K070055

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Vivoxid Ltd.
Turku, Finland

5. 510(k) Summary

JUN 25 2007

Submitter: Vivoxid Ltd.
Turku, Finland

Contact Information: Constance G. Bundy
C. G. Bundy Associates, Inc.
6470 Riverview Terrace
Fridley, MN 55432

Submission Date: December 29, 2006

Device Name and Classification: BonAlive™ Granules
Bone Grafting Material, Product Code: LYC
Class II per 872.3930

Equivalent Device Identification: NovaBone Perioglas®, NovaBone-C/M®, K053387

Device Description: BonAlive™ products are sterile medical devices made of S53P4 bioactive glass. Bioactive glasses are characterised by their ability to attach firmly to living tissue. Other properties include being able to bond chemically with surrounding bone in an implantation bed and promote new bone formation in the implanted area. Bone bonding is a physico-chemical process leading to continuity between an implant and bone matrix. It has been shown that tissue bonds to bioactive glass due to formation of a silica-gel layer on the glass. The silica-rich layer acts as a template for a calcium phosphate precipitation, which then bonds the bioactive glass to the surrounding bone. This makes the bioactive glass a unique material for filling defects and replacing damaged bony tissue.The composition of this synthetic, osteoconductive material is, by weight, SiO_2 53%, Na_2O 23%, CaO 20% and P_2O_5 4%.
BonAlive™ products are supplied as granules. The granules are bone grafting materials intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. BonAlive™ granules are sterilized in hot dry air. The granules are available as different granule and unit sizes.

Intended Use: BonAlive™ granules consist of bioactive glass, a bone grafting material that is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2007

Vivoxid Limited
C/O Ms. Constance G. Bundy
C.G. Bundy Associates, Incorporated
6470 Riverview Terrace
Fridley, Minnesota 55432

Re: K070055
Trade/Device Name: BonAlive™ Granules
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: June 15, 2007
Received: June 19, 2007

Dear Ms. Bundy:

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,

Chiu Y. Michaud MD.

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070055

4. Indications for Use

510(k) Number (if known): K070055

Device Name: BonAlive™ Granules

Indications for Use:

BonAlive™ Granules are sterile medical devices consisting of bioactive glass. Bioactive glass is a bone grafting material that is intended to fill, augment or reconstruct periodontal or bony defects. BonAlive™ Granules are indicated for use in the cranio-maxillofacial area including jaws.

Prescription Use __X__
(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)

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Susan Runner

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

510(k) Number K070055