K020407

FEB 2 2 2002

510(k) SUMMARY (per 21 CFR 807.92(c))

1. SUBMITTER

Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, FL 32218
FDA Registration No. 1032347

2. PRODUCT NAME

Common/Usual Name: Bone Lengthening Device/Plate, Fixation, Bone

Proprietary Name: Lorenz BLUE Device

3. DEVICE CLASSIFICATION

Bone Lengthening Devices have been cleared by the FDA via 510(k) Premarket Notifications as Product Code MQN, External Distractor – Class II. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic act for External Distractors.

4. PREDICATE DEVICE

The predicate device is the Lorenz Distraction System cleared under 510(k) number K992952 on November 19, 1999.

5. DESCRIPTION OF THE DEVICE

The Lorenz BLUE Device is a distractor that has a drive screw mechanism and external frame that is rigidly attached to the patient with cranial screws.

6. INTENDED USE OF THE DEVICE

The Lorenz BLUE Device is intended as a bone stabilizer, and distraction devices when correction of congenital deficiencies or post traumatic defects of oral (including the mandible, alveolar ridge, palate, and symphysis areas), cranial, and maxillo-facial bone require gradual distraction.

7. STATEMENT OF COMPARISON OF TECHNOLOGICAL FEATURES

Although the appearance of these devices is different; the implantable portions, implantable materials, the fundamental operating mechanism, the activation, and the intended use of these devices is the same. Attachment to the transporting bone segment is accomplished with internal plates and bone screws in each system. The modified device is being added to allow for additional options for screw placement in areas of good bone quality and improved vector control.

8. CONCLUSIONS

The use of the modified Lorenz BLUE Device and the predicate Lorenz Distraction System as bone lengthening devices is substantially similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2002

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

Re: K020407
Trade/Device Name: Lorenz Blue Device
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: February 5, 2002
Received: February 6, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K020407

Device Name: Lorenz BLUE Device

Indications For Use:

The Lorenz BLUE Device is intended as a bone stabilizer, and distraction devices when correction of congenital deficiencies or post traumatic defects of oral (including the mandible, alveolar ridge, palate, and symphysis areas), cranial, and maxillo-facial bone require gradual distraction. This is the same intended use as previously cleared for the Lorenz Distraction System (K992952).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020407