K063052

ATTACHMENT 2

W.LORENZ SURGICAL
A Biomet Company

510(k) Summary

November 9, 2006

JAN 12 2007

Contact: Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, FL 32218-2480
Kim Reed, Sr. Regulatory Specialist
904-741-9443 fax 904-741-3912

Common or Usual Name: Bone Plate
Classification Name Plate, Fixation, Bone
Device Classification: Class II
Device Product Code: 76 JEY (21 CFR 872.4760)

Device Name: Lorenz Titanium Fracture / Reconstruction Devices and Pre-bent Plates

Intended Use: The Lorenz Titanium Fracture / Reconstructive Devices and Pre-bent Plates are intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstructive surgical procedures.

Contraindications:
1. Active infection.
2. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
3. Patients with limited blood supply, insufficient quantity or quality of bone, or latent infection.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
   If used in mandibular resection cases, the mandibular reconstructive devices must be supported using a graft. If mandibular reconstructive devices are not supported by a graft, the devices can be expected to fracture, bend, break or fail.

Description: The Lorenz Titanium Fracture / Reconstructive Devices are comprised of a variety of titanium fracture and reconstruction plates and screws with shapes and sizes designed for internal fixation of mandibular fractures and reconstruction procedures. The screws have both cross drive and center drive head features, lag screw designs as well as modular screw designs. The plates will include straight, angle, double angle, and crescent, options with various lengths and thickness.

The Lorenz Titanium Fracture / Reconstructive Pre-Bent Plates are comprised of a specific range of existing plates. The plate is pre-shaped based on a CT Scan provided by the Surgeon specifically for a certain patient.

The Pre-bent plates may, in special cases, be attached to our Temporary Add-on Condyle (cleared under K002790). In these cases, the package inserts for both the plate and the Temporary Add-on Condyle will be included with the product. The package insert for the Temporary Add-on Condyle is specific in identifying that this particular product is only indicated for temporary reconstruction and is not intended to be a permanent implant.

Sterility Information: The places and screws will be marketed as non-sterile, single use devices.

Possible risks:
1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
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 a foreign body.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability 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.
10. Mandibular devices can fracture, bend, break or fail if used to bridge a mandibular resection site, in the absence of a graft.

Substantial Equivalence W. Lorenz considers the Lorenz Titanium Fracture / Reconstructive Devices and Pre-bent plate Modifications equivalent to the Lorenz Titanium Fracture / Reconstructive Devices cleared under K980512 and K001238.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kim Reed
Senior Regulatory Specialist
Walter Lorenz Surgical, Incorporated
1520 Tradeport Drive
Jacksonville, Florida 32218

JAN 12 2007

Re: K063052
Trade/Device Name: Mandibular Fracture/Reconstruction Devices and Pre-Bent Plates
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: December 21, 2006
Received: December 22, 2006

Dear Ms. Reed:

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.

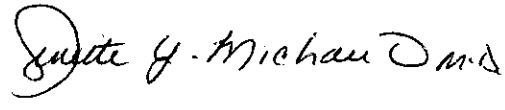
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K06 3052

Device Name: Mandibular Fracture/Reconstruction Devices and Pre-bent plates

Indications For Use:

Intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstructive surgical procedures.

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

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

510(k) Number: K063052