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

September 11, 2017

Jeil Medical Corporation
Ji Won Song
RA Specialist
55 Digital-ro, 34-gil
702, 703, 704, 705, 706, 804, 805, 807, 812-ho
Seoul, 152-728 KR

Re: K170368
Trade/Device Name: Sterile NS System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: August 9, 2017
Received: August 10, 2017

Dear Ji Won Song:

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 (DICE) 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 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 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 (DICE) 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,

Michael J. Hoffmann -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170368

Device Name
Sterile NS System

Indications for Use *(Describe)*
The Sterile NS 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.

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

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510(k) Summary

[As required by 21 CRF 807.92]

1. Date Prepared [21 CRF 807.92(a)(a)]

20. January 2017

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: Jeil Medical Corporation
  - Address: 702·703·704·705·706·804·805·807·812-ho,55 Digital-ro34-gil, Guro-gu, Seoul, 152-728, Korea
- Contact Name: Ji won Song / RA Specialist
  - Telephone No. : +82 2 850 3587
  - Fax No. : +82 2 850 3536
  - Email Address : sjw@jeilmed.co.kr
- Registration Number: 3004049923
- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name: Sterile NS System
- Common Name: Bone plate & screw
- Classification Name: Preformed alterable cranioplasty plate appliances and accessories
- Classification Panel: Neurology
- Classification Regulation: 21 CFR 882.5320, 21 CFR 882.5250, 21 CFR 882.5360
- Product Code: GWO, GXR, HBW
- Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow;

- 510(k) Number: K112812, K141452
- Applicant: Jeil Medical Corporation
- Common Name: Bone plate & screw
- Device Name: Leforte Neuro System Bone plate and screw

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Bone plate & screw
There are no significant differences between the subject devices and the predicate devices (K112812, K141452) that would adversely affect the use of the product.

5. Description of the Device [21 CFR 807.92(a)(4)]

The Sterile NS System is designed for use in selective trauma of the craniofacial skeleton, craniofacial surgery and reconstructive procedures. The Sterile NS System consists of bone plates in a variety of shapes and sizes, bone screws to secure the plates, and accessories to assist in the operational procedures. The Sterile NS System is made of pure titanium (ASTM F67) and titanium Alloy (ASTM F136). It is intended for use in selective trauma of cranial skeleton, cranial surgery and reconstructive procedures.

6. Intended Use [21 CFR 807.92(a)(5)]

The Sterile NS System is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

Sterile NS System, Neurology: With same thickness, titanium grade, dimensions. However, the subject device changed sterile method under the predicate devices (K112812, K141452).

Non-Clinical Test Summary:

The test was conducted to verify that the subject device met all design specifications. The test results demonstrated that the proposed device complies with the following standards and worst case criteria report:

- Plate
  - Dimension test
- Screws
  - Dimension test

The subject device has the same device characteristics as the predicate (unmodified) device.

Clinical Test Summary:

No clinical studies were considered necessary and performed.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

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 anodization, shape and dimensions. The differences are sterilization method; however; the performance test data provided in this submission proves that this differences do not raise new issues in safety and performance.

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	Predicate (Unmodified) device	Subject device
510k Number	K112812, K141452	-
Manufacturer	Jeil Medical Corporation	Jeil Medical Corporation
Product Code	GWO, GXR, HBW	GWO, GXR, HBW
Intended use	The Leforte Neuro System Bone Plate and Screw is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.	The Sterile NS System is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.
Material	Plate- Pure titanium Grade4 (ASTM F67) Screw- Titanium alloy (Ti-6AL-4V ELI, ASTM F136)	Plate- Pure titanium Grade4 (ASTM F67) Screw- Titanium alloy (Ti-6AL-4V ELI, ASTM F136)
Design features	**Plate** - Plate thickness 0.3mm ~ 1.0mm - Surface: Anodized **Screw** - Screw Outer Dia. 1.4 ~ 1.8mm - Screw Length 2.2~5.0mm - Surface: N/A	**Plate** - Plate thickness 0.3mm ~ 1.0mm - Surface: Anodized **Screw** - Screw Outer Dia. 1.4 ~ 1.8mm - Screw Length 2.2~5.0mm - Surface: N/A
Sterilization	Non-Sterile (Steam sterilization by user)	Sterile (Radiation-sterile)
Usage	Single use	Single use
Packaging	Polyethylene Zip Lock Pouch Cardboard Box	PET, Tyvek, Cardboard Box
Biocompatibility	Conform	Conform

9. Conclusion [21 CFR 807.92(b)(3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Jeil Medical Corporation concludes that Sterile NS System is as safe and effective and substantially equivalent to the predicate device as described herein.