November 27, 2019

Osteonic Co., Ltd
Choi Se Young
Associate Manager Engineer
1206Ho 38
Digital-ro 29-gil,
Guro-gu, Seoul, 08381 KR

Re: K190811
Trade/Device Name: Optimus Neuro Plating System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: March 19, 2019
Received: March 29, 2019

Dear Choi Se Young:

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 Matthew Krueger
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190811

Device Name

Optimus Neuro Plating System

Indications for Use *(Describe)*

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

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

Date: November 25, 2019

1. Applicant / Submitter:

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Tel : +82-2-6902-8415 Fax : +82-2-6902-8401

2. Submission Correspondent

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Guro-gu, Seoul, Korea
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Email: jisun@osteonic.com

3. Device:

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

4. Predicate Devices:

- Predicate devices: K183352- Neuro Plating System by Osteonic Co., Ltd.
- Predicate devices: K141911- Neuro Plating System by Osteonic Co., Ltd.

5. Product Codes & Regulation Numbers:

- GWO 21 C.F.R. 882.5320
- GRX 21 C.F.R 882.5250
- HBW 21 C.F.R. 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 comes in 3 anodized colors (silver, blue and gold). The screws range in diameter from 0.8mm to 1.95mm and in lengths of 3.0mm to 6.0mm. They are made of Ti- 6Al-4V ELI titanium alloy (ASTM F136) and come in 3 anodized colors (silver, green and gold).

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

The Neuro Plating System has two types of sterilization methods: 1.) the Neuro Plating System is non-sterile state packed in a PE bag which must be sterilized before use; and 2.) the Neuro Plating System - Sterile Kit is provided sterile using gamma sterilization packed in Tyvek and PET. Both are single use only.

7. Indication for use:

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

8. Non-clinical tests:

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

The following tests were performed on the modified devices to demonstrate substantial equivalence to the predicate devices.

- 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)
- MR safety test

The test results of the modified devices were overall higher than the predicate devices demonstrating that the modified devices are substantially equivalent to the predicate devices.
Biocompatibility testing was conducted in accordance with ISO 10993.

9. Substantial Equivalence:

The modified devices are 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. Although there are slight differences in dimensions, shapes and sterility between the modified devices and the predicate devices, the information and the data of non-clinical testing such as mechanical testing and sterilization testing provided in this submission proves substantial equivalence to the predicate devices in safety and performance.

	Modified Device	Unmodified (Predicate) Device	Unmodified (Predicate) Device	Equivalence
Manufacturer	OSTEONIC Co., Ltd.	OSTEONIC Co., Ltd.	OSTEONIC Co., Ltd.	-
Device Name	NEURO PLATING SYSTEM	NEURO PLATING SYSTEM	NEURO PLATING SYSTEM	-
510(K) #	K190811	K141911	K183352	-
Class	2	2	2	Equivalent
Product Code	GWO, GRX, HBW	GWO, GRX, HBW	GWO, GRX, HBW	Equivalent
Intended Use	Neuro Plating System is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.	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.	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: Anodized ▪ Screw: Anodized	▪ Plate: Anodized ▪ Screw: Anodized	▪ Plate: Anodized ▪ Screw: Anodized	Equivalent
Shape and Dimension	Straight, burr hole with various lengths and thickness. The range of plate sizes is from 0.3mm to 0.6mm thick. The screws range in diameter from 0.8mm to 1.95mm and in lengths of 3.0mm to 6.0mm.	Straight, angle, Y-shape, X-shape, burr hole, square, matrix and mesh with various lengths and thickness Plate has various length and thickness (0.1 to 0.6mm). The screws range in diameters of 0.8 to 1.8mm and lengths from 3.0 to 6.0mm	D-Y Shape, Y-Shape, Burr hole Plate and mesh with various lengths and thickness (0.3 to 0.6mm).	Plates and screws were found to be substantially equivalent through 4 point bending testing, torsional testing, and axial pullout strength testing. The modified devices passed all testing
Single Use	YES	YES	YES	Equivalent
Sterile	Neuro Plating System : Non sterile, steam sterilization before use Neuro Plating System Sterile Kit : sterile, gamma irradiation	Non sterile, steam sterilization before use	Non sterile, steam sterilization before use	Neuro Plating System - Sterile Kit (gamma irradiation) added. Plates and screws were evaluated through packaging process validation test, gamma sterilization validation and shelf life. The modified devices passed all testing.

10. Conclusions:

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