added this time are the same as the predicate device except for the plate_NST306X02A. The equivalence of NST306X02A with predicate device was verified.
Single Use	YES	YES	YES	Equivalent

Sterile	Neuro Plating System : Non sterile, steam sterilization before use Neuro Plating System Sterile Kit : sterile, gamma irradiation	Neuro Plating System : Non sterile, steam sterilization before use Neuro Plating System Sterile Kit : sterile, gamma irradiation	Sterile, gamma irradiation	Equivalent

10. Conclusions:

Based on documentation supplied with this submission, conclusions drawn from design control, risk analysis and verification & validation activities demonstrate that the subject devices are substantially equivalent to the predicate devices.