K081815

JAN – 5 2009

SECTION 4

510(k) Summary of Safety and Effectiveness

Trade Name:	Vocalis Gel
Common Name:	Vocal Cord Medialization
Classification Name:	System, Vocal Cord Medialization
Official Contact Name:	Greg Johnson President & CEO
Address:	Cytophil, Inc. 5546 N Santa Monica Blvd Whitefish Bay, WI 53217
Phone:	414-961-7372
Fax:	414-961-6167
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Date Prepared:	6/28/2008

4.1 Intended Use

Vocalis Gel is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue bulking agent. Vocalis Gel 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. The product is intended to be durable for a minimum of one month.

4.2 Product Description

Sterile, latex free, non-pyrogenic, high yield strength, isotonic, clear gel injectable implant. The gel consists primarily of sterile water for injection (USP), glycerin (USP) and mannitol (USP). The high yield strength is created by small amounts of carbomer (USP). The gel carrier allows tissue infiltration over time. All components are listed as GRAS (Generally Recognized as Safe 21 CFR 182). The character of the gel allows it to be very thick and cohesive but sheer to be easily injected through very fine needles with minimal force.

4.3 Substantial Equivalence

The following is the predicate device that is substantially equivalent to Vocalis Gel:

K080956
Modification to VF Gel
Coapt Systems, Inc.
1820 Embarcadero Rd.
Palo Alto, CA 94303

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

K070090
Radiesse Laryngeal Implant
BioForm Medical, Inc.
1875 South Grant St., Suite 110
San Mateo, CA 94402

K071663
VF Long Term
Coapt Systems, Inc.
1820 Embarcadero Rd.
Palo Alto, CA 94303

4.4 Biocompatibility Evaluations

The battery of preclinical safety studies and animal implant studies show that Vocalis Gel is biocompatible when injected into soft tissues.

4.5 Sterilization

Vocalis Gel is sterilized using steam. Processing is preformed by a contract sterilization company, Haemonetics, 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.

4.6 Pre-Clinical Tests Performed

In vivo and *in vitro* tests were performed to address irritation, sensitization, cytotoxicity, acute and sub-chronic toxicity, genotoxicity and hemolysis. Results identified Vocalis Gel as a nonirritant, and nontoxic with no concerns for long-term safety.

4.7 Risk Assessment

The primary risks with Vocalis Gel have been identified through a risk assessment procedure in accordance with EN 1441. The risks identified are primarily associated with nasopharyngoscopy and injection laryngoplasty.

4.8 Summary

Vocalis Gel 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cytophil, Inc.
c/o Mr. Greg Johnson
President & CEO
5546 N Santa Monica Blvd
Whitefish Bay, WI 53217

JAN - 5 2009

Re: K081815
Trade/Device Name: Vocalis Gel
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, and Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: MIX
Dated: December 12, 2008
Received: December 15, 2008

Dear Mr. Johnson:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Malvina B. Eydelman, M.D.

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

K081815

Indications for Use

510(k) Number: K081815

Device Name: Vocalis Gel

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ *or* Over-the-Counter Use _____
(Per 21 CFR 801.109

Daniel C Clapper

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

510(k) Number K081815