DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 9, 2015

OSTEONIC Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 E Chapman Ave. Suite 110
Fullerton, California 92831

Re: K141911
Trade/Device Name: OPTIMUS NEURO SYSTEM
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GWO, GRX, HBW
Dated: January 5, 2015
Received: January 8, 2015

Dear Ms. Chung,

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 remarket 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)*
K141911

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
(K141911)

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 02/08/2015

1. 510K Applicant

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2. US Agent/ Correspondent

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3. Device

- Trade Name: OPTIMUS NEURO SYSTEM
- Classification Name: Neuro Plating System
- Classification regulation: 21CFR§882.5320
  21CFR§882.5250
  21CFR§882.5360
- Product Code: GWO, GRX, HBW

4. Predicate Device:

- Neuro plating system (K121624) by Biomet Microfixation
- LEFORTE NEURO SYSTEM BONE PLATE and SCREW (K112812) by Jeil Medical Corporation
- Frontier Devices Neuro Closure System (K100205) by Frontier Devices

5. 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 3 colors (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, greenand gold) by anodizing. The plate and screw are a single use only, non-sterile product and they must be sterilized by the user before use. Each component is individually packed in a PE bag.

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.

6. Indications for use:

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

7. Comparison to the Cleared Device

The subject device is similar to the predicate devices in terms of indications, materials, 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 and shapes between the subject device and each predicate device; however, the test results of non-clinical testing including mechanical testing provided in this submission proves substantial equivalence to the predicate devices.

8. Performance Data

The following bench tests have been performed on the subject device and passed the pre-set criteria.

Test	Result	Conclusion
Sterilization Validation Test	Sterility assurance level(10^{-6}) for the recommended steam sterilization parameters is met.	The recommended sterilization parameters for the user are valid.
Mechanical Test	Worst case test articles have passed the pre-set criteria.	The subject devices have been validated in mechanical characteristics.
Cleaning Process Validation Test	The subject devices showed low bioburden level and met criteria of 2.15 EU/device for endotoxin.	The cleaning process at the manufacturing sites has been validated.
Packaging Validation Test	Final packaging of the subject deice has passed the testing for its complete sealing.	The subject device will be well protected until use in its packaging.

9. Conclusion

Based on the non-clinical testing data and the information provided in the submission, we have concluded that our devices are substantially equivalent to the predicate devices in the market. No new questions of safety and effectiveness have been raised.