510(k) SUMMARY
Vitoss™ BA Bimodal Bioactive Bone Graft Substitute

FEB - 7 2011

January 10, 2011

510(k) Number (if known): K103173

1. **Contact Person**

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2. **Device Name and Classification**

Product Name:	Vitoss BA Bimodal Bioactive Bone Graft Substitute
Classification Name:	Filler, bone void, calcium
Common or Usual Name:	Resorbable calcium salt bone void filler device
Classification Panel:	Orthopedic
Regulation Number:	888.3045
Device Class:	Class II
Product Code:	MQV

3. **Predicate Device(s)**

Orthovita's Vitoss Bioactive Foam Pack Bone Graft Substitute (K081439, K083033)
NovaBone Products, LLC's NovaBone AR – Resorbable Bone Graft Substitute (K041613)

4. **Device Description**

Vitoss BA Bimodal Bioactive Bone Graft Substitute is a resorbable porous bone void filler for the repair of bony defects. It is an osteoconductive, porous implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. The implant is >70% porous and the pore diameters range from 1 μm to 1000 μm.

Vitoss BA Bimodal Bioactive Bone Graft Substitute guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When Vitoss BA Bimodal Bioactive Bone Graft Substitute is placed in direct contact with host bone, new bone grows in apposition to the surfaces of the implant. As the implant resorbs, bone and other connective tissues grow into the space previously occupied by the scaffold.

5. **Indications for Use**

Vitoss BA Bimodal Bioactive Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss BA Bimodal is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Vitoss BA Bimodal Bioactive Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis and posterolateral spine) and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

6. **Performance Data**

Vitoss BA Bimodal 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 testing included wettability, fluid retention, wash away resistance, homogeneity, radiopacity, bioactivity, dissolution, and SEM comparisons. XRD, FTIR ICP and porosity were evaluated for the predicate device. 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 demonstrate that Vitoss BA Bimodal Bioactive Bone Graft Substitute is substantially equivalent to the predicate device and does not raise new questions of safety and effectiveness.

7. **Substantial Equivalence**

Vitoss BA Bimodal Bioactive Bone Graft Substitute, subject of the Special 510(k), is a product line extension to the Vitoss Bioactive Foam product line. Vitoss BA Bimodal Bioactive Bone Graft Substitute has the same intended uses and indications, technological characteristics, and principles of operation as its predicate device. The minor differences between Vitoss BA Bimodal Bioactive Bone Graft Substitute and the predicate device raise no new issues of safety or effectiveness. Thus, Vitoss BA Bimodal Bioactive Bone Graft Substitute is substantially equivalent to Vitoss Bioactive Foam.

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

Orthovita, Inc.
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Malvern, Pennsylvania 19355

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Re: K103173
Trade/Device Name: Vitoss™ BA Bimodal Bioactive Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 10, 2011
Received: January 11, 2011

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): **K103173**

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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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103173