

DEC 14 2000

K994337

**510(k) Summary**  
***Vitoss™ Scaffold Synthetic Cancellous***  
**Bone Void Filler**

Submitted by	Address	Telephone	Contact Person
Orthovita, Inc.	45 Great Valley Parkway Malvern, PA 19355	(610) 640-1775	Angie Ide Director, Regulatory Affairs
December 14, 2000	Subject Device	Predicate Device	
Trade Name →	<i>Vitoss™ Scaffold Synthetic Cancellous Bone Void Filler</i>	Pro Osteon 500 <sub>R</sub> Resorbable Bone Void Filler	
Common Name	Bone Void Filler	Bone Void Filler	
Classification Name	Filler, Calcium Sulfate Preformed Pellets	Filler, Calcium Sulfate Preformed Pellets	

**Device Description:**

*Vitoss Scaffold* is a porous calcium phosphate resorbable 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. Pore diameters in the scaffold range from 1 µm to 1000 µm (1 mm). The implant is provided sterile in block and morsel forms.

*Vitoss Scaffold* guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When *Vitoss Scaffold* 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. Results from animal studies demonstrate that eighty percent of *Vitoss Scaffold* is resorbed within twelve weeks.

**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 created from traumatic injury to the bone. *Vitoss Scaffold* 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 gently 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.

**Comparison to Predicate:**

<b>COMPARISON TO PREDICATE</b>		
	<i>Vitoss Scaffold</i>	<i>Pro Osteon 500R</i>
<b>Intended Use</b>	Synthetic Bone Void Filler	Synthetic Bone Void Filler
<b>Target Population</b>	Individuals with bony defects resulting from surgery or trauma	Individuals with bony defects resulting from surgery or trauma
<b>Anatomical Locations</b>	Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis	Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis
<b>Labeling</b>	Labeling contains same intended use, contraindications, warnings, precautions, and adverse events as predicate	Labeling contains same intended use, contraindications, warnings, precautions, and adverse events as <i>Vitoss</i>
<b>Materials</b>		
• <b>Chemical Composition</b>	Calcium salt	Calcium salts
• <b>Mineral Phase(s)</b>	$\beta$ -Tricalcium Phosphate $\text{Ca}_3(\text{PO}_4)_2$	Hydroxyapatite $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ Calcium Carbonate $\text{CaCO}_3$
<b>Design</b>		
• <b>Physical Structure</b>	Trabecular structure similar to cancellous bone	Trabecular structure similar to cancellous bone
• <b>Porosity</b>	Approximately 90%	Approximately 55%
• <b>Pore Size (range)</b>	1-1000 $\mu\text{m}$	280-779 $\mu\text{m}$
<b>Performance</b>		
• <b>Osteoconductivity</b>	Osteoconductive	Osteoconductive
• <b>Resorption</b>	Demonstrated as 76% resorbed at six weeks and 86% resorbed at twelve weeks	Reported as 20% resorbed at six weeks and 45% resorbed at twelve weeks
• <b>Bone Remodeling</b> Recorded as ratio of bone in implant to adjacent bone	Demonstrated as 0.6 at six weeks and 1.2 at twelve weeks	Demonstrated as 0.4 at six weeks and 0.5 at twelve weeks
• <b>Mechanical Strength</b>	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site
<b>Sterility</b>	Sterilized by gamma radiation, single use only	Sterilized by gamma radiation, single use only
<b>Biocompatibility</b>	Established	Established
<b>Dosage Form(s)</b>	Morsels (1-4 mm sizes) and blocks (9x23mm cylinder)	Morsels (1-4 mm sizes)

### **Non-clinical Performance Data:**

Pre-clinical animal data demonstrate that *Vitoss* Scaffold supports bone growth into a metaphyseal defect. These data show that *Vitoss* Scaffold resorbs at an early time period, accompanied by early bone ingrowth and bone remodeling. These results, in conjunction with biocompatibility data, demonstrate that *Vitoss* Scaffold Bone Void Filler is as safe and as effective as the predicate device, Pro Osteon 500R.

### **Clinical Performance Data:**

Calcium-based ceramic materials, including tricalcium phosphate, have been used in clinical practice for more than 25 years with no remarkable safety issues. Early successful results were achieved in dentistry and oral reconstructive surgery. Subsequently, successful results have been demonstrated in the treatment of many orthopedic problems, including filling defects secondary to trauma, benign tumors and cysts, and the filling of metaphyseal defects of long bones.

In terms of safety, calcium-based bone void fillers have the advantage of avoiding the potential morbidity associated with the harvesting of bone autografts and the potential for disease transmission by allografts. To date there have been no reports in the literature of adverse reactions to calcium-based ceramic materials. A review of FDA's Manufacturer and User Facility Device Experience Database (MAUDE), conducted on 12/13/1999, showed no records of adverse device experience with Pro Osteon 500R, the device to which *Vitoss* Scaffold claims substantial equivalence. Only two records were found reported for all devices with the product code MQV. These two records were for Wright Medical's product, Osteoset, the device to which Pro Osteon 500R was determined to be substantially equivalent. This confirms the continued safe use of the bone void fillers currently in commercial distribution.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 14 2000

Ms. Angie Ide  
Director, Regulatory Affairs  
Orthovita Company  
45 Great Valley Parkway  
Malvern, Pennsylvania 19355

Re: K994337

Trade Name: Vitoss™ Scaffold Synthetic Cancellous Bone Void Filler  
Regulatory Class: Unclassified  
Product Code: MQV  
Dated: October 26, 2000  
Received: October 27, 2000

Dear Ms. Ide:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

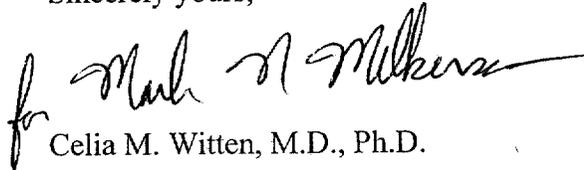
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

Celia M. Witten, M.D., Ph.D.

Director

Division of General, Restorative, and  
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

**510(k) Number: K994337**

**Device Name:** *Vitoss™ Scaffold Synthetic Cancellous Bone Void Filler*

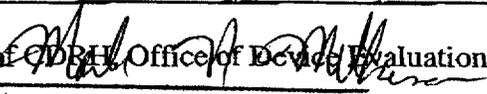
### Indications For Use:

*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 created from traumatic injury to the bone. Vitoss Scaffold should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.*

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Concurrence of  Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number \_\_\_\_\_

K994337

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_