



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Orthovita, Incorporated
Ms. Meriam Gabera
Senior Regulatory Affairs Specialist
59 Route 17 South
Allendale, New Jersey 07401

February 12, 2016

Re: K153608

Trade/Device Name: Vitoss BiModal Bioactive Bone Graft Substitute Foam Strip
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 21, 2016
Received: January 22, 2016

Dear Ms. Gabera:

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 Parts 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153608

Device Name

Vitoss BiModal Bioactive Bone Graft Substitute Foam Strip

Indications for Use (Describe)

Vitoss BiModal Bioactive Bone Graft Substitute Foam Strip 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 BiModal Foam Strip is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Vitoss BiModal Foam Strip 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) Summary: Vitoss BiModal Foam Strip	
Submitter:	Stryker Orthobiologics 74 East Swedesford Road Malvern, PA 19355
Contact Person	Meriam Gabera Senior Regulatory Affairs Specialist Phone: 201-749-8043 Fax: 201-831-3000 Email: Meriam.Gabera@Stryker.com
Date Prepared	December 16, 2015
Trade Name	Vitoss BiModal Bioactive Bone Graft Substitute Foam Strip
Common Name	Resorbable calcium salt bone void filler device
Proposed Class	Class II
Classification Name and Number	Filler, Bone Void, Calcium Compound 888.3045
Product Code	MQV
Predicate Devices	<u>Primary Predicate</u> <u>Secondary Predicate</u> Vitoss BA Foam Strip (K072184) Vitoss BiModal Foam Pack (K103173)
Device Description	<p>Vitoss BiModal Foam Strip 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. Pore diameters in the scaffold range from 1 to 1000 µm.</p> <p>Vitoss BiModal Foam Strip guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When Vitoss BiModal Foam Strip 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.</p>
Intended Use	Vitoss BiModal Bioactive Bone Graft Substitute Foam Strip 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 BiModal Foam Strip is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

510(k) Summary: Vitoss BiModal Foam Strip	
	<p>Vitoss BiModal Foam Strip 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.</p>
Summary of the Technological Characteristics	<p>As established in this submission, Vitoss BiModal Foam Strip was shown to be substantially equivalent and has equivalent technological characteristics to its predicate device through comparison in areas including intended use, material composition, principles of operation and design.</p>
Summary of the Performance Data	<p>Risk analysis was performed to demonstrate that Vitoss BiModal Foam Strip is substantially equivalent to its predicate devices. The risk analysis determined that the predefined acceptance criteria was met for the following:</p> <ul style="list-style-type: none"> • Wettability and Fluid Retention Verification • Porosity Verification • Bioactivity Verification • Clinical Handling Verification • Product Stability throughout shelf-life • Biocompatibility • Design Validation
Conclusion	<p>The proposed Vitoss BiModal Foam Strip has identical indications, technological characteristics, and principles of operation as its predicates. The risk analysis performed demonstrates that any minor differences do not impact device performance as compared to the predicates. The design verifications and validations performed as a result of the risk analysis and presented herein demonstrate the proposed device does not raise new questions of safety or effectiveness. Thus, the predicate devices (K072184 and K103173) and proposed device are considered substantially equivalent.</p>