

MAY 11 1998

Attachment II

K980512

## Summary of Safety and Effectiveness

Device Name: Lorenz Reconstruction System with Modular Screw

Classification Name: Bone Plate and Bone Screw

Device Product Code: Bone Plate - 76JEY (21 CFR 872.4760)  
Bone Screw - 87HWC (21 CFR 888.3040)

### Intended Use:

The Lorenz Reconstruction System with Modular Screw is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstructive surgical procedures.

### Device Description:

The Lorenz Reconstruction System with Modular Screw has been designed to include two plate thickness profiles; the low profile plates, 0.079" thick, and the high profile plates, 0.102" thick. Both plate profiles will have a threaded hole design for use with the modular screw. The threaded holes, spaced 0.295" apart, have an oval countersink to allow a standard screw greater angulation and compression, as necessary.

The modular screw is a two piece design; a detachable head and a threaded body for insertion into the bone. The detachable head has an inner and outer thread profile. The outer thread profile is for locking the screw head to the plate. The inner thread profile is for detaching and reattaching the head from the threaded body of the screw, as necessary. The detachable head can be taken off the threaded body of the screw after insertion into the bone. This allows the surgeon to correctly position the plate before a resection procedure. The screw head and reconstruction plate can then be removed for the resection procedure, leaving the body of the screw as points of reference for correct repositioning of the mandible after the procedure.

1.5 mm "add on" plates have been designed for use when the defect site includes bone fragments or pieces that require additional stabilization. The "add on" plates attach to the reconstruction plate using only the modular head or recon plug. The fixation of the "add on" plate to the bone site requires a standard 1.5 mm screw.

### Sterility Information:

The plates and screws will be marketed as non-sterile, single use devices.

**Substantial Equivalence:**

The Lorenz Reconstruction System with Modular Screw is believed to be substantially equivalent to Synthes Maxillofacial's Mandibular Modular Fixation System and Leibinger's Locking Screw Mandibular Reconstruction Plating System.

**Potential Risks:**

The following is a listing of potential risks, which will be included in the package insert.

- Nonunion or delayed union which may lead to breakage of the implant
- Bending or fracture of the implant
- Loosening of the implant
- Metal sensitivities or allergic reaction
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Necrosis of bone



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 11 1998

Ms. Diana Preston  
Regulatory Specialist  
Walter Lorenz Surgical, Incorporated  
P.O. Box 18009  
Jacksonville, Florida 32229-8009

Re: K980512  
Trade Name: Lorenz Reconstruction System with Modular  
Screw  
Regulatory Class: II  
Product Code: JEY  
Dated: February 9, 1998  
Received: February 10, 1998

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 premarket notification submission does

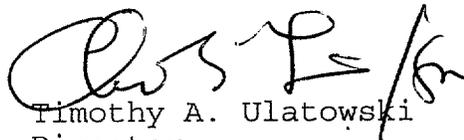
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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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

**Device Name:** Lorenz Reconstruction System with Modular Screw

**Indications For Use:** The Lorenz Reconstruction System with Modular Screw is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstructive surgical procedures.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*RSB for MSR*

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

510(k) Number K980512

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

Over-the-Counter Use \_\_\_\_\_