K121795

FEB 2 2 2013

Chapter 5 510(k) Summary [per 21 CFR 807.92(c)]

5. 510(k) Summary as required by section 807.92(c)

5.1. 510(k) Owner

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President & CEO

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5.2. 510(k) Preparer/submitter

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5.3. Date the summary was prepared [807.92(c)(1)]

12/June/2012

5.4. Device Name [807.92(a)(2)]

Proprietary Name	Calcium Hydroxylapatite Vocal Fold Implant
Common Name:	Vocal Cord Medialization
Regulation Number:	21 CFR 874.3620
Regulation Name:	Ear, Nose and Throat Synthetic Polymer Material
Regulatory Class:	Class II
Product Code:	MIX

5.5. Legally Marketed device to which your firm is claiming equivalence [807.92(a)(3)]

Table 3. Identification of Predicate

510(k) #	Title	Owner	Product Code
K070090	Radiesse Laryngeal Implant	BioForm, Inc. 4311 Courtney Road, #10 Franksville, WI 53126	MIX

5.6. Establishment Registration

Cytophil, Inc. has been issued the device establishment registration number: 3007225376.

5.7. Device Classification

21 CFR 874.3620

5.8. Manufacturing Facility

Cytophil, Inc.
2485 Corporate Circle, Unit 2
East Troy, WI 53120

5.9. Sterilization Facility

Biotest Laboratories
9303 West Broadway Avenue
Brooklyn Park, MN 55445

5.10. Description of the device [807.92(a)(4)]

Calcium Hydroxylapatite Vocal Fold Implant is a ready to use product. Calcium Hydroxylapatite Vocal Fold Implant is comprised of calcium hydroxylapatite particles, blended into an aqueous gel formulated from sodium carboxymethylcellulose, glycerin, and a phosphate buffer. The gel acts as a carrier for the particles to facilitate placement. The main component of Calcium Hydroxylapatite Vocal Fold Implant is synthetic calcium hydroxylapatite, a material with over thirty years of use as an implant material used in orthopedics, neurosurgery, dentistry, otolaryngology, plastic surgery and ophthalmology. Calcium hydroxylapatite is also the main mineral component found in bones and teeth so it is a major component of the body. The calcium hydroxylapatite meets the requirements of ASTM F1185. The carrier consists of glycerin (USP) sodium carboxymethylcellulose (USP) and phosphate buffer (USP). The carrier resorbs *in vivo*, so that the calcium hydroxylapatite remains at the site of implantation, providing a scaffold for local tissue infiltration. This cellular infiltrated hydroxylapatite scaffold provides the long-term restoration and augmentation.

5.11. Intended use of the device [807.92(a)(5)]

Calcium Hydroxylapatite Vocal Fold Implant is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue bulking agent. Calcium Hydroxylapatite Vocal Fold 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.

Per Product Code MIX, the indication for use of this product is consistent of the intended use, "Ear, nose, and throat synthetic polymer material is a device material that is intended to be

implanted for use as a space-occupying substance in the reconstructive surgery of the head and neck."

5.12. Summary of the technological characteristics of your device compared to the predicate device. [807.92(a)(6)]

Calcium Hydroxylapatite Vocal Fold Implant is a paste of calcium hydroxylapatite (calcium phosphate) particles in a gel carrier, identical to the predicate K070090 (Radiesse Laryngeal Implant)). The gel carrier is resorbable and acts to hold the particles together to facilitate placement. The resorption of the carrier provides the porosity for bone ingrowth. These "pores" are the interconnected pathways around and between the calcium hydroxylapatite particles. The calcium hydroxylapatite particles provide a non-resorbable scaffold for tissue infiltration. This is the same mechanism of action as the predicate device. The premixed and ready to use characteristic facilitates the delivery of Calcium Hydroxylapatite Vocal Fold Implant by allowing direct and controlled placement using the syringe. This may be enhanced for implantation in difficult to access locations by the use of a needle on the syringe. In addition, the carrier serves to reduce or prevent migration during the application and in the post-operative healing period prior to incorporation of the particles by tissue ingrowth. The implantation procedures for both the Calcium Hydroxylapatite Vocal Fold Implant and the predicate use direct injection to the laryngeal augmentation site with direct visualization via nasopharyngoscope and without the requirement for an open surgical procedure.

The Calcium Hydroxylapatite Vocal Fold Implant is identical chemically and physically to the predicate and has the identical intended use as the predicate device. The Calcium Hydroxylapatite Vocal Fold Implant and the predicate device are both intended to augment the size of the displaced or deformed vocal fold. The predicate device and the Calcium Hydroxylapatite Vocal Fold Implant are composites of resorbable (carrier) and non-resorbable (calcium phosphate particles) components. The tissue infiltration provides the final form of the implant.

The principle component of the Calcium Hydroxylapatite Vocal Fold Implant, calcium hydroxylapatite, is identical to the calcium hydroxylapatite chemically and in size, 25 to 45 microns, to the calcium hydroxylapatite used in the predicate. Calcium hydroxylapatite used in Calcium Hydroxylapatite Vocal Fold Implant and the predicate meet the same biocompatibility requirements. Calcium Hydroxylapatite Vocal Fold Implant and predicate are substantially equivalent in terms of biocompatibility and biological mechanism of action in that both of the products utilize tissue ingrowth to support and sustain augmentation.

5.13. Biocompatibility Evaluations

The battery of preclinical safety studies and animal implant studies show that the Calcium Hydroxylapatite Vocal Fold Implant is biocompatible when injected into soft tissues.

5.14. Sterilization

Calcium Hydroxylapatite Vocal Fold Implant will be sterilized using steam in accordance with ISO 17665. A contract sterilization company, Biotest Laboratories, will perform processing. Cycle parameters are validated using an overkill methodology to 10^{-6} SAL. Sterilization by the user is not required.

5.15. Pre-Clinical Tests Performed

In vivo and *in vitro* tests were performed for biocompatibility. Results identified the Calcium Hydroxylapatite Vocal Fold Implant as a nonirritant, nontoxic, with no concerns for long-term safety.

5.16. Risk Assessment

The primary risks with Calcium Hydroxylapatite Vocal Fold Implant have been identified through a risk assessment procedure in accordance with ISO 14971. The risks identified are primarily associated with nasopharyngoscopy and injection laryngoplasty surgery.

5.17. Summary

The Calcium Hydroxylapatite Vocal Fold Implant is a safe and effective implant when used as a space filling material for soft tissue augmentation in laryngeal procedures for vocal fold medialization and augmentation.

5.18. Conclusion

In summary, Calcium Hydroxylapatite Vocal Fold Implant is substantially equivalent to the cited predicate device K070090 (Radiesse Laryngeal Implant). The predicate has the same intended use, augment the size of the vocal folds. The components used in the Calcium Hydroxylapatite Vocal Fold Implant and the predicate device are the same and the biocompatibility is equivalent, based on the history use in many medical devices as well as from preclinical testing and the very extensive clinical utilization of this formulation. The predicate and the device both function as a composite that utilizes a resorbable carrier and a non-resorbable calcium phosphate particulate. The carrier facilitates placement and the particles function as a tissue integration matrix. Both attain their final form after tissue infiltration. Both are used with the same implantation placement procedures. Therefore, the Calcium Hydroxylapatite Vocal Fold Implant is substantially equivalent in intended use, technical characteristics and is as safe as the predicate device cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 22, 2013

Cytophil, Incorporated
% William G. Hubbard, Ph.D.
President & CEO
2485 Corporate Circle, Suite 2
East Troy, WI 53120

Re: K121795
Trade/Device Name: Calcium Hydroxylapatite Vocal Fold Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose and throat synthetic polymer material
Regulatory Class: Class II
Product Code: MIX
Dated: January 18, 2013
Received: January 22, 2013

Dear Dr. Hubbard:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for 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

K121795

Chapter 4 Indication for Use Statement

4. Indications for Use

4.1. 510(k) Number (If known): K_____

4.2. Device Name Calcium Hydroxylapatite Vocal Fold Implant

4.3. Indications for Use

Calcium Hydroxylapatite Vocal Fold Implant is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue-bulking agent. Calcium Hydroxylapatite Vocal Fold 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.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use _____ (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)

Vasant G. Malshet

Digitally signed by Vasant G. Malshet
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Vasant G. Malshet, 0.9.2342.19200300.100.1.1=1300087851
Date: 2013.02.28 06:02:18 -05'00'