K070090

MAR 0 1 2007

4. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

4.1 Manufacturing Facility

BioForm Medical, Inc.
4133 Courtney Road, Suite 10
Franksville, WI 53126

Contact: James Miller
Vice President
Regulatory Affairs and Quality Assurance
Telephone: (262)835-3043

4.2 Trade Name

Radiesse Laryngeal Implant

4.3 Intended Use

BioForm's Radiesse Laryngeal Implant is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue bulking agent. Radiesse Laryngeal Implant injection augments the size of the displaced or deformed vocal fold so that it may meet the opposing fold at the midline for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulties may be an urgent indication.

4.4 Product Description

Radiesse Laryngeal Implant is a sterile, non-pyrogenic injectable material consisting of calcium hydroxylapatite (CaHA) suspended in an aqueous formulation of USP grade pharmaceutical excipients consisting of sterile water, glycerin, and sodium carboxymethylcellulose, stabilized with a phosphate buffer. These excipients have prior and extensive use in intramuscular injectable pharmaceutical products including Cortone®, Decadron®, and Dalalone® drugs. Glycerin, sodium carboxymethylcellulose and phosphate buffer are listed in 21 CFR 182 as Generally Recognized as Safe (GRAS), Sections 182.1320, 182.1745, and 182.6285, respectively.

Calcium hydroxylapatite particles (30%-40% by volume) are combined with this aqueous formulation to create the implant media. The calcium hydroxylapatite meets ASTM F1185.

4.5 Substantial Equivalence

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

K060815
Juliesse™ Injectable Laryngeal Augmentation Implant
BioForm Medical, Inc.
4133 Courtney Road, Suite 10
Franksville, WI 53126

K013243[1]
Coaptite Laryngeal Augmentation System
BioForm Medical, Inc.
4133 Courtney Road, Suite 10
Franksville, WI 53126

4.6 Biocompatibility Evaluations

The battery of preclinical safety studies and animal implant studies show that the Radiesse Laryngeal Implant is biocompatible when injected into soft tissues.

4.7 Sterilization

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

4.8 Pre-Clinical Tests Performed

In vivo and *In vitro* tests were performed to address cytotoxicity, sensitization, mutagenticity, and hemolysis. Results identified the Radiesse Laryngeal Implant as non-toxic with no concerns for long-term safety.

4.9 Summary

The Radiesse Laryngeal Implant is a safe and effective implant used as a space filling material for soft tissue augmentation in laryngeal procedures for vocal fold medialization and augmentation. All syringe component share extensive safety history in medicine.

[1] Pre-market notification 510(k) K013243 was initially approved for the Coaptite product and subsequently has been expanded to include the Radiesse product. The only difference between these two products is the size of the calcium hydroxylapatite particles.

9. INTENDED USE

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 1 2007

BioForm Medical, Inc.
c/o James S. Miller
Vice President
Regulatory Affairs and Quality Assurance
1875 South Grant St., Suite 110
San Mateo, CA 94402

Re: K070090
Trade/Device Name: Radiesse Laryngeal Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: Class II
Product Code: MIX
Dated: February 23, 2007
Received: February 23, 2007

Dear Mr. Miller:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070090

Device Name: Radiesse Laryngeal Implant

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070090