

MAY 14 2004

K030425

## Summary of Safety and Effectiveness

510(k) Summary (per CFR 807-92(c))

**Device Name:** Lorenz Resorbable Distraction System

**Classification Name and Reference:** Plate, Fixation, Bone (21 CFR 888.3030); and  
Screw, Fixation, Bone (21 CFR 888.3040)

**Product Code:** 76 JEY

**Device Classification:** Class II

This distractor system is identical to the one cleared in 510(k) Premarket Notification (K002083). This device is composed of the same Lactosorb® end plates and fixation screws, and stainless steel drive screws as the predicate device. The only difference is the added indication of mandibular distraction.

The **Mandibular Distractor** is the same as our previously cleared Alveolar Ridge Resorbable Distractor (K002083) which is an implantable device used to increase the height of the maxilla or mandible to replenish lost bone of the alveolar process. The device is composed of two resorbable plates and a stainless steel drive screw with permanently attached stainless steel flexible cable. The device has two different sizes, small plates for single tooth use and large plates for multiple tooth deficiencies. Several lengths of drive screw can be selected to achieve up to 25 mm of distraction.

The **Mandibular Distractor** can incorporate either of the two Alveolar Ridge resorbable devices detailed above and be used for mandibular or ramus lengthening with no design changes. In addition, a third device is included that is identical to the two Alveolar Ridge resorbable devices but incorporates more screw holes to provide more options for screw placement. Each device is composed of two resorbable plates and a stainless steel drive screw with permanently attached stainless steel flexible cable. Advancements can be either unilateral or bilateral. The Mandibular Distractors would be used in patients under two years of age. Devices would be positioned internally with drive screws extending through soft tissue for external activation. Osteotomies of the mandible would be completed prior to device placement. Lactosorb plates would be affixed to either side of the osteotomy with Lactosorb screws. Distraction is achieved by activating the drive screw using the attached shaft extension, causing the plates to separate. Upon completion of the distraction and consolidation, the drive shaft is detached from the plates and removed while the plates and screws remain internal and are resorbed.

**Intended Use:** The Lorenz Resorbable Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) when correction of oral (alveolar ridge), cranial, maxillofacial deficiencies or post-traumatic defects require gradual bone distraction. The Lorenz Resorbable Distraction System also includes devices intended for use in bone stabilization and elongation (lengthening) when correction of mandibular deficiencies or post-traumatic defects require gradual bone distraction patients two (2) years old or younger. The mid-face distractor is intended primarily for LeFort III osteotomies.

**Materials** Bone Plates: Lactosorb® (resorbable copolymer) – a polyester derivative of lactic and glycolic acids  
Bone Screws: Lactosorb®  
Drive Screw: Stainless steel  
Shaft Extension: Titanium, Stainless Steel

Lactosorb® is made of 82% L-Lactide/18% Glycolide copolymer that degrades by hydrolysis into L-Lactic and glycolic acids. These hydrolytic products are then further degraded into carbon dioxide and water via the cellular Krebs cycle. Lactosorb® has been previously cleared by 510(k) notifications for use in bone plates (K992355, K992158, K971870, K960988, K955729) and bone screws (K981666, K960988) for cranial and maxillofacial use.

### POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS

1. Poor bone formation, osteoporosis, osteolysis, osteomyelitis, inhibited revascularization, or infection can cause loosening, migration, bending, cracking or fracture of the device.
2. Nonunion or delayed union may lead to breakage of the implant.
3. Bending, loosening, stripping the threads or fracture of the implant.
4. While rare, implantation of foreign materials can result in an inflammatory response or allergic reaction.
5. If metal parts of the device remain implanted, decrease in bone density due to stress shielding.

6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Nerve damage due to surgical trauma.
8. Necrosis of bone.
9. Biomechanical complications after distraction due to positioning of the device.
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.
12. Other conditions brought on by the surgical procedure including skin irritation and infection.
13. Soft tissue adherence to device during activation.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

### **Substantial Equivalence**

#### Distraction Systems

Lorenz Resorbable Distractor System (K002083)

Lorenz Distraction System (K992952)

#### Resorbable Fixation Screws and Plates

Lactosorb® Trauma Plating System (K971870)

Lactosorb® Trauma Plating System (K955729)

2.5 MM Lactosorb® Screws (K981666)

Lactosorb® Panels (K974309)

#### RELATED ARTICLES:

1. Burstein MD, Fernando D., Williams MD, Joseph K., Hudgins MD, Roger, Graham MD, Leroy, Teague MD, Gerald, Paschal PA-C, Michelle, Simms RN, Catherine. Single-Stage Craniofacial Distraction Using Resorbable Devices. *The Journal of Craniofacial Surgery* Vol. 13 No. 6 November 2002 pp. 776-782.
2. Chin M, Toth BA. Distraction Osteogenesis in Maxillofacial Surgery using Internal Devices: Review of Five Cases. *Journal of Oral Maxillofacial Surgery* 54:45, 1996.
3. Chin M, Toth BA, LeFort III Advancement with Gradual Distraction Using Internal Devices. *Plastic and Reconstructive Surgery* 100: 819, 1997
4. Diner PA (Discussion) Chin M, Toth BA. LeFort III Advancement with Gradual Distraction Using Internal Devices. *Plastic and Reconstructive Surgery* 100: 831, 1997.
5. Toth BA, Kim JW, Chin M, Cedars M. Distraction Osteogenesis and its Application to the Midface and Bony Orbit in Craniosynostosis Syndromes. *Journal of Craniofacial Surgery* 9:2, 100-112, 1997.
6. Eppley, Barry L, Sandove, A Michael, A Comparison of Resorbable and Metallic Fixation in Healing of Calvarial Bone Grafts, *Plastic and Reconstructive Surgery*, August 1995.

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**Internal Distraction Devices**  
**ATTENTION OPERATING SURGEON**

**WARNINGS AND PRECAUTIONS FOR USE OF**  
**RESORBABLE MID-FACE, ALVEOLAR RIDGE,**  
**MANDIBULAR DISTRACTORS**  
ALL INSTRUCTIONS MUST BE READ CAREFULLY PRIOR  
TO CLINICAL USE

**DESCRIPTION**

Walter Lorenz Surgical, Inc. manufactures and distributes distraction devices for use in bone stabilization and elongation (lengthening) when correction of oral, cranial, mandibular and maxillofacial deficiencies or post traumatic defects require gradual bone distraction. Each implantable distraction device has a titanium alloy drive screw mechanism and LactoSorb® resorbable connection plates, which are implanted by fixation with LactoSorb® bone screws.

Each device is made from one of the following material(s): LactoSorb®, Titanium 6Al 4V Alloy, ASTM F-136, Stainless Steel, ASTM F-138

LactoSorb® is a resorbable copolymer, a polyester derivative of lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis into lactic and glycolic acids that are then metabolized by the body.

**INDICATIONS**

1. Correction of congenital or developed deficiencies of the oral (alveolar ridge), cranial, and maxillofacial bone.
2. Correction of congenital or developed deficiencies of the mandibular bone in patients 2 years old or younger.
3. Post-traumatic defects of the oral (alveolar ridge), cranial, and maxillofacial skeleton.
4. Post traumatic defects of the mandibular skeleton in patients 2 years old or younger.
5. Correction of midface deformities
6. LeFort III correction of deformity.
7. Mandibular distraction osteogenesis in patients 2 years old or younger.

**CONTRAINDICATIONS**

1. Active infection.
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, or parents/guardians of patients are unwilling or incapable of following postoperative care instructions.
5. Patients with bleeding disorders or poor wound healing.
6. Patients with metabolic disorders.

**WARNINGS**

Distraction devices aid the surgeon in the defined step by step elongation of bone in the oral, cranial, mandibular, and maxillofacial skeleton. Correct handling, connection and placement of these implants are extremely important. The surgeon is to be thoroughly familiar with the implant, the specific method of application, as well as the local biomechanical situation of each patient. The surgeon must be thoroughly knowledgeable with the components, instruments and surgical procedure. Incomplete osteotomy or premature osteosynthesis may cause the device to bend, break, or the distraction screw to strip resulting in device

malfunction or failure. The surgeon must plan proper placement and orientation of the device for each patient prior to implantation. Correct positioning of the device reduces the risk of device loosening from bone or possible biomechanical complications after distraction is complete. In Mandibular distraction, airway integrity should be closely monitored due to patient population. In all cases, sound surgical practice is to be followed.

1. Improper selection, placement, positioning, and fixation of the devices can cause a subsequent undesirable result. The surgeon is to be familiar with the devices, the method of application, and the surgical procedure prior to performing surgery.
2. Correct handling of the implant is extremely important. Implants should be modified only when necessary. Modifications or excessive contouring of implants may cause damage to the device. Notches, dents, and scratches resulting from the modifications can contribute to breakage.
3. Intraoperative fracture of screws or plates can occur if excessive force is applied while seating bone screws.
4. The resorbable plates can be heated and shaped as desired up to and including three times using a LactoSorb® Heat Pack or a hot sterile saline/water bath. LactoSorb® exposure to the bath should be a maximum of 15 seconds per bath with the temperature not exceeding 85°C. LactoSorb® plates cannot be applied, removed, and reapplied after fixation with screws is completed.
5. Implants may be removed after the fracture has healed. Implants can loosen, fracture, corrode or cause pain. If an implant remains implanted after complete healing, the implant may cause stress shielding, which may increase the risk of refracture.
6. Adequately instruct the patient, parents or guardians. The cooperation and willingness of the patient, parents or guardians over the course of the complete treatment is extremely important. Postoperative care and the patient's, parents' or guardians' ability and willingness to follow instructions are important aspects of successful distraction and healing. A daily distraction plan should be worked out with the patient and / or guardian. The patient, parent or guardian is to be warned that failure to follow postoperative instructions can cause failure of the device or the treatment. If loosening or metal fatigue occurs before distraction is complete, revision surgery may be necessary to replace or remove the device.
7. For mandibular distraction, the patient should be limited to a soft diet throughout distraction and consolidation phases. Soft diet should consist of food no harder than cooked pasta.
8. The patient's parent or guardian is to be made fully aware and warned that the device can break, bend or be damaged as a result of stress, activity, and load bearing. The patient is to be made aware and warned of general surgical risks, complications, and all possible adverse effects.
9. The surgeon should weigh the risks versus benefits when deciding to remove the implant. Generally, LactoSorb® devices require only the removal of titanium alloy components (plates and screws are not removed). Adequate postoperative management should follow implant removal.
10. Discard and DO NOT USE previously opened or damaged devices. Use only devices that are packaged in unopened or undamaged containers.
11. DO NOT USE if there is loss of sterility of the device, or if the expiration date has passed.

**PRECAUTIONS**

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce

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the service life of the implant. Do not treat patients with implants that have been even momentarily placed in a different patient.

Surgical instruments must be used only for the device systems for which they are designed. Use of other manufacturer instruments can involve incalculable risks for the implant and instrument, thereby potentially endangering the patient, user, or third party. Intra-operative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Walter Lorenz recommends that all instruments be regularly inspected for wear and disfigurement.

**Bone Plates:**

Distraction devices have resorbable bone plates for implanting the device. These plates may require contouring to the surface of the bone by heat contouring using a LactoSorb® Heat Pack or a hot sterile saline/water bath. LactoSorb® exposure to the bath should be a maximum of 15 seconds per bath with the temperature not exceeding 85°C. Do not attempt to bend resorbable plates with plate benders.

- Care must be taken to achieve the appropriate contour with as few bends as possible.
- Sharp angles and small bending radii must be avoided to reduce the risk of the device breaking.
- Do not over-trim the plates. Trimming the connection plates may cause premature weakening and failure of the plates.

**Bone Screws:**

- The screwdriver which has been designed for a particular system of screws must always be used to be sure that proper screwdriver/screw head connection is achieved.
- Incorrect alignment or fit of the screwdriver to the screw head may increase the risk of damage to the implant or screwdriver.
- Excessive torque can cause the screw or plate to fracture.
- A sufficient number of screws should be used in each plate to assure solid fixation through the distraction/consolidation period. Implanting a plate using an insufficient quantity of screws can lead to premature failure of the procedure.
- LactoSorb® bone screws should never be heated.

**Drive Shaft Extensions and Connections**

- Flexible shafts may be weakened or break as a result of excessive force.
- The connection sleeve must be locked down and remain locked during the entire distraction period.

**Twist Drills:**

- Twist drills are labeled for single procedure use only.
- When using twist drills, appropriate cooling is necessary to minimize thermal damage to bone tissue. It should be combined with low speed drilling to prevent the risk of bone demineralization and possible loosening of the bone screw.
- The manufacturers instructions for the hand piece used with the twist drill must be followed. The manufacturer of the handpiece may recommend proper speeds to avoid failures such as breakage of the twist drill.
- Excessive force may cause unusual stress conditions and result in breakage or fracture of the device.
- Breakage of twist drills may result in injury to the patient, the user, or third party.
- If a twist drill fails during use, the drill guides aid in the protection of the patient, user or third party.

**POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS**

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**STERILITY**

Distraction devices are supplied sterile by exposure to ethylene oxide (ETO) gas. DO NOT RESTERILIZE. DO NOT USE after expiration date has passed.

STORE AT OR BELOW ROOM TEMPERATURE. DO NOT EXPOSE PRODUCT TO TEMPERATURES GREATER THAN 120° F OR 49° C.

**Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Operating Surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities which they are involved in the handling and use of this product.**

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 14 2004

Food and Drug Administration  
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Ms. Kim Reed  
Senior Regulatory Specialist  
Walter Lorenz Surgical, Incorporated  
1520 Tradeport Drive  
Jacksonville, Florida 32218

Re: K030425  
Trade/Device Name: Lorenz Resorbable Distraction System  
Regulation Number: 872.4760  
Regulation Name: Bone Plate  
Regulatory Class: II  
Product Code: JEY  
Dated: March 4, 2004  
Received: March 5, 2004

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. 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 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,



Chiu Lin, Ph.D.

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 K030425

**Device Name:** Lorenz Resorbable Distraction System

**Indications for Use:**

The Lorenz Resorbable Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) when correction of oral (alveolar ridge), cranial, and maxillofacial deficiencies or post-traumatic defects require gradual bone distraction. The Lorenz Resorbable Distraction System also includes devices intended for use in bone stabilization and elongation (lengthening) when correction of mandibular deficiencies or post-traumatic defects require gradual bone distraction in patients two (2) years old or younger. The mid-face distractor is indicated primarily for LeFort III osteotomies.

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

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

OR

Over-the-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)



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

510(k) Number: K030425