DEC 2 2 2011

K110198

5 510(k) SUMMARY

DATE: December 12, 2011

OWNER:
Blue Sky Bio, LLC
888 E. Belvidere
Suite 212
Grayslake, IL 60030
Telephone: 847-548-8499
Fax: 888-234-3685

OFFICIAL CONTACT:
Michele Vovolka
Vantage Consulting International
P.O. Box 848
Grayslake, IL 60030
Telephone: 815-856-0355
Fax: 888-234-3685
Email: vantagemv@comcast.net

DEVICE NAME:

Trade Name:	Blue Sky Bio TCP Bone Graft Substitute Bone Grafting Material, for Dental Bone Repair
Common Name:	Bone Grafting Material
Classification Name:	Bone Grafting Material, Synthetic
Class:	Class II
Regulation Number:	21 CFR 872.3930
Product Code:	LPK, Tricalcium Phosphate Bone Grafting Material

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PREDICATE DEVICE(S):

Predicate 510(k)	Device Name	Indication	Clearance Date	Company
K051443	Cerasorb® M Dental	Cerasorb® M DENTAL 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 perio-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)	22 July 2005	Curasan AG, Kleinostheim, Germany
K083372	ArrowBone-β	ArrowBone-β is intended for use in the reconstruction of natural or surgical periodontal defects of the oral and maxillofacial region, including sinus floor elevation and augmentation of the alveolar crest. ArrowBone-β is intended for filling into the site of a bony defect in combination with patient blood, autologous bone, membranes or sterile saline after removal of cysts or surgical removal of retained teeth.	8 December 2009	BrainBase Corporation, Tokyo, Japan

DEVICE DESCRIPTION:

Blue Sky Bio TCP Bone Graft Substitute is porous, resorbable, and biocompatible calcium phosphate ceramic consisting of β-tricalcium phosphate. β-tricalcium phosphate is an osteoconductive implant that is biodegradeable. Blue Sky Bio TCP Bone Graft Substitute is provided sterile in granular form, pyrogen-free and available in granule sizes up to 2000 µm.

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STATEMENT OF INTENDED USE:

Blue Sky Bio TCP Bone Graft Substitute is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects.

- Filling of periodontal/infrabony defects
- Ridge augmentation
- Filling of extraction sites (implant preparation/placement)
- Sinus lifts
- Filling of cystic cavities

The device gradually resorbs and is replaced with bone during the healing process.

TECHNOLOGICAL CHARACTERISTICS:

The Blue Sky Bio TCP Bone Graft Substitute consists of pure β-tricalcium phosphate as described in ASTM F1088-04, Standard Specification for β-tricalcium Phosphate for Surgical Implants.

The following biocompatibility tests have been completed and results support that Blue Sky Bio TCP Bone Graft Substitute is compatible with surrounding tissues.

Biocompatibility Tests	Results
Cytotoxicity	Pass
Intracutaneous Irritation Test	Pass
Maximization Sensitization Test	Pass
Pyrogen Test	Pass
Acute Toxicity	Pass

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BASIS FOR SUBSTANTIAL EQUIVALENCE:

Blue Sky Bio TCP Bone Graft Substitute meets the requirements of established standards for materials, biocompatibility, pyrogenicity and sterilization.

Blue Sky Bio TCP Bone Graft Substitute is substantially equivalent to the currently marketed Cerasorb® M DENTAL and BrainBase Corporation ArrowBone-β, as a bone void filler for defects in the oral/maxillary and dental region. These bone graft materials are equivalent in that they consist of β-tricalcium phosphate with a phase purity of more than 95% and comply with ASTM F 1088-04. The devices are substantially equivalent with regard to materials as demonstrated by comparison of XRD profiles and dissolution testing, intended use, indications for use, anatomical site and performance data.

The information provided in this submission demonstrates that the Blue Sky Bio TCP Bone Graft Substitute is substantially equivalent to the predicate devices.

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

Ms. Vovolka
Consultant
Blue Sky Bio, LLC
888 E Belvidere Road, Suite 212
Grayslake, Illinois 60030

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Re: K110198
Trade/Device Name: Blue Sky Bio TCP Bone Graft Substitute
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LPK
Dated: December 12, 2011
Received: December 17, 2011

Dear Ms. Vovolka:

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,

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

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INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **Blue Sky Bio TCP Bone Graft Substitute**

Indications for Use: Blue Sky Bio TCP Bone Graft Substitute is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects.

- Filling of periodontal/infrabony defects
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- Sinus lifts
- Filling of cystic cavities

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Susan Runner

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

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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)