K032288

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DEC 1 9 2003

510(k) Summary
Vitoss® Scaffold Foam Bone Graft Material

Submitted by	Address	Telephone	Contact Person
Orthovita, Inc.	45 Great Valley Parkway Malvern, PA 19355	(610) 640-1775	Gina M. Nagvajara, Ph.D. Director of Research and Intellectual Property

	Subject Device	Predicate Devices
Trade Name	*Vitoss*® Scaffold Foam Bone Graft Material	Vitoss® Scaffold Synthetic Cancellous Bone Void Filler; Healos® Bone Graft Material
Common Name	Bone Void Filler	Bone Void Filler
Classification Name	Filler, Calcium Sulfate Preformed Pellets	Filler, Calcium Sulfate Preformed Pellets

Device Description:

Vitoss Scaffold Foam is a porous calcium phosphate resorbable material admixed with Type I bovine collagen 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 both cylinder and strip forms. *Vitoss* Scaffold Foam may be mixed with autogenous blood or bone marrow.

Vitoss Scaffold Foam guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When *Vitoss* Scaffold Foam is placed in direct contact with viable 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.

Intended Use:

Vitoss Scaffold Foam Bone Graft Material 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 Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. *Vitoss* Scaffold Foam should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Vitoss Scaffold Foam Bone Graft Material is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Comparison to Predicate:

	NEW DEVICE: *VITOSS* SCAFFOLD FOAM	PREDICATE: VITOSS SCAFFOLD SYNTHETIC	PREDCATE: HEALOS BONE GRAFT MATERIAL
Intended Use	Bone Void Filler	Bone Void Filler	Bone Void Filler
Target Population	Individuals with bony defects resulting from surgery or trauma	Individuals with bony defects resulting from surgery or trauma	Individuals with bony defects resulting from surgery or trauma
Anatomical Locations	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	Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis
Labeling	*Vitoss* Scaffold Foam's product label contains the same intended use, contraindications, warnings, precautions, and adverse events as for the Vitoss Scaffold Synthetic Cancellous Bone Void Filler with the addition of collagen related contraindications and adverse events from the Healos Bone Graft Material product label; wording is not identical but is substantially equivalent		
Materials			
• **Chemical Composition**	Calcium salt with Type I bovine collagen	Calcium salt	Calcium salt with Type I bovine collagen
• **Mineral Phase(s)**	β-Tricalcium phosphate $Ca_3(PO_4)_2$	β-Tricalcium phosphate $Ca_3(PO_4)_2$	Hydroxyapatite $Ca_{10}(PO_4)_6(OH)_2$
Design			
• **Physical Structure**	Trabecular structure similar to cancellous bone	Trabecular structure similar to cancellous bone	Three dimensional, open-cell matrix
• **Pore Size (range)**	1-1000 μm	1-1000 μm	4-200 μm
Performance			
• **Osteoconductivity**	Osteoconductive	Osteoconductive	Osteoconductive
• **Mechanical Strength**	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site
Sterility	Sterilized by gamma irradiation, single use only	Sterilized by gamma irradiation, single use only	Sterilized by e-beam, single use only
Biocompatibility	Established	Established	Established
Dosage Form(s)	Cylinders (Blocks), Strips	Blocks, Morsels	Strips, Pads

Non-clinical Performance Data:

Pre-clinical animal data demonstrate that *Vitoss* Scaffold Foam supports bone growth into a metaphyseal defect. These data show that *Vitoss* Scaffold Foam is resorbed concurrently with bone ingrowth and remodeling. These results, in conjunction with in-vitro data, demonstrate that *Vitoss* Scaffold Foam is as safe and as effective as the predicate devices, Vitoss Scaffold Synthetic Cancellous Bone Void Filler and Healos Bone Graft Material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2003

Gina M. Nagvajara, Ph.D.
Director of Research and Intellectual Property
Orthovita, Inc.
45 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K032288
Trade/Device Name: *Vitoss*® Scaffold Foam Bone Graft Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Bone void filler
Regulatory Class: II
Product Code: MQV
Dated: December 1, 2003
Received: December 2, 2003

Dear Dr. Nagvajara:

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,

for Mark N. Melkerson

Celia M. Witten, PhD, MD
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 (If Known): K032288

Device Name: *Vitoss*® Scaffold Foam Bone Graft Material

Indications For Use:

Vitoss Scaffold Foam Bone Graft Material 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 Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. *Vitoss* Scaffold Foam should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Vitoss Scaffold Foam Bone Graft Material is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

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)

for Mark N. Melkerson

Division of General, Restorative and Neurological Devices

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