K032130

NOV - 5 2003



# 510(k) Summary

| Submitted by | Address | Telephone | Contact Person |
|---|---|---|---|
| Orthovita, Inc. | 45 Great Valley Parkway<br>Malvern, PA 19355 | (610) 640-1775 | Andreina Ide<br>Sr. Director, Regulatory Affairs |

| September 2002 | Subject Device | Predicate Device |
|---|---|---|
| Trade Name | Vitoss-Filled Cartridge | Vitoss Scaffold, K994337 and Imbibe II Syringe, K030208 |
| Common Name | Kit: Bone Void Filler and Bone Graft Delivery Syringe | Bone Void Filler and Bone Graft Delivery Syringe |
| Classification Name | Bone Void Filler and Piston Syringe | Bone Void Filler and Piston Syringe |

## Device Description:

The Vitoss-Filled Cartridge is a device that combines two Orthovita products, Vitoss Scaffold Synthetic Cancellous Bone Void Filler (K994337) and the Imbibe II Syringe (K030208) into a kit configuration. The convenience kit provides the Imbibe II Syringe loaded (filled) with Vitoss Scaffold and an empty 30cc secondary syringe (Merit Piston Syringe, K875196). An adapter valve, which can be connected to the vacuum line in the surgical suite, is also provided. The surgeon can use either the secondary syringe or the vacuum line adapter to aspirate blood or marrow into the Vitoss-Filled Cartridge.

## Intended Use:

VITOSS® Scaffold Synthetic Cancellous Bone Void Filler is intended only for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. VITOSS Scaffold is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. VITOSS should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

VITOSS Scaffold is intended to be packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). Following placement in the bony void or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

The Cartridge, containing Vitoss Scaffold, is intended for use as a piston syringe for the aspiration of bone marrow, autologous blood, plasma or other blood components. The cartridge provides the surgeon with a convenient way to mix autologous blood or bone marrow with Vitoss Scaffold Bone Void Filler and deliver the material to the orthopaedic surgical site.

## Comparison to Predicate:

The Vitoss-Filled Cartridge claims substantial equivalence to the Vitoss Scaffold Synthetic Cancellous Bone Void Filler (K994337) and the Imbibe II Syringe (K030208), cleared December 14, 2000 and April 16, 2003 respectively.

The Vitoss-Filled Cartridge is a device that combines Vitoss Scaffold (K994337) and the Imbibe II Syringe (K030208) into a convenience kit whereby the Imbibe II Syringe is loaded (filled) with Vitoss Scaffold. No changes have been made to the Vitoss Scaffold or the Imbibe II Syringe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

Ms. Andreina Ide
Sr. Director, Regulatory Affairs
Orthovita, Inc.
45 Great Valley Parkway
Malvern, PA 19355

Re: K032130
Trade Name: Vitoss Scaffold Synthetic Cancellous Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: October 23, 2003
Received: October 27, 2003

Dear Ms. Ide:

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.

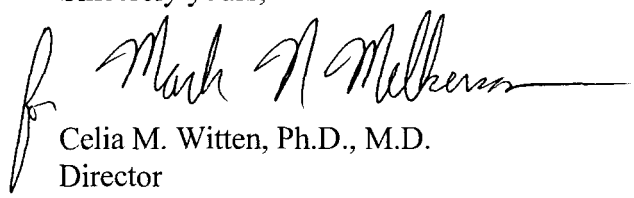
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

October 30, 2003

## 510(k) NUMBER (IF KNOWN): K032130

## DEVICE NAME: Vitoss-Filled Cartridge

## INDICATIONS FOR USE:

VITOSS® Scaffold Synthetic Cancellous Bone Void Filler 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 Scaffold is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. VITOSS should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

VITOSS Scaffold is intended to be packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) and may be combined with autogenous blood and/or bone marrow. Following placement in the bony void or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

The VITOSS-Filled Cartridge is intended for use as a piston syringe system for the aspiration of autogenous blood and/or bone marrow. This Cartridge provides the surgeon with a convenient way to mix autologous blood or bone marrow with Vitoss Scaffold® and deliver the material to the orthopaedic surgical site.

**PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED.**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** ✓ **OR** **Over-The-Counter-Use** ____
**(Per 21 CFR 801.109)**

for Mark N Milburn
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032130