SEP 17 1999

K992873

Summary of Safety and Effectiveness

Device Name: Lorenz External Mandibular Distractor

Predicate Device: Lorenz Mandibular Distractor, 510(k) number K955640

Classification Name: External Mandibular Fixator and/or Distractor

Device Product Code and Regulation Number: MQN, 21 CFR 872.4760

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.

Device Description:
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.

Bone screws (or K-wire) are inserted percutaneously into the bone and attached to the distractor frame with a clamp.

The frame is locked by set screws which tighten and thereby lock the ball joint and rails in place. Adjustments can be made intra-operatively or post-operatively.

Device Modifications:

1. **Materials:**
   - Predicate distractor K955640:
     1. external distractor frame- hard coat anodized aluminum
     2. bone fixation pins-Ti-6Al-4V
     3. lengthening screw- stainless steel
   - Modified distractor:
     1. external distractor frame (rails and ball joint)- stainless steel
     2. ball locking collar-Ti-6Al-4V
     3. bone screws/k-wire-316 LVM Stainless Steel
     4. clamp-hard coat anodized aluminum

Device Modifications cont.

2. **Device**:

- Predicate distractor K955640:
    1. unilateral distraction with ball joint
    2. 4mm screw with 0.5mm pitch
    3. 2.7mm percutaneous bone fixation pins
- Modified distractor:
    1. Biplanar distraction with ball joint
    2. 6mm screw (rail) M6 x 1 thread (1mm pitch)
    3. 3.0/2.5mm taper trocar tipped bone fixation screws
       2.5/2.0mm taper trocar tipped bone fixation screw
       1.6 & 2.0mm K-wire

3. **Design**:

- Predicate distractor
    1. The frame has a ball joint at one end and a lengthening screw at opposite end.

- Modified distractor
    1. Frame has two threaded rails, a longer straight ball rail, and a shorter, angled rail to accommodate the anatomic angles of the mandible. The two rails are connected with a locking collar placing the ball joint in the center.
    2. Bone screws/K-wire attach to frame by clamps.

Potential Risks:

1. Bending, loosening of bone screws, k-wire, or ball joint, stripping the threads, or fracture of the device.
2. Nonunion, delayed union, or premature union.
3. Metal sensitivity or allergic reaction.
4. Pain, discomfort or abnormal sensations due to the presence of the device.
5. Nerve damage.
6. Other conditions brought on by the surgical procedure including skin irritation and infection.
7. Biomechanical complications due to improper positioning of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 1999

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

Re: K992873
Trade Name: Lorenz External Mandibular Distractor
Regulatory Class: II
Product Code: MQN
Dated: August 23, 1999
Received: August 26, 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) 594-4690. 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 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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992873

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)