K063386

W.LORENZ SURGICAL
A Biomet Company

1520 Tradeport Drive
Jacksonville, FL 32218
904-741-4400 fax 904-741-3912
Kim Reed, Sr. Regulatory Specialist

FEB 9 2007

510(k) Summary

Trade Name: Lorenz Orthodontic Anchorage System

Classification and Common Name and Reference: Bone Plate CFR 21 872.4760

Product Code: JEY

Device Classification: Class II

Device Description: The Walter Lorenz Surgical Orthodontic Anchorage System is comprised of a variety of plates and screws designed to provide anchorage for orthodontic procedures.

Intended Use: These implants are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth.

Materials Commercially Pure Titanium, ASTM F-67
Titanium 6Al 4V Alloy, ASTM F-136

Possible Adverse Effects:

1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the implant.
2. Migration, bending, fracture or loosening of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Decrease in bone density due to stress shielding.
5. Pain, discomfort, abnormal sensation, or palpability due to the presence of the implant.
6. Increased fibrous tissue response around the implant.
7. Necrosis of bone.
8. Inadequate healing.
9. Injury or damage to teeth or periodontal structures.
10. Failure to achieve desired orthodontic result.
11. Undesirable orthodontic result.

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.

Substantial Equivalence: The Lorenz Orthodontic Anchorage System is believed to be substantially equivalent in application and function to the KLS-Martin Ortho Anchorage System K040891, the Stryker Leibinger Skeletal Anchoring System K041651, the Lorenz Craniofacial/Neuro Bone Plates and Screws 1.0, 1.5 and 2.0mm System K953385 and to the Lorenz IMF and Self-Drilling IMF Screws K983728 and K040983.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

FEB 9 2007

Re: K063386
Trade/Device Name: Lorenz Orthodontic Anchorage System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: February 6, 2007
Received: February 7, 2007

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.

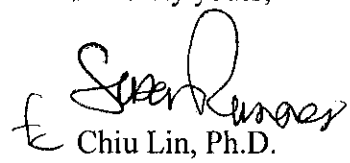
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Device Name: Lorenz Orthodontic Anchorage System

Indications For Use:

The Lorenz Orthodontic Anchorage System implants are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth.

Prescription Use _____ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(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)

Susan Runyon

Sign-Off)
Anesthesiology, General Hospital,
Control, Dental Devices

ber: K063356