



Food and Drug Administration  
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September 17, 2015

Jeil Medical Corporation  
c/o Ms. Priscilla Chung  
LK Consulting Group USA, Inc.  
2651 East Chapman Avenue, Suite 110  
Fullerton, CA 92831

Re: K150965

Trade/Device Name: LeForte System II  
Regulation Number: 21 CFR 872.4760  
Regulation Name: Bone plate  
Regulatory Class: II  
Product Code: JEY  
Dated: August 14, 2015  
Received: August 19, 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 premarket notification" (21CFR 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,

 Tina  
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K150965

Device Name: LeForte System II

Indication for Use:

The LeForte System II is intended for use in selective trauma of mid-face, reconstruction procedure and selective orthognathic surgery of the maxilla and chin.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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## **510(k) Summary**

[As required by 21 CFR 807.92]

### **1. Date Prepared [21 CFR 807.92(a)(a)]**

August 31, 2015

### **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: Jieun KIM (Ms.) / RA Specialist
  - Telephone No. : +82 2 850 3500
  - Fax No. : +82 2 850 3525
  - Email Address : jekim@jeilmed.co.kr
  
- Registration Number: 3004049923
  
- Name of Manufacturer: Same as Sponsor

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

- Trade Name: LeForte System II
- Common Name: Bone plates and screws
- Classification Name: Single/multiple component metallic bone fixation appliances and accessories
- Classification Panel: Dental
- Classification Regulation: 21 CFR 872.4760
- Product Code: JEY
- Device Class: II

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

Primary Predicate Device:

- 510(k) Number: K112457
- Applicant: Jeil Medical Corporation
- Common Name: Bone plates and screws
- Device Name: LeForte System

Reference Predicate Device:

- 510(k) Number: K080694
- Applicant: OsteoMed L.P.

- Common Name: Bone plates and screws
- Device Name: OsteoMed Modular Locking Fixation System

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

The LeForte System II is rigid fixation consisting of plates and screws in various configurations, shapes and sizes.

	Plate	Self-tapping Screw	Self-drilling Screw	Self-tapping Locking Screw
<b>Type / Configuration</b>	242.Series	241.01 Series	241.02 Series	241.03 Series
<b>Material</b>	ASTM F 67 Pure Titanium	ASTM F 136 Titanium Alloy (Ti-6Al-4V)	ASTM F 136 Titanium Alloy (Ti-6Al-4V)	ASTM F 136 Titanium Alloy (Ti-6Al-4V)

The LeForte System II is made of Pure Titanium and Titanium Alloy (Ti-6AL-4V), which meet ASTM F67: Standard Specification for Unalloyed Titanium for Surgical Implant Applications, and ASTM F136: Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well-known biocompatibility. The plates vary essentially through different lengths and number of plate holes. The Self-tapping screws, Self-drilling screws & Self-tapping locking screws diameter is from 1.3 to 2.7mm and lengths is from 2mm to 20mm. It also includes various manual surgical instruments such as drill guides, drill bits, driver shafts, depth gauge, bender and hand body, etc.. The LeForte System II is not provided sterile. It is required to be sterilized via autoclave method to reach a SAL of 10<sup>-6</sup> by the user prior to surgery.

**6. Indications for Use [21 CFR 807.92(a)(5)]**

The LeForte System II is intended for use in selective trauma of the mid-face, reconstruction procedure and selective orthognathic surgery of the maxilla and chin.

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

**LeForte System II Bone Plates:** Based on a technical feature comparison, the subject device was found to be similar to the predicate devices in regards to design and materials. The subject plates also have a polyaxial locking feature, similar to the design used in the primary predicate device (K112457).

**LeForte System II Bone Screws:** Both the subject and the predicate devices share similar head, neck and thread designs.

**Non-Clinical Test Summary:**

Bench tests were conducted to verify that the proposed device met all the design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ASTM F 382-99, Standard Specification and Test Method for Metallic Bone Plates
- ASTM F 543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws

The following tests were performed on the subject device and the primary predicate device:

- Plates
  - Dimension test
  - Bending strength test per ASTM F382
- Screws
  - Dimension test
  - Driving torque test per ASTM F543-07
  - Axial pull-out test per ASTMV F543-07
  - Torsion test per ASTM F543-07

The results of the testing support that the LeForte System II is substantially equivalent to the predicate device.

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

	Subject Device	Primary Predicate Device	Reference Predicate Device	Similarity/Difference Discussion
Device Name	LeForte System II	LeForte System Bone Plate & Screw	OsteoMed Modular Locking Fixation System	Different
510(k) Number	K150965	K112457	K080694	Different
Manufacturer	Jeil Medical Corporation	Jeil Medical Corporation	OsteoMed L.P.	Different
Indications for Use	Intended for use in Selective trauma of the mid-face, reconstruction procedures and selective orthognathic surgery of the maxilla and chin.	Intended for use in Selective trauma of the mid-face, reconstruction procedures and selective orthognathic surgery of the maxilla and chin.	Indicated for fracture fixation in cranio-maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction.	Same

	Subject Device	Primary Predicate Device	Reference Predicate Device	Similarity/Difference Discussion
Plate Design	<ul style="list-style-type: none"> <li>• Non-Locking Type</li> <li>- Curved Type</li> <li>- Straight Type</li> <li>- Square Type</li> <li>- Quad Type</li> <li>- L Type</li> <li>- Double Y Type</li> <li>- X Type</li> <li>- I Type</li> <li>- Chin Type</li> </ul>	<ul style="list-style-type: none"> <li>• Non-Locking Type</li> <li>- Curved Type</li> <li>- Straight Type</li> <li>- Square Type</li> <li>- L Type</li> <li>- Double Y Type</li> <li>- X Type</li> <li>- I Type</li> <li>- Chin Type</li> <li>- Calvarium Type</li> <li>- Mesh Type</li> <li>- H Type</li> <li>- Hexagon Type</li> <li>- Quad Type</li> <li>- T Type</li> <li>- Y Type</li> <li>- RC Type</li> <li>- Z Type</li> <li>- Rigid Straight Type</li> <li>- MG Type</li> <li>- A Type</li> <li>- Angled Type</li> <li>- Angled Reconstruction Type</li> <li>- Multi Reconstruction Type</li> <li>- Reconstruction Type</li> <li>- BSSO Type</li> </ul>	<ul style="list-style-type: none"> <li>• Non-Locking Type</li> <li>- Curved Type</li> <li>- Straight Type</li> <li>- L Type</li> <li>- Double Y Type</li> <li>- X Type</li> <li>- I Type</li> <li>- Chin Type</li> <li>- Mesh Type</li> <li>- H Type</li> <li>- Quad(Square) Type</li> <li>- Y Type</li> <li>- Z Type</li> <li>- BSSO Type</li> <li>- Orbital Type</li> </ul>	<p><u>Similarity</u> There are three same plate type categories in the subject device and the predicate devices.</p> <p><u>Difference</u> There are a few additions with minor shape changes to each category in the subject device comparing to the primary predicate device. However, the difference in shape is very minor; it is not introducing significantly different design, and the performance test results supported that this difference does not raise an issue in performance.</p> <p>Overall, the subject device plates are designed to enhance strength; the width and the cross-sectional area are larger than the primary predicate devices.</p>
	<ul style="list-style-type: none"> <li>• Compression Type</li> <li>- Straight Type</li> <li>- Angled Type</li> <li>- Curved Type</li> </ul>	<ul style="list-style-type: none"> <li>• Compression Type</li> <li>- Straight Type</li> <li>- Angled Type</li> </ul>	<ul style="list-style-type: none"> <li>• Compression Type</li> <li>- Straight Type</li> </ul>	

	Subject Device	Primary Predicate Device	Reference Predicate Device	Similarity/Difference Discussion
	<ul style="list-style-type: none"> <li>• Locking Type</li> <li>- AJ Type</li> <li>- Curved Type</li> <li>- L Type</li> <li>- Square Type</li> <li>- Straight Type</li> <li>- X Type</li> <li>- I Type</li> <li>- Double Y Type</li> <li>- Z Type</li> <li>- Angled Type</li> <li>- Angled Reconstruction Type</li> <li>- Multi Reconstruction Type</li> <li>- Reconstruction Type</li> <li>- BSSO Type</li> </ul>	<ul style="list-style-type: none"> <li>• Locking Type</li> <li>- Curved Type</li> <li>- Straight Type</li> <li>- Angled Type</li> <li>- Reconstruction Type</li> <li>- Angled Reconstruction Type</li> <li>- Multi Reconstruction Type</li> <li>- BSSO Type</li> </ul>	<ul style="list-style-type: none"> <li>• Locking Type</li> <li>- Curved Type</li> <li>- Straight Type</li> <li>- Angled Type</li> <li>- Condyle Plate</li> <li>- Comminution Type</li> <li>- Strut Type</li> <li>- Reconstruction Type</li> </ul>	
Plate Thickness	0.5mm 0.6mm 0.8mm 1.0mm 1.3mm 2.5mm	0.1mm 0.2mm 0.3mm 0.4mm 0.5mm 0.6mm 0.8mm 1.0mm 1.3mm 2.5mm	0.25~2.5mm 1.0mm~2.5mm	<u>Similarity</u> The plate thickness range of the subject device is within the range of the predicate devices.
Hole Shape	“O” shape (circle)	“O” shape (circle)	“O” shape (circle)	Same
Screw Type and Diameter	<ul style="list-style-type: none"> <li>• Self-tapping Screw</li> <li>1.3mm</li> <li>1.5mm(Emergency)</li> <li>1.6mm</li> <li>1.8mm(Emergency)</li> <li>2.0mm</li> <li>2.3mm(Emergency)</li> <li>2.4mm</li> <li>2.7mm(Emergency)</li> </ul>	<ul style="list-style-type: none"> <li>• Self-tapping Screw</li> <li>1.2mm</li> <li>1.5mm (Emergency)</li> <li>1.6mm</li> <li>1.9mm (Emergency)</li> <li>2.0mm</li> <li>2.3mm (Emergency)</li> <li>2.4mm</li> <li>2.7mm (Emergency)</li> </ul>	<ul style="list-style-type: none"> <li>• Self-tapping Screw</li> <li>1.2mm</li> <li>1.5mm</li> <li>1.6mm</li> <li>1.9mm</li> <li>2.0mm</li> <li>2.3mm</li> <li>2.4mm</li> <li>2.7mm</li> </ul>	<u>Similarity</u> The subject device screws are designed to enhance strength; the core-diameter of the screws is larger than the primary predicate devices.  The screw diameter and length range of the subject device is within the range of the
	<ul style="list-style-type: none"> <li>• Self-drilling Screw</li> <li>1.4mm</li> <li>1.6mm</li> <li>2.0mm</li> </ul>	<ul style="list-style-type: none"> <li>• Self-drilling Screw</li> <li>1.4mm</li> <li>1.6mm</li> <li>2.0mm</li> </ul>	<ul style="list-style-type: none"> <li>• Self-drilling Screw</li> <li>1.2mm</li> <li>1.6mm</li> <li>2.0mm</li> </ul>	

	Subject Device	Primary Predicate Device	Reference Predicate Device	Similarity/Difference Discussion	
	<ul style="list-style-type: none"> <li>Self-tapping Locking Screw</li> <li>2.0mm</li> <li>2.4mm</li> </ul>	<ul style="list-style-type: none"> <li>Locking Screw (Self-tapping Locking Screw)</li> <li>2.0mm</li> <li>2.3mm Emergency</li> <li>2.4mm</li> <li>2.7mm Emergency</li> </ul>	<ul style="list-style-type: none"> <li>Locking Screw (Self-tapping Locking Screw)</li> <li>2.0mm</li> <li>2.3mm</li> <li>2.4mm</li> <li>2.7mm</li> </ul>	predicate devices.	
Screw Length	<ul style="list-style-type: none"> <li>Self-tapping Screw 2 - 20mm</li> </ul>	<ul style="list-style-type: none"> <li>Self-tapping Screw 2 - 20mm</li> </ul>	<ul style="list-style-type: none"> <li>Self-tapping Screw 2 - 20mm</li> </ul>		
	<ul style="list-style-type: none"> <li>Self-drilling Screw 3 - 12mm</li> </ul>	<ul style="list-style-type: none"> <li>Self-drilling Screw 3 - 12mm</li> </ul>	<ul style="list-style-type: none"> <li>Self-drilling Screw 3 - 8mm</li> </ul>		
	<ul style="list-style-type: none"> <li>Self-tapping Locking Screw 3 - 20mm</li> </ul>	<ul style="list-style-type: none"> <li>Self-tapping Locking Screw 4 - 18mm</li> </ul>	<ul style="list-style-type: none"> <li>Self-tapping Locking Screw 4 - 22mm</li> </ul>		
Bone plates are used with general surgical instrumentation	Yes	Yes	Yes	Same	
Material	Plate	Titanium (ASTM F67)	Titanium (ASTM F67)	Titanium (ASTM F67)	Same
	Screw	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Same
Surface casting	Plate - Anodizing Screw - Anodizing	Plate - Anodizing	Plate - Anodizing Screw - Anodizing	Same	
Sterilization	Non-sterile, Steam sterilization prior to use	Non-sterile, Steam sterilization prior to use	Non-sterile, Steam sterilization prior to use	Same	
Single Use	Yes	Yes	Yes	Same	

When compared to the predicate device (K112457), the LeForte System II presented in this submission has similar;

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Biocompatibility
- Materials
- Size
- Method of sterilization and sterility assurance level

The subject device has slight differences in design from the predicate devices which are intended to enhance strength with the wider plates and the screws having larger core diameter. However, the performance test results support that this difference does not raise an issue in performance.

OsteoMed Modular Locking Fixation System (K080694) is identified as a reference predicate device which encompasses the length range of the subject device.

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

In all the respects, the LeForte System II is the substantially equivalent to currently marketed devices. This device is made of the same materials and has similar dimensions and characteristics. Based on the information provided in this submission, we conclude that the LeForte System II is substantially equivalent to the predicates in design, material, and functions.