



**MAY 25 2005**

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Diana Preston  
Regulatory Affairs Specialist  
Walter Lorenz Surgical, Incorporated  
1520 Tradeport Drive  
Jacksonville, Florida 32218-2480

Re: K983728  
Trade/Device Name: Lorenz IMF Screw  
Regulation Number: 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: II  
Product Code: DZE  
Dated: February 12, 1999  
Received: February 16, 1999

Dear Ms. Preston:

This letter corrects our substantially equivalent letter of February 12, 1999 regarding the incorrect product code of the Lorenz IMF Screw.

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 (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.

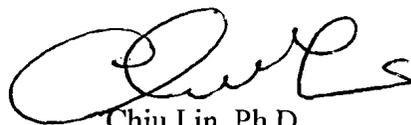
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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K983728

## **Summary of Safety and Effectiveness**

**Device Name:** Lorenz IMF Screw

**Classification Name and Reference:** Screw, Fixation, Intra osseous (21 CFR 872.4880)

**Intended Use:** The Lorenz IMF Screw is intended for use as a bone screw in temporary fixation of the maxilla and mandible, providing indirect stabilization of fractures of the maxilla and/or the mandible.

**Device Description:** The bone screw for maxillomandibular fixation is 1.7mm in diameter and lengths may range from 8mm - 20mm. The head has a relief groove which may or may not have a hole in which a wire or elastic bands can be wrapped around the screws which are temporarily implanted in the maxilla and mandible. The tip of the screw is designed so that a predrilled hole is not required, but may be used.

### **Potential Risks:**

- Nonunion or delayed union which may lead to breakage of device.
- Metal sensitivity or allergic reaction to a foreign body.
- Pain, discomfort or abnormal sensations due to the presence of the device.
- Nerve damage due to trauma or improper placement of the device.
- Other conditions brought on by the surgical procedure including skin irritation and infection.
- The device may bend, loosen, or fracture while implanted.
- Biomechanical complications due to improper positioning of the mandibular condyle.

**Substantially Equivalent Devices:** The device is believed to be substantially equivalent to Leibinger IMF Screw K963030.

**Sterility Information:** The device is being labeled nonsterile. Sterility recommendations are included in the package insert.