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

October 6, 2016

Orthovita, Inc.
% Ms. Lia Gonzalez
Senior Regulatory Affairs Specialist
Stryker Corporation
2 Pearl Court
Allendale, New Jersey 07401

Re: K161447
Trade/Device Name: HydroSet XT
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, FMF
Dated: September 1, 2016
Received: September 2, 2016

Dear Ms. Gonzalez:

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,

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)*
K161447

Device Name
HydroSet XT

Indications for Use *(Describe)*
The Hydroset XT Mixing and Delivery System is intended to be used for the delivery of Hydroset XT to an orthopedic surgical site.

HydroSet XT is a self-setting calcium phosphate cement indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, craniofacial, posterolateral spine, and pelvis). These defects may be surgically created or osseous defects created from traumatic injury to the bone. HydroSet XT is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.

HydroSet XT cured in-situ provides an open void/gap filler that can augment provisional hardware (e.g. k-wires, plates, screws) to help support bone fragments during the surgical procedure. The cured cement acts only as a temporary support medium and is not intended to provide structural support 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.***

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*"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: HydroSet XT (K161447) | |
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| Submitter: | Orthovita, Inc.<br>45 Great Valley Parkway<br>Malvern, PA 19355 |
| Contact Person | Lia Gonzalez<br>Sr. Regulatory Affairs Specialist<br>Stryker Spine<br>2 Pearl Court<br>Allendale, NJ 07401<br>Phone: 201-749-8699<br>E-mail: lia.gonzalez@stryker.com |
| Date Prepared | September 1, 2016 |
| Trade Name | HydroSet XT |
| Common Name | Resorbable calcium salt bone void filler device<br><br>Piston syringe |
| Proposed Class | Class II |
| Classification Name and Number | Filler, Bone Void, Calcium Compound<br>21 CFR §888.3045<br><br>Syringe, Piston<br>21 CFR §880.5860 |
| Product Code | MQV, FMF |
| Predicate Devices | **Predicate Device:**<br>Stryker Injectable Cement (K060061)<br>ETEX MIXING AND DELIVERY SYSTEM (K141245) |
| Device Description | HydroSet XT is a self-setting calcium phosphate cement. The device includes a pre-filled liquid syringe and a pre-filled powder syringe utilized for mixing and delivery of the cement. The device also includes the necessary components to prepare and deliver the cement (syringe cap, luer adapter, luer cap, threaded plunger, and cannula). After preparation, the cement may be delivered by traditional plunger advancement or by rotating the threaded plunger to deliver the cement. |
| Indications for Use | The Hydroset XT Mixing and Delivery System is intended to be used for the delivery of Hydroset XT to an orthopedic surgical site.<br><br>HydroSet XT is a self-setting calcium phosphate cement indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, craniofacial, posterolateral spine, and pelvis). These defects may be surgically created or osseous defects created from traumatic injury to the bone. HydroSet XT is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.<br><br>HydroSet XT cured in-situ provides an open void/gap filler that can augment provisional hardware (e.g. k-wires, plates, screws) to help support bone fragments during the surgical procedure. The cured cement acts only as a temporary support medium and is not intended to provide structural support during the healing process. |
| Summary of the Technological Characteristics | The subject device and the predicate device have similar technological characteristics as the mixed powder and liquid components are identical and combine chemically in identical fashion. Both devices are provided sterile and for single use only. Any differences in mixing method do not raise new questions of safety or effectiveness. |
| Summary of Non-Clinical Performance Testing | Performance testing was completed for HydroSet XT to determine its suitability for use. The following tests were performed to evaluate the performance of HydroSetXT:<br>• Working Time (Injectability and Torque) |

| 510(k) Summary: HydroSet XT (K161447) | |
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| | • Compression<br>• Setting Time (Wet Field Penetration Resistance)<br><br>Bacterial endotoxin testing (BET) as specified in USP 39 <85>, Ph. Eur. 8.0 2.6.14 is used for pyrogenicity testing to achieve the Endotoxin limit of < 20EU/Device. Based on an endotoxin limit of 20 EU/Device and an extraction volume of 40 ml the Maximum Valid Dilution (MVD) will be a 1:50 dilution. |
| Conclusions | Based upon a comparison of intended use, technological characteristics and device performance in the non-clinical tested listed above, HydroSet XT has demonstrated substantial equivalence to its predicate device. |