Osteonic Co., Ltd
% Jung Hyeon Park
Official Correspondent
BT Solutions, Inc.
904, Eonju-ro 68-gil 5, Gangnam-gu
Seoul, 06210 Kr

January 2, 2019

Re: K183352
Device Name: Optimus Neuro System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: November 29, 2018
Received: December 3, 2018

Dear Jung Hyeon Park:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

John Marler -S

Digitally signed by John Marler -S
Date: 2019.01.02 21:09:44 -05'00'

For 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)*
K183352

Device Name

Optimus Neuro System

Indications for Use *(Describe)*

Optimus Neuro 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 16, 2018

1. Applicant / Submitter:

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2. Submission Correspondent

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3. Device:

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

4. Predicate Device:

- Primary Predicate Device: K141911-OPTIMUS NEURO SYSTEM by Osteonic Co., Ltd.

5. Product Code & Regulation Number:

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

6. Device Description:

The Optimus NEURO 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 3colors (silver, blue and gold) by anodizing. The range of screw diameter is from 0.8mm to 1.8mm 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.

The device is packed separately in a PE bag. The plate and screw are single use only, non-sterile products. The devices must be sterilized before use.

Optimus NEURO 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

7. Indication for use:

Optimus NEURO 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 unmodified devices and the modified 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 differences do not raise a question of safety and effectiveness.

The following tests were performed on the subject device and the predicate devices.

- 4 Point Bending Test
- Packaging Process Validation Test

The test results of the subject device were overall higher than the predicate devices supporting that the subject device is substantially equivalent to the predicate devices. Validation of sterilization parameters and biocompatibility of the submission device are supported by sterilization validation and biocompatibility testing as provided in the primary predicate K141911

9. Substantial Equivalence:

The subject device has the same device characteristics as the predicate (unmodified) device. They have the same intended use, raw material, and use concept and employ the same manufacturing processes including anodization and sterilization method. The differences are in shape and dimensions; however; the performance test data provided in this submission proves that this differences do not raise new issues in safety and performance.

	Subject Device	Unmodified (Predicate) Device	Equivalence
Manufacturer	OSTEONIC Co., Ltd.	OSTEONIC Co., Ltd.	-
Device Name	OPTIMUS NEURO SYSTEM	OPTIMUS NEURO SYSTEM	-
510(K) #	-	K141911	-
Class	2	2	Equivalent
Product Code	GWO, GXR, HBW	GWO, GXR, HBW	Equivalent
Intended Use	Optimus NEURO System is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedure.	Optimus NEURO 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	Equivalent
Surface Treatment	▪ Plate: Anodizing ▪ Screw: Anodizing	▪ Plate: Anodizing ▪ Screw: Anodizing	Equivalent
Shape and Dimension	D-Y Shape, Y-Shape, Burr hole Plate and mesh with various length and thickness (0.3 to 0.6mm).	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	Plates were found to be safe and effective through standard strength testing methods.
Single Use	YES	YES	Equivalent
Sterile	Non sterile, steam sterilization before use	Non sterile, steam sterilization before use	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 device.