K050669

MAY 26 2005

EXHIBIT 2

Jeil Medical Corporation
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March 7, 2005
Contact: N.K.Kim, R&D Director

510(k) Summary

1. Identification of the Device:
   Proprietary-Trade Name: Jeil Bone Fixation System
   Classification: Class II per regulations 872.4760
   Classification Name/Product Codes: JEY
   Common/Usual Name: Bone Screw, Bone Plate

2. Equivalent legally marketed devices: Straumann GBR System (K011698) Osteo-Mesh TM-300 (K984230), Dual Top Anchor System (K033767), Leforte System Plate (K023360), Leforte System Screw (K023365).

3. Indications for Use (intended use). The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity. Single patient use only

4. Description of the Device: The Jeil Bone Fixation System is comprised of bone screws, bone plates and instruments. (Refer the below table) The bone screws are composed of the titanium alloy (ASTM F136-98) and the bone plates are composed of the pure titanium (ASTM F67 Grade 1). The screws are offered in following range; diameter (1.4 ~ 2.0mm) and length (4.0 ~ 16.0mm). Also, the tip of screw has different 2 types; the self-drilling and self-tapping available type and the type that require the pre-drilling. (Surgeon's option) The bone plate is offered in 0.1mm and 0.2mm thickness and in length 37mm and 24mm. The applied titanium mesh over the cavity provides stable mechanical support while maintaining the sufficient flexibility for placement with decreasing tissue compliance related complication. The applied titanium screw for the on-lay bone above the alveolar bone provides stable mechanical rigidity and stability. This device system and each device are provided non-sterile. Therefore, this device must be sterilized prior to use. Steam sterilization is recommended. This device is provided with kit or Polyethylene package bag. The top of package bag is sealed with sealing strip. This system could be used with various instruments as follows.
   - Screw Block
   - Screw driver body
   - Driver shaft
   - Pilot drill

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.
   - Migration, bending, fracture or loosening of the implant.
   - Metal sensitivity, or allergic reaction to a foreign body.
   - 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

Safety and Effectiveness, comparisons to predicate devices:

Device Name	Straumann GBR System	Osteo-Mesh TM-300	Dual Top Anchor System	Le forte System Screws	Le forte System Plates	**Jeil Bone Fixation System**
Applicant	Straumann USA	Osteogenics Biomedical, Inc	Jeil Medical Corp.	Jeil Medical Corp.	Jeil Medical Corp	**Jeil Medical Corp.**
510(K) Number	K011698	K984230	K033767	K023365	K023360	-
Material	Pure Titanium (ASTM F 67 Gr 1/4)	Pure Titanium (ASTM F67)	Titanium Alloy (ASTM F 136-98)	Titanium Alloy (ASTM F 136-98)	Pure Titanium (ASTM F67 Gr 1)	**Titanium Alloy (ASTM F 136) Pure Titanium (ASTM F 67 Gr 1)**
Intended use	Use in stabilizing and fixating bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity. For the placement of dental implants in previously unsuitable sites.	For stabilization and support of bone grafts in dento-alveolar bony defect sites	use as a bone screw in temporary fixation of the maxilla and mandible, providing indirect stabilization of orthodontic treatment of the maxilla and/or the mandible	Fracture fixation as well as reconstruction and stabilization of small (i.e. toe, foot, finger, hand, etc) and the mandibulofacial (i.e. mandible and maxilla) bones	Used for internal fracture fixation of small bone(toe, finger etc and reconstruction of mandible & maxillar (Craniomaxillofacial skeleton)	**Use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity**
Single use	Yes	Yes	YES	YES	YES	**YES**
Sterile	Non-Sterile (Sterilize before use)	No comment	Non-Sterile (Sterilize before use)	Non-Sterile (Sterilize before use)	Non-Sterile (Sterilize before use)	**Non-Sterile (Sterilize before use)**

6. Conclusion: In all respects, the Jeil Bone Fixation system components 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. These devices are manufactured from titanium alloys that are used generally in this kind of bone screw and bone plate in devices that are manufactured and sold around the world. This device is substantially equivalent in design, material, intended use and function to the products on the table above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2005

Jeil Medical Corporation
C/O Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K050669
Trade/Device Name: Jeil Bone Fixation System (various models)
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY, DZL
Dated: March 7, 2005
Received: March 15, 2005

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050669

Device Name: Jeil Bone Fixation System

Indications For Use: The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity. Single patient use only.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K050669