

OCT 23 1998

Summary of Safety and Effectiveness

K982604

Device Name: Lorenz Maxilla (Le Fort) Distraction System

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

Device Description: This device is a linear distractor with a drive screw and two connection plates. Normally both a left and right device is implanted together. The two plates cap the resected zygoma such that the screws only prevent the device from slipping but are not relied upon to carry the distraction load.

The device is placed internally with the drive mechanism protruding through the skin anteriorly. Two lengths for the threaded rod will allow up to 32mm (1.27") of distraction. After distraction is complete, the drive mechanism can be detached and the plates and screws and drive screw may be left under the skin. The device is advanced using a separate torque wrench.

Intended Use: The Lorenz Maxilla (Le Fort) Distraction System is intended for use in the maxilla as a bone stabilizer and lengthening device when correction of congenital midfacial deficiencies or post traumatic defects require gradual bone distraction

Potential Risks: The potential risks associated with the maxilla distraction implant include but are not limited to the following;

- Inadequate bone quality
- Nonunion or delayed union
- Metal sensitivity or allergic reaction to the foreign body
- Malpositioning of implant
- Infection
- Nerve Injury
- Bending, loosening, stripping, or fracture of implant

Substantially Equivalent Devices: The device is believed to be substantially equivalent to Howmedica Leibinger's Guerrero-Bell Distractor (K972166), and Cohen Distractor (K972154), and Synthes Mini Lengthening Apparatus (K973018)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 1998

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

Re: K982604
Trade Name: Lorenz Maxilla (Le Fort) Distraction System
Regulatory Class: II
Product Code: MQN
Dated: July 24, 1998
Received: July 27, 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 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 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. 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) 594-4692. 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

Device Name: Lorenz Maxilla (Le Fort) Distraction System

Indications For Use: The Lorenz Maxilla (Le Fort) Distraction System is intended for use in the maxilla as a bone stabilizer and lengthening device when correction of congenital midfacial deficiencies or post traumatic defects require gradual bone distraction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Merald Stupp

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K982604

Prescription Use
(Per 21 FR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)