K092788

SECTION 4

4.0 510K (k) Summary of Safety and Effectiveness

DEC 18 2009

Trade Name:	Periophil Biphasic
Common Name:	Synthetic Bone Graft Material
Classification Name:	Bone Filling and Augmentation Material
Official Contact Name:	Victor M. Bowers VP Medical Affairs
Address:	Cytophil, Inc. 2485 Corporate Circle, Suite 2 East Troy, WI 53120
Phone:	262-642-2765
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E-mail:	vbowers@cytophil.com
Date Prepared:	9/04/2008

4.1 Indication for Use

Periophil Biphasic is intended for use as a bone grafting material to fill, augment, or reconstruct periodontal or oral/maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Periophil Biphasic can be used with autogenous bone grafting materials. Typical uses include: periodontal/infrabony defects, ridge augmentation, extraction sites (implant preparation/placement), sinus lifts, and cystic cavities.

4.2 Product Description

Periophil Biphasic is a bone graft substitute. Periophil Biphasic is a microporous and macroporous biphasic calcium phosphate ceramic consisting of 60% hydroxyapatite (HA) and 40% beta tricalcium phosphate (β-TCP). Periophil Biphasic is available as granules and is provided sterile for single patient use.

Periophil Biphasic is a multidirectional interconnected porosity structure, similar to that of human cancellous bone. Periophil Biphasic slowly resorbs during the remodeling and bone defect repair process and is progressively replaced with bone and soft tissues. The progressive resorption of Periophil Biphasic resorbable bone filler is intended to prevent premature resorption.

4.3 Substantial Equivalence

4.8 Summary

In summary, Periophil Biphasic is substantially equivalent to the cited predicate devices. All have the same indication for use. Periophil Biphasic is intended for use as a bone grafting material to fill, augment, or reconstruct periodontal or oral/maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Periophil Biphasic can be used with autogenous bone grafting materials. Typical uses include: periodontal/infrabony defects, ridge augmentation, extraction sites (implant preparation/placement), sinus lifts, and cystic cavities.

The components used in Periophil Biphasic and the predicate devices are biocompatible, based on the history and use in many medical devices as well as from preclinical testing. Periophil Biphasic is substantially equivalent in indication for use, technical characteristics, and is as safe as the predicate device K051885 - MBCP™, BIOMATLANTE, ZA DES IV NATIONS, 5, rue Edouard Belin, -F- 44360 VIGNEUX DE BRETAGNE, France.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. Victor M. Bowers
Vice President of Medical Affairs
Cytophil, Incorporated
2485 Corporate Circle, Unit 2
East Troy, Wisconsin 53120

DEC 18 2009

Re: K092788
Trade/Device Name: Periophil Biphasic
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: December 11, 2009
Received: December 16, 2009

Dear Mr. Bowers:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 2

2.0 Indications for Use

510(k) Number: K092788

Device Name: Periophil Biphasic

Indications for Use:

Periophil Biphasic is intended for use as a bone grafting material to fill, augment, or reconstruct periodontal or oral/maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Periophil Biphasic can be used with autogenous bone grafting materials. Typical uses include: periodontal/infrabony defects, ridge augmentation, extraction sites (implant preparation/placement), sinus lifts, and cystic cavities.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____
(Per 21 CFR 801.109)

R.S. Betz DDS for Dr. K. P. Mulay (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092788