Premarket Notification 510(k) Summary

DEC - 4 2006

Date Prepared:
September 1, 2006

Submitter (Contact):
Roxanne Dubois, VP, Regulatory Affairs
Carbylan BioSurgery, Inc.
Address: 3181 Porter Drive, Palo Alto, CA 94304
Telephone: 650-855-6775
Fax: 650-855-9119
Email: rdubois@carbylan.com

Device Name and Classification:
Proprietary Name: AdvaCoat™ Sinus Gel and Stent
Common Name: Sinus Packing, Gel or Stent
Classification Name: Splint, Intranasal Splint
Classification: Class I, Per 21 CFR 874.4780
Product Code Number: LYA

Performance Standards:
No FDA performance standards exist for this product.

Predicate Devices:
Hyalsine Hylan B Gel (K012532)
MeroPack (K041381)
Merogel Nasal Dressing And Sinus Stent (K982731)

Device Description:
AdvaCoat™ Sinus Gel and Stent (AdvaCoat™) is a sterile, non-pyrogenic, non-swelling, viscoelastic, bioresorbable material composed of cross-linked polymers of a derivatized hyaluronan. AdvaCoat™ is produced from a non-animal, non-pathogenic source using a highly purified hyaluronan. AdvaCoat™ Sinus Gel and Stent and its break down products are biocompatible, non-immunogenic and non-toxic.

AdvaCoat™ Sinus Gel and Stent are provided in two formats, a gel and a stent. The gel is delivered using a syringe and the stent is applied dry as a packing material.

Due to its tissue adhesive properties, AdvaCoat™ will not migrate or be dislodged from the application site. AdvaCoat™ may be used as a space occupying dressing and/or stent to minimize bleeding. Upon application,

AdvaCoat™ forms a viscous and transparent gel conforming to mucosal surfaces.

The final packaged product is sterilized with E-beam radiation to a Sterility Assurance Level (SAL) of 10^{-6} and intended for single use only. The sterilization information for AdvaCoat™ is substantially equivalent to the data for the predicate devices.

Significant Performance Characteristics

There are no new performance characteristics for AdvaCoat™ compared to the substantially equivalent predicate devices marketed for sale. These devices are indicated for use to prevent adhesions and minimize edema and bleeding following nasal/sinus surgery or trauma.

Indication For Use:

AdvaCoat™ Sinus Gel and Stent are indicated for use in patients undergoing nasal/sinus surgery as a space-occupying dressing and/or stent intended to prevent adhesions in the nasal cavity, separate mucosal surfaces compromised by surgery or trauma, minimize edema and help control minimal bleeding following surgery or trauma, and act as an adjunct to aid in the natural healing process.

Technological Characteristics:

There are no significant differences in the technological characteristics of this device compared to the predicate devices which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of AdvaCoat™ and the predicate devices.

Table 1.1 Technological Characteristics of AdvaCoat™ and Predicate Devices

Attribute	Proposed Device AdvaCoat™, Gel and Stent	Hyalsine Hylan B Gel (K012532)	MeroPack (K041381)	Merogel Nasal Dressing And Sinus Stent (K982731)
Company Name:	Carbylan BioSurgery, Inc.	Genzyme	Medtronic Xomed	Xomed, Inc.
Date Cleared:	N/A	10/30/01	9/10/04	2/2/99
Code/Class:	LYA, Class I	SAME	SAME	EMX, Class I
21 CFR No.	874.4780	SAME	SAME	SAME
Device Name	splint, intranasal septal	SAME	SAME	balloon, epistaxis
Intended Use	nasal / sinus surgery	SAME	SAME	SAME
Indications	Post-op, help control minimal bleeding and	SAME	SAME	SAME

	separate mucosal surfaces / adhesion prevention			
Material / Construction	Derivative hyaluronic acid	SAME	Derivative hyaluronic acid and collagen	SAME
Absorbant Qualities	In excess of 10 times weight of the device	unknown	In excess of 10 times weight of the device	In excess of 10 times weight of the device
Sterility	E-beam irradiation	unknown	Gamma irradiation	Gamma irradiation
Resorption Time	If the material is still seen at 14 days follow-up, any residual material may be removed by the surgeon	SAME	SAME	SAME
Biocompatibility	ISO 10993-1	SAME	SAME	SAME
Method of Action	Hygroscopic, forms gelatinous mass in contact with fluids	SAME	SAME	SAME
Method of Removal	Natural elimination or gentle irrigation of residues	SAME	SAME	SAME
Bioresorbable	Yes	SAME	SAME	SAME

Summary of Substantial Equivalence:

The information submitted in this Premarket Notification supports a determination that AdvaCoat™ Gel and Stent are substantially equivalent to the predicate devices. The design, technological characteristics and intended use (safety and effectiveness) of AdvaCoat™ are substantially equivalent to those for the predicate devices (Hyalsine Hylan B Gel, K012532; MeroPack, K041381; and, Merogel Nasal Dressing And Sinus Stent, K982731). The risks and benefits to the patient are the same as those normally attributed to the use of an intranasal splint. The technological characteristics, design and intended use are well known, low risk, and are substantially equivalent to the previously cleared predicate devices. In addition, the biocompatibility data support the safety of the material.

Conclusions

The device meets all the biocompatibility test requirements and is substantially equivalent in design, intended use and technological characteristics to the predicate devices. Therefore, a determination can be made that AdvaCoat™ Gel and Stent are considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Carbylan Biosurgery
c/o Roxanne J. Dubois
Vice President, Regulatory Affairs
3181 Porter Drive
Palo Alto, CA 94304

DEC - 4 2006

Re: K063308
Trade/Device Name: AdvaCoat™ Sinus Gel and Stent
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal splint
Regulatory Class: Class I
Product Code: LYA
Dated: November 1, 2006
Received: November 2, 2006

Dear Ms. Dubois:

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): K063308

Device Name: **AdvaCoat™ Sinus Stent**

Indications for Use:

AdvaCoat™ Sinus Stent is intended for use in patients undergoing nasal/sinus surgery as a space-occupying dressing and/or stent intended to prevent adhesions in the nasal cavity, separate mucosal surfaces compromised by surgery or trauma, minimize edema and help control minimal bleeding following surgery or trauma, and act as an adjunct to aid in the natural healing process.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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 _____

Prescription Use X
(Per 21 CFR 801.109)

Indications for Use

510(k) Number (if known): K063808

Device Name: **AdvaCoat™ Sinus Gel**

Indications for Use:

AdvaCoat™ Sinus Gel is intended for use in patients undergoing nasal/sinus surgery as a space-occupying dressing and/or stent intended to prevent adhesions in the nasal cavity, separate mucosal surfaces compromised by surgery or trauma, minimize edema and help control minimal bleeding following surgery or trauma, and act as an adjunct to aid in the natural healing process.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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 _____