



510(k) Summary

General Information

Classification Name: Endosseous Implant for Bone Filling and/or Augmentation
 Common Name: Bioglass® Synthetic Bone Graft Particulate
 Trade Name: PerioGlas®
 Submitter's Name : USBiomaterials Corporation
 Address: One Progress Boulevard, #23
 Alachua, FL 32615
 Telephone: (904) 462-7660
 Facsimile: (904) 462-7605
 Contact: Albert Fosmoe II, Director of Quality Assurance and Regulatory Affairs
 Date of Summary: July 1999

Device Description

PerioGlas® is a synthetic osteoconductive particulate bone/void filler that is intended for oral/maxillofacial and dental intraosseous defects use. The material composed of Bioglass® (24.5 wt % CaO, 24.5 wt % Na₂O, 45 wt % SiO₂, 6 wt % P₂O₅) with a particle size range of 90-710 µm. It is supplied sterile in a Tyvek sealed PET-G cup that is protected by a shrink wrapped cardboard box. It is mixed with sterile water (saline) or the patient's own blood to form a wet sandy paste which is applied to the defect.

Predicate Device

PerioGlas® is substantially equivalent to legally marketed osteoconductive bone filling and/or augmentation devices in the U.S. including Calcitite (K852682) and Bio-Oss (K970321). Any minor differences between PerioGlas® and the predicate devices do not raise new questions of safety or effectiveness.

Intended Use

PerioGlas® is intended to fill and/or augment dental intraosseous and oral/maxillofacial defects including:

- Periodontal defects
- Ridge augmentation
- Extraction Sites
- Cranio-facial Augmentation
- Sinus Lifts
- Cystic Defects

Device Testing

The performance of PerioGlas® was evaluated in animal models versus hydroxylapatite predicate devices. The rate of bone formation, amount of bone formed and the biomechanical

properties including peak compressive loads and compressive stiffness were substantially equivalent to each other and normal bone.

PerioGlas[®]/Bioglass[®] particulate was also evaluated as a graft extender with finely ground autogenous bone in a rabbit calvarial defect model and a canine split-rib model. In both of these models, bone formation or graft site augmentation was greater for the mixture of bone and Bioglass[®] than for either alone.

Clinical Data including prospective, retrospective and case studies were reviewed and evaluated for various dental and oral/maxillofacial intraosseous defects including a variety of ridge, periodontal, extraction sites, sinus augmentation and cystic defects using PerioGlas[®] alone and/or as a graft extender.

Periodontal studies showed no significant differences between PerioGlas[®]/Bone graft mixtures and PerioGlas[®] alone for a variety of clinical parameters including Clinical Attachment Level (CAL), Pocket Depth Reduction (PDR) and osseous fill. Results did suggest that there may be a synergistic effect when the two graft materials are combined.

Ridge augmentation, extraction site, sinus augmentation, cystic defect and general osseous reconstruction studies demonstrated safe and efficacious use of PerioGlas[®] alone and/or as a graft extender in these indications. Results from a four clinician retrospective study, as measured by the overall implant success rate (91%), indicate that the use of PerioGlas[®] as a bone graft extender is safe and efficacious for ridge augmentation, extraction sites and sinus augmentation.

Documented case reports representing all of the summarized categories with clinical evaluations and radiographs support the safety and efficacy of PerioGlas[®] alone or as a bone graft extender in bone/void filling.

Conclusions

The animal and/or clinical performance, safety and effectiveness data show that the device performs as well as or better than predicate hydroxylapatite devices as an osteoconductive bone void filler both alone or as a bone graft extender.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 1999

Mr. Albert Fosmoe II
Director of Regulatory Affairs
US Biomaterials Corporation
One Progress Boulevard #23
Alachua, Florida 32615

Re: K992416
Trade Name: Perioglas - Bioglass Bone Graft Particulate
Regulatory Class: Unclassified
Product Code: LYC
Dated: July 16, 1999
Received: July 20, 1999

Dear Mr. Fosmoe II:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

Page 2 - Mr. Fosmoe II

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992416

Device Name: PerioGlas®

Indications For Use:

The intended use of PerioGlas is to provide a safe, biocompatible synthetic bone graft material for oral/maxillofacial and dental intraosseous defects use. It is to be used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (DFDBA demineralized freeze dried bone) or may be mixed with each as a bone graft extender. Typical uses include:

- Periodontal/Infrabony defects
- Ridge augmentation
- Extraction sites
- Cranio-facial augmentation
- Cystic cavities
- Sinus lifts

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Susan Remy

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K992416