K103820

NOV - 3 2011

510(k) Summary

ceramisys

ReproBone®

Preparation Date: 31st October 2011

1. Submitter's Information

Company: Ceramisys Ltd
Address Alison Business Centre
Alison Crescent
Sheffield S2 1AS, England

Telephone: + 44 114 242 7630
Facsimile: + 44 114 242 7631
Contact: Mr Wayne Austin (Managing Director)

2. Name of Device

Trade Name: ReproBone®
Common Name: Resorbable calcium salt bone void filler device
Classification name: Bone Grafting Material, Synthetic
Product Code: LYC
Device panel: Oral/Dental

3. Legally Marketed Predicate'Device

The subject device is substantially equivalent to previously cleared devices.
Bio-Oss® Granules (K033815)
Bioactys® (K082286)
MBCP® (K051885)

4. Device Description

ReproBone® is a sterile, single-use, resorbable bone void filler. ReproBone® is a microporous and macroporous two-phase calcium phosphate ceramic made of 60% Hydroxyapatite and 40% beta-tricalcium phosphate. ReproBone® has a highly interconnected, highly porous structure, similar to that of human cancellous bone, and is available in the form of granules of size range 0.5 – 1.0mm, and also 0.8-1.5mm. Following placement in the bony voids or gap, ReproBone® acts as an osteoconductive scaffold for the ingrowth of adjacent viable bone. ReproBone® gradually resorbs and is replaced with bone during the healing process

5. Intended Use

ReproBone® is recommended for augmentation or reconstructive treatment of the alveolar ridge, filling of infrabony periodontal defects, filling of defects after root resection apicoectomy and cystectomy, filling of extraction sockets to enhance preservation of the alveolar ridge, elevation of the maxillary sinus floor, filling of periodontal defects in conjunction with products intended for guided tissue regeneration (GTR) and guided bone regeneration (GBR), and filling of peri-implant defects in conjunction with products intended for guided bone regeneration (GBR).

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6. Technological characteristics

ReproBone® and the predicate devices have the same technological characteristics, function and intended use. The Bioactys® predicate device (K082286) is constructed of the ratio 60% hydroxyapatite and 40% tricalcium phosphate which is identical to the composition of ReproBone®. All have a similar highly porous structure that promotes bone ingrowth by osteoconduction, and are gradually resorbable. ReproBone® and the predicate devices are provided sterile for single-use.

7. Non clinical performance data

Tests applied are those specified in ISO 13779-1 for hydroxyapatite which include chemical analysis, trace elements, chrystalline content and mechanical properties (compressive strength).

In vivo (animal) and in vitro cell studies were carried out whereby compared to a predicate device, Reprobone was equivalent in terms of cell attachment and proliferation as well as bone formation and device reesorption.

8. Conclusion

The safety and effectiveness and performance equivalence of ReproBone® resorbable bone graft substitute for use in dental and periodontal bone voids is adequately supported by the substantial equivalence information as well as comparative biocompatibility testing, and safety and performance data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV - 3 2011

Mr. Hillard W. Welch
U.S. Representative for Ceramisys Limited
Ceramisys Limited
344 Annabelle Point Road
Centerville, Massachusetts 02632

Re: K103820
Trade/Device Name: ReproBone®
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: October 18, 2011
Received: October 20, 2011

Dear Mr. Welch:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

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Indications for Use

510(k) Number (if known): K103820

Device Name: _ReproBone_____

Indications for Use:

ReproBone is recommended for augmentation or reconstructive treatment of the alveolar ridge. Filling of infrabony periodontal defects. Filling of defects after root resection apicoectomy and cystectomy. Filling of extraction sockets to enhance preservation of the alveolar ridge. Elevation of the maxillary sinus floor. Filling of periodontal defects in conjunction with products intended for guided tissue regeneration (GTR) and guided bone regeneration (GBR). Filling of peri-implant defects in conjunction with products intended for guided bone regeneration (GBR).

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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