K022367
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EXHIBIT 2

Jeil Medical Corporation
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Seoul, KOREA
Telephone : 82-2-2109-6781~9
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October 2, 2002
Contact: N.K.Kim, R&D Director

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: Leforte System Bone Plate
   Classification Name: Plate, Fixation, Bone, Product Code HRS
   Common/Usual Name: Bone Plate

2. Equivalent legally marketed device: Osteo BOS™ System, K972323; Lorenz Small Fragment System, K992961; and Syntec-Taichung Non-sterile Titanium Mimi Plate, K983988

3. Indications for Use (intended use) . The device is used for internal fracture fixation of small bone (toe, finger etc) and reconstruction of Mandible & Maxilla. (Craniomaxillofacial Skeleton)

4. Description of the Device: Leforte system bone plate is made of unalloyed Titanium (ASTM F67-95 G1) and is manufactured and intended for internal fixation of small bones (toe, foot, finger, hand etc.) and reconstruction of Mandible & Maxilla. (Craniomaxillofacial Skeleton). Jeil Medical Co., Ltd. utilizes the state of the art technology and apply the essential requirement of MDD (93/42/EEC) and ISO 14630, 1997 from the device design to manufacturing and QC..

5. Potential Adverse Affects and Complications: (Common to all devices of this type)
   - Poor bone formation, 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.
   - Nonunion or delayed union which may lead to breakage of the implant.
   - Migration, bending, fracture or loosening of the implant.
   - Metal sensitivity, or allergic reaction to a foreign body.
   - Decrease in bone density due to stress shielding.
   - Pain, discomfort, or abnormal sensation due to the presence of the device.
   - Increased fibrous tissue response around the fracture site and/or the implant.
   - Necrosis of bone.
   - 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

6. Safety and Effectiveness, comparisons to predicate devices:

Device name	Osteo BOS System	Lorenz small fragment system	Syntec-Taichung nonsterile titanium mimi plate	Leforte System Bone Plate
Device Classification Name	Plate, fixation, bone 888.3030	Plate, fixation, bone 888.3030	Plate, fixation, bone 888.3030	Plate, fixation, bone 888.3030
Applicant	Osteonics Corp.	Walter Lorenz Surgical Inc.	Syntec-taichung Medical Instruments co.	Jeil Medical Corp.
510(K) Number	K972323	K992961	K983988	(This submission)
Material	Unalloyed Titanium (ASTM F67-95 G1)	Titanium, grade not specified in 510(k) summary	Unalloyed Titanium(ASTM F67-95 G1)	Unalloyed Titanium(ASTM F67-95 G1)
Intended Use	Long and small bone fracture fixation	Stabilization & fixation of fresh fracture, revision procedure, joint fusion & reconstruction of small bone	To treat fracture of various bones & small bone	Used for internal fracture fixation of small bone (toe, finger etc) and reconstruction of Mandible & Maxilla. (Craniomaxillofacial Skeleton)

7. Conclusion: In all respects, the Leforte System Bone Plates are the equivalent of currently marked devices. They are made of the same materials and have similar dimensions and characteristics. Potential adverse effects are identical to those of predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2002

Jeil Medical Corporation
c/o Kamm & Associates
Daniel Kamm, P. E.
P. O. Bos 7007
Deerfield, Illinois 60015

Re: K023360
Trade/Device Name: Leforte System Bone Plate
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTW
Dated: October 2, 2002
Received: October 7, 2002

Dear Mr. Kamm:

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.

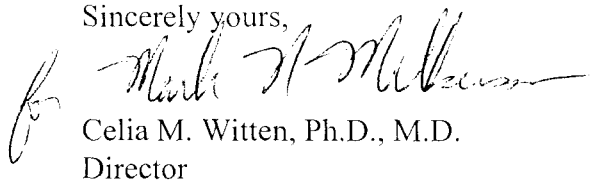
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) . premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

j) Indications for Use

510(k) Number K023360

Device Name: LeForte System Plates (various models)

Indications for Use: The device is used for internal fracture fixation of small bone (toe, finger etc) and reconstruction of Mandible & Maxilla. (Craniomaxillofacial Skeleton).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023360