DEC 1 2 2003

510(k) Summary of Safety and Effectiveness

Manufacturing Facility:
BioForm, Inc.
4133 Courtney Road, #10
Franksville, WI 53126

Trade Name:
Laryngeal Augmentation Implant

Common Name:
Vocal cord medialization implant

Classification Name:
Vocal cord medialization system

Official Contact:
Tessa Yamut
Director of Regulatory Affairs
BioForm, Inc.
1875 South Grant Street, Suite 110
San Mateo, CA 94402
Tel. 650-286-4043

Date Modifications of this Summary of Safety and Effectiveness:
December 4, 2003

Intended Use

BioForm's Laryngeal Augmentation Implant is indicated as a resorbable implant material to aid in surgical reconstructions as a space occupying material in laryngeal surgical procedures for vocal fold medialization and augmentation. The Laryngeal Augmentation Implant is a temporary implant and resorbs within a period of 3-6 months.

Product Description

The Laryngeal Augmentation Implant is a flexible, resorbable implant used as a space filling material for soft tissue augmentation. The Laryngeal Augmentation Implant is placed via percutaneous injection under local anesthesia with direct visualization via nasopharyngoscope. The ability to place the implant without open surgery offers both safety and convenience to the surgeon and patient. The system is designed to resorb with eventual in-growth of surrounding tissue. Every component of the implant has a minimum of twenty years use as a biomaterial.

Substantial Equivalence

The following are predicate devices that are substantially equivalent to the Laryngeal Augmentation Implant:

K013243
Coaptite Laryngeal Augmentation System
BioForm, Inc.
4133 Courtney Road, #10
Franksville, WI 53126

K030682
Calcium Hydroxylapatite Implant
BioForm Inc.
1875 South Grant Street
San Mateo, CA 94402

K942014
Sterile Water Wet Dressing
Trinity Laboratories, Inc.
201 Kiley Drive
Salisbury, MD 21801

Biocompatibility Evaluations

The battery of preclinical safety studies and canine implant studies has shown that Laryngeal Augmentation Implant is biocompatible when injected into various submucosal or other tissues of animals.

Sterilization

The Laryngeal Augmentation Implant is sterilized using steam; processing is performed in-house using a computer controlled autoclave system. Cycle parameters were validated using an overkill methodology to 10^{-6} SAL. Sterilization by the user is not required.

Pre-Clinical Tests Performed

In vivo tests were performed to address sensitization, irritation, tissue reaction during short-term implantation, systemic reactions and long term safety issues. Results identified the Laryngeal Augmentation Implant as nonantigenic, a nonirritant, and nontoxic with no concerns for long-term safety issues based on thirty-six month data.

Summary

BioForm, Inc.
510(k) No. K033398: Laryngeal Augmentation Implant Additional Information

The Laryngeal Augmentation Implant™ is a safe and effective cohesive implant used as a space filling material for soft tissue augmentation in laryngeal procedures for vocal fold medialization and augmentation. All system components share extensive safety history in medicine.

The differences between the Laryngeal Augmentation Implant and the predicate devices do not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2003

BioForm, Inc.
c/o Tessa Yamut
Director of Regulatory Affairs
BioForm, Inc.
1875 South Grant Street, Suite 110
San Mateo, CA 94402

Re: K033398
Trade/Device Name: Laryngeal Augmentation Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: Class II
Product Code: MIX
Dated: October 23, 2003
Received: October 24, 2003

Dear Ms. Yamut:

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,

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

Enclosure

510(k) Number: K033398
Device Name: Laryngeal Augmentation Implant

Indications for Use:

BioForm's Laryngeal Augmentation Implant is indicated as a resorbable implant material to aid in surgical reconstructions as a space occupying material in laryngeal surgical procedures for vocal fold medialization and augmentation. The Laryngeal Augmentation Implant is a temporary implant and resorbs within a period of 3-6 months.

Karen H Burkhart

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K033398

Prescription Use ✓
(Per 21 CFR 801.109)