DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 2, 2017

Orthovita, Inc.
% John Rossman
Regulatory Affairs Project Manager
Stryker Corporation
Stryker Spine
59 Route 17 South
Allendale, New Jersey 07401

Re: K163621
Trade/Device Name: Vitoss Bioactive (BA) Injectable
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: March 13, 2017
Received: March 17, 2017

Dear Mr. Rossman:

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 Part 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" (21 CFR 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163621

Device Name
Vitoss Bioactive (BA) Injectable

Indications for Use *(Describe)*
Vitoss BA Injectable 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 BA Injectable is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Vitoss BA Injectable is intended to be used for filling bony voids and gaps of the skeletal system (i.e. the extremities and pelvis), 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.

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510(k) Summary: Vitoss BA Injectable Bone Graft Substitute	
Submitter:	Stryker Orthobiologics 74 East Swedesford Road Malvern, PA 19355
Contact Person :	Name: John Rossman Phone: (201) 749-8193 Fax: (201) 831-3000 Email: john.rossman@stryker.com
Date Prepared:	04/24/2017
Trade Name:	Vitoss Bioactive (BA) Injectable
Common Name:	Resorbable calcium salt bone void filler device
Proposed Class:	Class II
Classification Name:	Filler, Bone Void, Calcium Compound (21 CFR 888.3045) Syringe, Piston (21 CFR 880.5860)
Product Code:	MQV FMF
Predicate Devices:	Primary Predicate: Vitoss BA Foam Pack (K081439) Additional Predicates: Vitoss BA BiModal (K103173) NanOss Bioactive Loaded (K141600) Carricell (K132868)
Device Description:	Vitoss BA Injectable bone graft substitute is a synthetic resorbable porous bone void filler for the repair of bony defects made from a combination of beta tricalcium phosphate and bioactive glass in a carrier of porcine gelatin and sodium carboxymethyl cellulose. It is an osteoconductive porous implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. Vitoss BA Injectable is provided prepackaged in a syringe. At the time of use a specified volume of hydration fluid is combined with the dry component of the device. Mixing is facilitated by a syringe to syringe mixing system. The resulting material can be administered to the treatment site by injection through a cannula or by manual application. After injection or insertion into the defect site 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.

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510(k) Summary: Vitoss BA Injectable Bone Graft Substitute	
Intended Use:	Vitoss BA Injectable 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 BA Injectable is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. Vitoss BA Injectable is intended to be used for filling bony voids and gaps of the skeletal system (i.e. the extremities and pelvis), 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.
Summary of the Technological Characteristics	Vitoss BA Injectable was shown to be substantially equivalent and has equivalent technological characteristics to its predicate devices through comparison in areas including intended use, material composition, principles of operation and design.
Summary of the Performance Data	Risk analysis was performed to demonstrate that Vitoss BA Injectable is substantially equivalent to its predicate devices. The risk analysis determined that the predefined acceptance criteria was met for the following: • Comparative animal performance testing in a rabbit model • Bioactivity testing included in-vitro studies in which calcium phosphate growth was induced on the surface of Vitoss Bioactive Injectable in the presence of simulated body fluid. This phenomenon was not observed in control samples in which there was no bioactive glass component. The bioactivity has not been evaluated in human clinical trials. • Permeability testing • Irrigation testing • Usability testing • Extrusion testing • Packaging and shelf life validations • Sterilization validation • Biocompatibility
Conclusion	The proposed Vitoss BA Injectable has equivalent 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 in the submission demonstrate the proposed device does not raise new questions of safety or effectiveness. Thus, the aforementioned predicate devices and subject device are considered substantially equivalent.