JUN 17 2003

K031696

Summary of Safety and Effectiveness

Device Name: Lorenz External Mandibular Distraction

Intended Use: The Lorenz External Mandibular Distractor is an external Fixator used for mandibular bone lengthening. It is used in treatment of mandibular asymmetry and hypoplasia.

Contraindications:

1. Active infection and sepsis.
2. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
3. Patients with limited blood supply, insufficient quantity or quality of bone, or latent infection.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
5. Bone disorders which limit bone generation.

Description: (SAME AS ORIGINAL SUBMISSION ~~K001238~~ K992873) "The distractor frame is comprised of two threaded rails, a longer straight rail, and a shorter, angled rail to accommodate the anatomic angles of the mandible. These two rails are connected with a locking collar placing the ball joint in the center allowing three-dimensional contouring to match facial curvatures. This biplanar distractor allows for up to 40mm distraction with the straight rail, and up to 30mm distraction with the angled rail."

Sterility Information: The places and screws will be marketed as non-sterile, single use devices

Possible risks:

1. Bending, loosening of bone screws, K-wire, or ball joint, stripping of threaded rails, or fracture of the device.
2. Nonunion, delayed union, or premature union may lead to breakage of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Pain, discomfort or abnormal sensations due to the presence of the device.
5. Nerve damage due to surgical trauma.
6. Other conditions brought on by the surgical procedure including skin irritation and infection.
7. Biomechanical complications due to positioning of the device.
8. Poor done formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
9. Necrosis of bone or soft tissue.
10. Tension of the soft tissue depending on the speed of distraction and quality of the soft tissues and therefore irritation and/or atrophy.
11. Inadequate healing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2003

Ms. Kim Reed
Sr. Regulatory Specialist
Walter Lorenz Surgical, Incorporated
1520 Tradeport Drive
Jacksonville, Florida 32218-2480

Re: K031696
Trade/Device Name: Lorenz External Mandibular Distractor
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Codes: MQN
Dated: May 30, 2003
Received: June 05, 2003

Dear Ms. Reed:

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 application (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 such 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 begin 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 (301) 594-4613. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K031696

Device Name: External Mandibular Distractor

Indications For Use:

The Lorenz External Mandibular Distractor is an external Fixator used for mandibular bone lengthening. It is used in treatment of mandibular asymmetry and hypoplasia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use _____ (Optional Format 1-2-96)

Kevin Mulley for H HB

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

510(k) Number: K031696