NOV 19 1999 K992952

Summary of Safety and Effectiveness

Device Name: Lorenz Distraction System

Classification Name and Reference: Plate, Fixation, Bone; 87 HRS (21 FR 888.3030)

Device Description: The Lorenz Distraction System includes several designs of implantable distractors which all have a drive screw mechanism and connection plates. Three basic types are included; without rails, with one rail, and with two rails. Each distractor is made of either Titanium or 316 LVM Stainless Steel materials.

Intended Use: The Lorenz Distraction System includes devices intended as a bone stabilizer, and distraction devices when correction of congenital deficiencies or post traumatic defects of oral (including the mandible, alveolar ridge, palate, and symphysis areas), cranial, and maxillo-facial bone require gradual distraction.

Potential Risks: The potential risks associated with the distraction system implants include but may not be limited to the following;

1. Nonunion, delayed union, or premature union may lead to breakage of the device.
2. Bending, loosening, or stripping of the threads or fracture of the device.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. If device remains implanted, decrease in bone density due to stress shielding.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Nerve damage due to surgical trauma.
7. Necrosis of bone.
8. Biomechanical complications after distraction due to positioning of the device.
9. Inadequate healing.
10. Other conditions brought on by the surgical procedure including skin irritation and infection.

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 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1999

Ms. Diana Preston
Regulatory Specialist
Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K992952
Trade Name: Lorenz Distraction System
Regulatory Class: II
Product Code: MQN
Dated: August 30, 1999
Received: September 1, 1999

Dear Ms. Preston:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~Unknown~~ K992952

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 FR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K992952