K071663

12 510(k) SUMMARY

12.0 510(k) Summary

Coapt Systems is providing a summary of the safety and effectiveness information available for the VF Gel Plus. This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92 and pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990.

SPONSOR/APPLICANT NAME AND ADDRESS

Coapt Systems, Inc.
1820 Embarcadero Road
Palo Alto, CA 94303
Telephone: (650) 461-7600
Facsimile: (650) 213-9336

CONTACT INFORMATION

Linda Ruedy
Director, Regulatory and Clinical Affairs
Coapt Systems, Inc.
1820 Embarcadero Road
Palo Alto, CA 94303
Telephone: (650) 461-7647
Facsimile: (650) 213-9336
Email: lruedy@coaptsystems.com

DATE OF PREPARATION OF 510(K) SUMMARY

February 6, 2008

DEVICE TRADE OR PROPRIETARY NAME

VF Gel Plus

DEVICE COMMON OR CLASSIFICATION NAME

Classification Name: Vocal Cord Medialization Implant
Regulation Number: 874.3620
Class: II
Product Code: MIX

IDENTIFICATION OF THE LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS BEING CLAIMED

Name of Predicate Device	Product Code	Name of Manufacturer	510(k) or PMA Number
Radiesse Injectable Laryngeal Medialization Implant	MIX	Bioform Medical	K033398

DEVICE DESCRIPTION

Sterile, latex free, non-pyrogenic, semi-solid, cohesive subdermal implant. The principal durable component is synthetic calcium hydroxylapatite. The semi-solid nature is created by suspending the calcium hydroxylapatite particles in a high yield strength thixotropic gel. The isotonic gel carrier consists primarily of sterile water for injection (USP), glycerin (USP) and mannitol (USP). The thixotropic high yield strength gel is created by the carbomer (NF). The calcium hydroxylapatite particles are 25 to 45 microns in size while being smooth but irregular in shape and are present in the product at 30% by volume.

INTENDED USE STATEMENT

The VF Gel Plus is indicated for vocal fold medialization in the treatment of vocal fold insufficiency, where insufficiency may be improved by injection of a soft tissue bulking agent. VF Gel Plus injection augments the size of the displaced or deformed vocal fold so that it may meet the opposing fold at the midline for improved glottal closure. Improved glottal closure may allow improved phonation, improvement of cough, and an improved ability to protect the airway during swallowing. VF Gel Plus is a temporary implant that degrades over time. The product is intended to be durable for a minimum of one month.

SUBSTANTIAL EQUIVALANCE COMPARISON

1. Indications Summary

The "Indication Statement" for the VF Gel Plus is substantiated by the results of the performance evaluations and comparison testing to the predicate device. The differences between the Subject and the Predicate do not affect the safety and effectiveness of the VF Gel Plus.

2. Technological Characteristics Summary

The VF Gel Plus is substantially equivalent in design, materials and fundamental scientific technology to the predicate device. Any differences between the Subject and the Predicate device are minor and do not raise issues regarding safety or effectiveness.

3. Performance Summary

The VF Gel Plus performance data meet the applicable standards and fulfill the device requirements as defined in the user specifications.

SUBSTANTIAL EQUIVALENCE CONCLUSION

Based on the design, materials, function, intended use, and performance evaluations discussed herein, Coapt Systems believes the VF Gel Plus is substantially equivalent to the predicate device currently marketed under the Federal Food, Drug and Cosmetic Act. No new issues of safety or effectiveness were raised for the VF Gel Plus Device. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance for commercial sale.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2008

Coapt Systems, Inc.
c/o Ms. Linda Ruedy
Director, Regulatory and Clinical Affairs
1820 Embarcadero Road
Palo Alto, CA 94303

Re: K071663
Trade/Device Name: VF Gel Plus
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: Class II
Product Code: MIX
Dated: January 24, 2008
Received: January 25, 2008

Dear Ms. Ruedy:

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

K071663

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K071663

Device Name: VF Gel Plus

Indications for Use: The VF Gel Plus is indicated for vocal fold medialization in the treatment of vocal fold insufficiency, where insufficiency may be improved by injection of a soft tissue bulking agent. VF Gel Plus injection augments the size of the displaced or deformed vocal fold so that it may meet the opposing fold at the midline for improved glottal closure. Improved glottal closure may allow improved phonation, improvement of cough, and an improved ability to protect the airway during swallowing. VF Gel Plus is a temporary implant that degrades over time. The product is intended to be durable for a minimum of one month.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) And/Or Over-the-Counter_____ (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

Daniel C Clapp

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

510(k) Number K071663