JUL 0 2 2014
K141452

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92

Date: May 27, 2014

1. 510K Applicant / Submitter:

Jeil Medical Corporation
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Republic of Korea
Tel : +82-2-850-3524 Fax: +82-2-850-3525

2. Submission Contact Person

LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110, Fullerton, CA 92831
Priscilla Juhee Chung
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Email: juhee.c@lkconsultinggroup.com

3. Device

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

4. Predicate Device

LeForte Neuro System Bone Plate & Screw by Jeil Medical Corporation (K112812)

5. Product Codes:

GWO, GXR, HBW

6. Classification Regulation:

21CFR§882.5320
21CFR§882.5250
21CFR§882.5360

7. **Description:**

The LeForte Neuro System is designed for use in selective trauma of the craniofacial skeleton, craniofacial surgery and reconstructive procedures. The LeForte Neuro System consists of bone plates in a variety of shapes and sizes, bone screws to secure the plates, convenience kits of bone plates and bone screws, and accessories to assist in the operational procedures. The LeForte Neuro System Bone Plate & Screw 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.

8. **Substantial Equivalence Discussion:**

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 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
510K Number		K112812
Product Code	GWO, GRX, HBW	GWO, GRX, HBW
Manufacturer	Jeil Medical Corporation	Jeil Medical Corporation
Indications for Use	This device is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.	This device is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.
Materials	Plate – CP Ti Gr.1,2,3, and 4 (ASTM F7) Screw – Ti 6Al 4V ELI (ASTM F136)	Plate – CP Ti Gr.1,2,3, and 4 (ASTM F7) Screw – Ti 6Al 4V ELI (ASTM F136)
Dimensions	Plate thickness 0.3mm~1.0mm Screw Outer Dia. 1.4~1.8mm Screw Length 2.2~5.0mm	Plate thickness 0.3mm~0.6mm Screw Outer Dia. 1.4~1.8mm Screw Length 2.2~5.0mm
Surface Treatment	Plate – Anodization Screw – N/A	Plate – Anodization Screw – N/A
Sterilization	Non-Sterile (Steam sterilization by user using same parameters as the unmodified device)	Non-Sterile (Steam sterilization by user)
Usage	Single Use	Single Use
Packaging	Polyethylene Zip Lock Pouch Cardboard Box	Polyethylene Zip Lock Pouch Cardboard Box

9. **Performance Tests:**

- The modified LeForte Neuro System plates were tested for tensile strength. All the test

data met pre-set criteria (over N150).
- The modified LeForte Neuro System bone screws were tested for torsion and pull out. All the test data met pre-set criteria (0.20N•m for torsion, 20N for pull out).

10. Conclusions:

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 the LeForte Neuro System Bone Plate & Screw is safe and effective and substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 2, 2014

Jeil Medical Corporation
% Ms. Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave, Ste. 110
Fullerton, California 92831

Re: K141452
Trade/Device Name: Leforte neuro system bone plate and screw
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: May 27, 2014
Received: June 2, 2014

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 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 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,

Felipe Aguel -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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K141452

Device Name
LeForte Neuro System Bone Plate & Screw

Indications for Use *(Describe)*

This device 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S

Date: 2014.07.02 17:29:34 -04'00'