

JUL 13 1998

K981789

Summary of Safety and Effectiveness

Device Modification Name: Lorenz Pectus Support Bar Stabilizer

Name of previously cleared 510(k): Lorenz Pectus Support Bar - 510(k) K972420

Classification Name and Reference: Plate, Fixation, Bone
87 HRS (CFR 888.3030)

Intended use:

For use during surgical procedures to repair Pectus Excavatum and other sternal deformities with Lorenz Pectus Support Bar 510(k) number K972420 when additional stabilization is necessary.

Device Modification Description:

Stabilizer for a single bar: Two designs will be offered for stabilization of a single bar. One design will be an elongated plate and one will be a triangular plate which will be added at the ends of the Lorenz Pectus Support Bar. The stabilizers have a dovetail slot in the center of the plate for the pectus bar to slide into. Two lips come up over the bar to secure the pectus bar within the slot of the stabilizer. The stabilizers have two holes on either side of the slot to suture the stabilizer to the lateral chest wall together with the support bar preventing lateral movement and flipping of the bar.

Stabilizer for two bars: The design is a triangular plate with two dovetail slots to slide the Lorenz Pectus Support Bars into. Two lips will come up over the bars to secure the pectus bars within the stabilizer. The stabilizer will have a single hole to suture the stabilizer and the bars to the lateral chest wall preventing lateral movement and flipping of the bar.

Potential Risks:

The potential risks associated with the stabilizer used in conjunction with the support bar are the same as with the pectus support bar alone and any long-term, metallic implant. These include but are not limited to the following:

- Metal sensitivity reactions or allergic reaction to the implant material.
- Pain, discomfort, or abnormal sensation due to the presence of the device.
- Surgical trauma; permanent or temporary nerve damage, permanent or temporary damage to heart, lungs, and other organs, body structures or tissues.
- Skin irritation, infection, and pneumothorax.
- Fracture, breakage, migration, or loosening of the implant.
- Inadequate or incomplete remodeling of the deformity or return of deformity, prior to or after removal of implant.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K981789
Trade Name: Lorenz Pectus Support Bar Stabilizer
Regulatory Class: II
Product Code: HRS
Dated: May 19, 1998
Received: May 20, 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 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). 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.

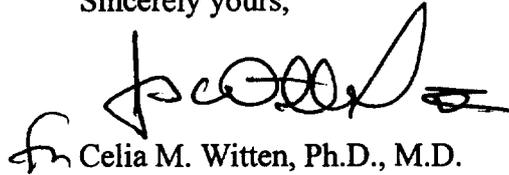
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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.

Page 2 - Ms. Diana 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) 594-4659. 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 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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is stylized and cursive, with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.

Director

Division of General and

Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): unknown K981789

Device Name: Lorenz Pectus Support Bar Stabilizer

Indications For Use: For use during surgical procedures to repair Pectus Excavatum and other sternal deformities with Lorenz Pectus Support Bar 510(k) number K972420 when additional stabilization is necessary.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Div. Sign-Off) _____
Div. General Restorative Devices K981789
510(k) number _____

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____