K013243

JAN 0 9 2002

4.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: Coaptite™ Laryngeal Augmentation System
Common Name: Vocal fold medialization implant
Classification Name: Ear, nose and throat synthetic polymer material

Official Contact Name: Victor M. Bowers
Director Market Development

Address: BioForm, Inc.
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Franksville, WI 53126

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Date Prepared: 9-27-01

4.1 INTENDED USE

Coaptite™ Laryngeal Augmentation System is intended as an injectable, space-occupying implant for vocal fold medialization and augmentation.

4.2 PRODUCT DESCRIPTION

The Coaptite™ Laryngeal Augmentation System consists of a single use, non-pyrogenic, space-occupying implant contained in a prefilled syringe with an injection needle for laryngeal vocal fold augmentation and medialization.

Coaptite™ is available in 1.0cc syringes that are filled with either 1.0cc or a 0.5 cc volume. Coaptite™ contains calcium hydroxylapatite $(Ca_5(PO_4)_3OH)_2$ particles (75-125 microns) suspended in a gel of USP glycerin, sterile water for injection and sodium carboxymethylcellulose (NaCMC). The calcium hydroxylapatite meets ASTM F1185. The excipients glycerin, sterile water, and NaCMC are both pharmaceutical USP grade and listed as GRAS. Calcium hydroxylapatite is radiopaque.

The properties of Coaptite™ facilitate ingrowth of surrounding tissue-over time. The implantation procedure uses direct injection to the laryngeal augmentation site with direct visualization via nasopharyngoscope.

4.3 SUBSTANTIAL EQUIVALENCE

The Coaptite™ Laryngeal Augmentation System is substantially equivalent to the Smith & Nephew VoCoM Vocal Cord Medialization System (K974311; Gore ReVox Thyroplasty Implant (K983525); and Xomed Silicone Pre-form Blocks (K982294). All of the predicate devices have the same intended use as a space-occupying material for vocal fold medialization and augmentation.

The principle component in the Coaptite™ Laryngeal Augmentation System is calcium hydroxylapatite, the same material used in the cleared VoCoM System. Coaptite™ is available as an injectable gel form while the VoCoM System comes in blocks and shims.

The space-occupying material of the Gore ReVox Thyroplasty Implant and the Xomed Silicone Pre-formed Blocks are polytetrafluoroethylene and silicone respectively. These predicates, when used in the larynx for vocal fold medialization and augmentation, serve the same intended use as the Coaptite™ Laryngeal Augmentation System

The Gore ReVox Thyroplasty Implant is equivalent to the Coaptite™ Laryngeal Augmentation System in terms of biological action for facilitation of ingrowth of surrounding tissue. The patient's laryngeal tissue integrates with the implanted material over time to help further augment laryngeal tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 9 2002

Bioform, Inc.
c/o Victor M. Bower
4133 Courtney Road, No. 10
Franksville, Wisconsin 53126

Re: K013243
Trade/Device Name: Coaptite™ Laryngeal Augmentation System
Regulation Number: 21 CFR 874.3620
Regulation Name: ENT Synthetic Polymer Material
Regulatory Class: Class II
Product Code: MIX
Dated: September 27, 2001
Received: September 28, 2001

Dear Mr. Bower:

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 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.

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

2.0 INDICATIONS FOR USE / INTENDED USE STATEMENT

510(k) Number (if known): K013243

Device Name: Coaptite™

Indications For Use:

Coaptite™ is intended as an injectable, space-occupying implant for vocal fold medialization and augmentation.

(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)

1/4/02

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

510(k) Number K013243