

**510(k) SUMMARY**  
**FM-02 Bone Graft Substitute**  
October 26, 2010

510(k) Number (if known): K102545

OCT 27 2010

**1. Contact Person**

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**2. Device Name and Classification**

Product Name: FM-02 Bone Graft Substitute  
Classification Name: Resorbable calcium salt bone void filler device  
Common or Usual Name: Bone Void Filler  
Classification Panel: Orthopedic  
Regulation Number: 888.3045  
Device Class: Class II  
Product Code: MQV

**3. Predicate Device(s)**

Vitoss Bioactive Foam Bone Graft Substitute (K072184)  
Vitoss Bioactive Foam Bone Graft Substitute STRIP and PACK (K081439)  
Vitoss Bioactive Foam Bone Graft Substitute STRIP and PACK (K083033)

**4. Device Description**

FM-02 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  $\mu\text{m}$  to 1000  $\mu\text{m}$ .

FM-02 Bone Graft Substitute guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When FM-02 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. Intended Use / Indications for Use**

FM-02 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. FM-02 is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

FM-02 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**

FM-02 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, 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 FM-02 Bone Graft Substitute is substantially equivalent to the predicate device and does not raise new questions of safety and effectiveness.

#### **7. Substantial Equivalence**

FM-02 Bone Graft Substitute, subject of the Special 510(k), is a product line extension to the Vitoss Bioactive Foam product line. FM-02 Bone Graft Substitute has the same intended uses and indications, technological characteristics, and principles of operation as its predicate device. The minor differences between FM-02 Bone Graft Substitute and the predicate device raise no new issues of safety or effectiveness. Thus, FM-02 Bone Graft Substitute is substantially equivalent to Vitoss Bioactive Foam.



Food and Drug Administration  
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Silver Spring, MD 20993-0002

Orthovita, Inc.  
% Ms. Deborah L. Jackson, RAC  
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45 Great Valley Parkway  
Malvern, Pennsylvania 19355

OCT 27 2010

Re: K102545  
Trade Name: FM-02 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: October 1, 2010  
Received: October 4, 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.

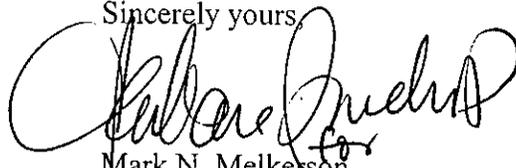
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

Mark N. Melkerson

Director

Division of Surgical, Orthopedic,  
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

**Indications for Use Statement**

510(k) Number (if known): K102545

OCT 27 2010

Device Name: FM-02 Bone Graft Substitute

Indications for Use:

FM-02 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. FM-02 is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

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

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