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

Submitted by: Orthovita, Inc.
Address: 45 Great Valley Parkway
Malvern, PA 19355
Telephone: (610) 640-1775
Contact Person: 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
Classification Name         Bone Void Filler
                             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:

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>NEW DEVICE: VITOS SCAFFOLD FOAM</th>
<th>PREDICATE: VITOS SCAFFOLD SYNTHETIC</th>
<th>PREDICATE: HEALOS BONE GRAFT MATERIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone Void Filler</td>
<td>Bone Void Filler</td>
<td>Bone Void Filler</td>
<td>Bone Void Filler</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Target Population</th>
<th>Individuals with bony defects resulting from surgery or trauma</th>
<th>Individuals with bony defects resulting from surgery or trauma</th>
<th>Individuals with bony defects resulting from surgery or trauma</th>
</tr>
</thead>
</table>

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<tr>
<th>Anatomical Locations</th>
<th>Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis</th>
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| 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 |
|-----------------------|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------|

<table>
<thead>
<tr>
<th>Materials</th>
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<tbody>
<tr>
<td>Chemical Composition</td>
<td>Calcium salt with Type I bovine collagen</td>
<td>Calcium salt</td>
<td>Calcium salt with Type I bovine collagen</td>
</tr>
<tr>
<td>Mineral Phase(s)</td>
<td>β-Tricalcium phosphate Ca_3(PO_4)_2</td>
<td>β-Tricalcium phosphate Ca_3(PO_4)_2</td>
<td>Hydroxyapatite Ca_{10}(PO_4)_{6}(OH)_2</td>
</tr>
</tbody>
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<thead>
<tr>
<th>Design</th>
<th></th>
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<tbody>
<tr>
<td>Physical Structure</td>
<td>Trabecular structure similar to cancellous bone</td>
<td>Trabecular structure similar to cancellous bone</td>
<td>Three dimensional open-cell matrix</td>
</tr>
<tr>
<td>Pore Size (range)</td>
<td>1-1000 μm</td>
<td>1-1000 μm</td>
<td>4-200 μm</td>
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<thead>
<tr>
<th>Performance</th>
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<tr>
<td>Osteoconductivity</td>
<td>Osteoconductive</td>
<td>Osteoconductive</td>
<td>Osteoconductive</td>
</tr>
<tr>
<td>Mechanical Strength</td>
<td>Does not impart mechanical strength to surgical site</td>
<td>Does not impart mechanical strength to surgical site</td>
<td>Does not impart mechanical strength to surgical site</td>
</tr>
<tr>
<td>Sterility</td>
<td>Sterilized by gamma irradiation, single use only</td>
<td>Sterilized by gamma irradiation, single use only</td>
<td>Sterilized by e-beam, single use only</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
</tr>
<tr>
<td>Dosage Form(s)</td>
<td>Cylinders (Blocks), Strips</td>
<td>Blocks, Morsels</td>
<td>Strips, Pads</td>
</tr>
</tbody>
</table>

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.
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" (21 CFR 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, 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.

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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)

[Signature]

Division of Neurological Devices

K032288