Exhibit 5 510(k) Summary of Safety and Effectiveness

Model: LeForté Neuro System Bone Screw (Various Models)

1. **Submitter and US Official Correspondent**
   - **Submitter:** Jeil Medical Corporation
   - **Address:** #702, Kolon Science Valley 2nd
     811, Guro-dong, Guro-gu
     Seoul, 152-050, Korea
   - **Official Correspondent:** Shin Kuk Yoo, Consultant
   - **Telephone No.:** 714-313-7442
   - **Fax No.:** 801-303-7455
   - **Email:** skyone@LSKBioPartners.com

2. **Establishment Registration Number**
   - 3004049923

3. **Device Information**
   - **Proprietary/Trade Name:** LeForté Neuro System Bone Screw
   - **Common/Usual Name:** Bone Screw
   - **Classification Name:** Screw, Fixation, Intraosseous
   - **Classification Product Code:** DZL
   - **Device Class:** Class II per regulation 21 CFR 872.4880

4. **New or Modification**
   - The application is intended for premarket notification of new medical device, LeForté Neuro System Bone Screw, for US market.

5. **Previously Legally Marketed Device**
   - Plate, Bone (Model: Synthes (USA) Neuro Plate and Screw System) manufactured by Synthes (USA) – K042365. Decision Date: 11/18/2004, JEY (Class II per regulation 21 CFR 872.4760)
2) Screw, Fixation, Intraosseous (Model: Synthes (USA) 1.3mm Craniofacial Screws) manufactured by Synthes (USA) – K021850. Decision Date: 06/10/2002, DZL (Class II per regulation 21CFR 872.4880)

6. **Description of the Device**

The LeForte Neuro system bone screw is made of Titanium alloy (ASTM F136) and consists of common bone screw, self-drilling screw (auto screw & NS auto screw). The common bone screws are classified to 4 classes: Micro screw, Mid screw, Mini screw, Maxi screw. And the auto screws (self-drilling screws) are divided to 3 classes; Micro auto, Mid auto, Mini auto screws. Additionally, the NS auto screws are divided to 2 classes. This device is manufactured and intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; selective orthognathic surgery of the maxilla and chin. Jeil Medical Corporation utilizes the state of the art technology and apply the essential requirements of MDD(93/42/EEC) and ISO 14630:1997 from the device design to manufacturing and QC.

7. **Indications for Use (Intended Use)**

This device is intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; selective orthognathic surgery of the maxilla and chin.

8. **Potential Adverse Affects and Complications (Common to all devices of this type)**

1) Poor bone formulation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device or premature loss of fixation with the bone, leading to nonunion.

2) Nonunion or delayed union which may lead to breakage of the implant.

3) Migration, bending, fracture or loosening of the implant.

4) Metal sensitivity, or allergic reaction to foreign body.

5) Decrease in bone density due to stress shielding.

6) Pain, discomfort, or abnormal sensation due to the presence of the device.

7) Increased fibrous tissue response around the fracture site and/or the implant.

8) Necrosis of bone.

9) Inadequate healing.

Apart from these adverse effects there are always possible complications of any surgical procedure.
such as, but not limited to, infection, nerve damage and pain which may not be related to the implant.

9. Safety and Effectiveness, Comparison to Predicate Devices

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Leforte Neuro System Bone Screw (New)</th>
<th>Synthes(USA) L.3mm Craniofacial Screws (K021850)</th>
<th>Synthes(USA) Neuro Plate &amp; Screw System (K042365)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicant</td>
<td>Jeil Medical Corporation</td>
<td>Synthes(USA)</td>
<td>Synthes(USA)</td>
</tr>
<tr>
<td>Classification</td>
<td>Screw, Fixation, Intraosseous</td>
<td>Screw, Fixation, Intraosseous (Class II, 21 CFR 872.4880)</td>
<td>Intraosseous fixation screw or wire (Class II, 21 CFR 872.4880)</td>
</tr>
<tr>
<td></td>
<td>(Class II, 21 CFR 872.4880)</td>
<td>(Class II, 21 CFR 872.4880)</td>
<td>Bone Plate (Class II, 21 CFR 872.4760)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Burr hole cover (Class II, 21 CFR 882.5250)</td>
</tr>
<tr>
<td>Material</td>
<td>Titanium Alloy</td>
<td>Titanium Alloy</td>
<td>Titanium Alloy</td>
</tr>
<tr>
<td>Intended Use</td>
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<tr>
<td>Single use</td>
<td>Single Use</td>
<td>Single Use</td>
<td>Single Use</td>
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</tbody>
</table>
In all respects, the LeForte Neuro System Bone Screws are the equivalent of currently marketed devices. They are made of the same materials and have similar dimensions and characteristics. Potential adverse effects are identical to those of the predicate devices. This device is manufactured from material of titanium alloy (ASTM F136) that is used generally in this kind of bone screw. Similar devices made from titanium alloy (ASTM F136) to this device are manufactured and sold around the world. This device, LeForte Neuro system bone screw is substantially equivalent in design, material, and function to the products on the table above. These devices are certificated by notified body for CE.
Jeil Medical Corporation  
C/O Mr. Shin Kuk Yoo  
Manager  
LSK BioPartners, Incorporated  
215 South State Street, Suite 100B  
Salt Lake City, Utah 84111

Re: K091686  
Trade/Device Name: LeForte Neuro System Bone Screw (Various Models)  
Regulation Number: 21 CFR 872.4880  
Regulation Name: Intraosseous Fixation Screw or Wire  
Regulatory Class: II  
Product Code: DZL  
Dated: October 19, 2009  
Received: October 21, 2009

Dear Mr. Yoo:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOfl'ices/ucmI 5809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Exhibit 4 Indications for Use

510(k) number (if known): ____________________________

Device Name: LeForte Neuro System Bone Screw (Various Models)

Indications for Use:

This device is intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

Prescription Use Y AND/OR Over-The-Counter Use ____________

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091686