

NOV - 8 1999

K992961
1 of 1

510(k) Summary

Diana Preston
Regulatory Affairs Specialist
Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, FL 32218-2480

Device Name: Lorenz Small Fragment System

Common or Usual Name: Small Bone Plating System

Classification Name: Single / Multiple Component Metallic Bone Fixation
Appliances and Accessories

Device Classification: Class II

Device Product Code: 87 HRS (21 CFR - 888.3030)

Device Description: The Lorenz Small Fragment System is comprised of a variety of titanium plates and screws with shapes and sizes designed for internal fixation of small bones. The screws will have both cross drive and center drive head features and be 1.2mm - 2.7mm in diameter. The plates will include straight, rectangle, parallelogram, trapezoid, T, L, Y, Z, and condylar pin options with various lengths and thicknesses.

Intended Use: The Small Fragment System consists of bone plates and screws to be used for stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, toes, and craniomaxillofacial skeleton.

Potential Adverse Affects and Complications:

- 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.
- Nonunion or delayed union which may lead to breakage of the implant.
- Migration, bending, fracture or loosening of the implant.
- Metal sensitivity, or allergic reaction to a foreign body.
- Decrease in bone density due to stress shielding.
- 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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K992961
Trade Name: Lorenz Small Fragment System
Regulatory Class: II
Product Code: HRS
Dated: September 1, 1999
Received: September 2, 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.

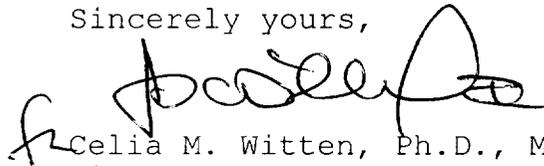
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 pre-market 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.

Page 2 - Ms. Diana Preston

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) 594-4659. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

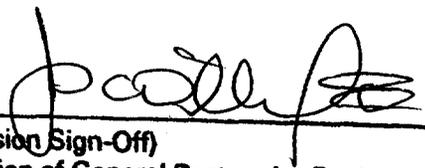
510(k) Number (if known): unknown

Device Name: Lorenz Small Fragment System

Indications For Use: The Small Fragment System consists of bone plates and screws to be used for stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, toes, and craniomaxillofacial skeleton.

(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 General Restorative Devices
510(k) Number K99296

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)