K012409

OCT 1 8 2001

Summary of Safety and Effectiveness

Specification Holder:

Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, FL 32218-2480
Establishment Registration: 1032347
Walter Lorenz Surgical, Inc. is a wholly owned subsidiary of Biomet, Inc.

Contact Person: Sheryl Malmberg
Walter Lorenz Surgical, Inc.
Jacksonville, FL 32218
Phone: (904) 741-4400 ext. 258
Fax: (904) 741-4500

Proprietary Name: Lorenz LactoSorb® Laryngotracheal Reconstruction Implants

Common Name: Ear Nose & Throat Synthetic Polymer Material

Classification Name: 21 CFR 874.3620

Legally Marketed Devices to which substantial Equivalence is Claimed: Eliachar Laryngeal foam Stent (K000154), Lorenz Stent (K896667), and Montgomery Laryngeal Stent (K842287).

Device Description: The Lorenz Lactosorb® Laryngotracheal Reconstruction (LTR) Implants consist of mesh sheets for the temporary treatment and repair of laryngotracheal fractures and laryngotracheomalacia, and graft plates for lumen augmentation in the temporary treatment and repair of glottic stenosis. The mesh sheets are 0.75mm thick and 50mm wide by 50mm long. The mesh sheets are offered with two different hole configurations to facilitate attachment to the tracheal cartilage using suture and/or screws. The graft plate is a one-piece device consisting of a rectangular base with an elliptical top. The top is available in widths of 3mm, 4mm, 5mm, and 6mm to allow for various amounts of augmentation of the lumen. The base is 0.5mm thick and 10mm wide by 15mm long. The base has holes around the outer edges to allow for fixation to the tracheal cartilage using suture and/or screws. The Lactosorb® Screws and Lactosorb® Direct Drive Screws have a 1.5 diameter with a range of lengths available from 3 to 8mm.

Intended Use: The Lorenz Lactosorb® Resorbable Laryngotracheal Reconstruction Implants are intended to be used for the temporary treatment and repair of laryngotracheal fractures and laryngotracheomalacia and lumen augmentation in the temporary treatment and repair of glottic stenosis.

Summary of Technologies:

Comparison Information	Lorenz Lactosorb® Laryngotracheal Reconstruction Implants	Eliachar Laryngeal Foam Stent	Lorenz Stent	Montgomery Lryngeal Stent
Manufacturer	Walter Lorenz Surgical, Inc.	Hood Laboratories	Walter Lorenz Surgical, Inc.	Boston Medical Products, Inc.
510(k)	New	K000154	K896667	K842287
Indications for Use	Reconstruction for stenosis, tracheomalacia, and laryngeal fracture.	Reconstruction for stenosis and laryngeal fracture.	Glottic and subglottic stenosis aud upper tracheal stenois with or without laryngeal stenosis	For the prevention and treatment of laryngeal stenosis when the glottic stenosis involves the midglottis, posterior glottis, supraglottis, and subglottis, singularly or in combination.
Design	Prefabricated	Prefabricated	Prefabricated	Prefabricated
Material	Lactosorb®	Silicone Foam	PTFE	Silicone
Sizes	50 x 50mm mesh, 50 x 50mm sheet 15 x 10mm plate with 4 available top width sizes (3,4,5, and 6mm)	2 sizes: 25mm, 40mm, 15mm and 25mm, 52mm, 17mm	16 sizes, ranging from 6 mm to 18mm	Child, Small Adult, Medium Adult, and Large Adult
Method of Placement	Screws and/or Sutures	Adherence to laryngeal contours with strap for additional control and anchoring	Sutures	Sutures with silicone buttons
Method of Deployment	Not applicable	Not applicable	Not applicable	Not applicable

Non - Clinical Testing: Animal studies have been undertaken demonstrating the acceptability of Lactosorb® implants for laryngotracheal reconstruction. From these studies it has been concluded that Lactosorb® implants represent an advancement in the management of tracheomalacia and other conditions requiring temporary airway stenting, including graft procedures.

Clinical Testing: Studies have been undertaken demonstrating the acceptability of Lactosorb® implants for laryngotracheal reconstruction. From these studies it has been concluded that Lactosorb® implants were well tolerated by tissue and provided adequate support for healing of bone and cartilage, along with the potential advantage of a lack of interference with growth.

Lactosorb is a trademark of Biomet, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2001

Walter Lorenz Surgical, Inc.
c/o Ms. Sheryl Malmerg
Regulatory Manager
1520 Tradeport Drive
Jacksonville, FL 32218-2480

Re: K012409
Trade/Device Name: Lorenz Resorbable Laryngotracheal Reconstruction Implants
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear Nose and Throat Synthetic Polymer Material
Regulatory Class: II
Product Code: NHB
Dated: July 19, 2001
Received: July 30, 2001

Dear Ms. Malmerg:

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,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K012409

Device Name: Lorenz Resorbable Laryngotracheal Reconstruction Implants

Indications For Use:

The Lorenz Resorbable Laryngotracheal Reconstruction Implants are intended to be used for the temporary treatment and repair of laryngotracheal fractures, laryngotracheomalacia, and lumen augmentation in the temporary treatment and repair of glottic stenosis.

(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)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012409