510(k) Summary
VITOMATRIX

510(k) Number (if known): K091618

Sponsor: Orthovita, Inc.
45 Great Valley Parkway
Malvern, PA 19355 USA
(t) 610-640-1775 - (f) 484-323-8803

SEP 27 2010

Company Representative: Deborah L. Jackson, RAC
Senior Regulatory Affairs Specialist
(email) djackson@orthovita.com

Date Prepared: September 17, 2010

Device Trade Name: VITOMATRIX

Common or Usual Name: Bone grafting material

Regulation Number: 872.3930

Regulation Name: Bone grafting material, synthetic

Regulatory Class: Class II

Product Code: LYC

Predicate Devices: K081561 - OSferion D (Olympus Terumo Biomaterials Corp.)
K051443 - Cerasorb DENTAL / Cerasorb M DENTAL / Cerasorb Perio (Curasan AG)

Device Description: VITOMATRIX is a resorbable bone grafting material composed of β-Tricalcium Phosphate intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. It is an osteoconductive porous implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. The implant is provided sterile and available in .25-1mm and 1-2mm morsel sizes.

VITOMATRIX guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When VITOMATRIX is placed in direct contact with viable host bone, new bone grows in apposition to the calcium phosphate surfaces of the implant. As the implant resorbs, bone and other connective tissues grow into the space previously occupied by the scaffold.

Intended Use:

VITOMATRIX is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

- 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).

Performance Data:

VITOMATRIX is a medical grade beta-tricalcium phosphate which satisfies the requirements of ASTM F 1088-04a, *Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation.*

Comparative non-clinical performance testing included physical and chemical characteristics of the implant. Testing included ICP, XRD, FTIR, BET, SEM and BSEI, mercury porosimetry, bulk density and high resolution x-ray, simulated clinical packing, and wettability.

Animal performance testing evaluated the resorption rate of the implant in 1-4mm morsel size and D9x23mm block and the corresponding bone healing when implanted out to 1 year in the proximal humeral metaphyses of adult mongrel dogs. A published study evaluated the resorption rate of the implant (1-4mm morsels) and the corresponding bone healing compared to the predicate device (1-3mm morsels) in a bilateral rabbit tibial defect model.

Biocompatibility of the implant has been established in accordance with ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing.*

Data supplied demonstrates that VITOMATRIX is substantially equivalent to the predicate devices and any differences do not raise new questions of safety and effectiveness.

Substantial Equivalence:

Information within this submission supports substantial equivalence.

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. Deborah L. Jackson
Senior Regulatory Affairs Specialist
Orthovita, Incorporated
45 Great Valley Parkway
Malvern, Pennsylvania 19355

SEP 27 2010

Re: K091618
Trade/Device Name: VITOMATRIX
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: September 17, 2010
Received: September 20, 2010

Dear Ms. Jackson:

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.

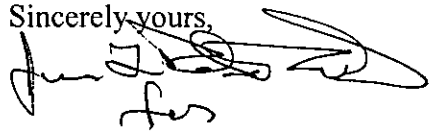
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR Over-The Counter Use (21 CFR 807 Subpart C)	

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for MSR

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

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