



September 1, 2023

Orthocon, Inc.  
Howard Schrayer  
Consultant  
8 Lookout  
Hilton Head Island, South Carolina 29928

Re: K231270

Trade/Device Name: Montage Flowable Settable, Resorbable Bone Paste  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device  
Regulatory Class: Class II  
Product Code: MQV, OIS  
Dated: August 3, 2023  
Received: August 3, 2023

Dear Howard Schrayer:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Jesse Muir -S**

Jesse Muir, Ph.D.

Assistant Director

DHT6C: Division of Restorative, Repair  
and Trauma Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K231270

Device Name

Montage Flowable Settable, Resorbable Bone Paste

Indications for Use (Describe)

Orthocon MONTAGE Flowable Settable, Resorbable Bone Paste is indicated to fill bony voids or gaps in the skeletal system (i.e., extremities and pelvis). These defects may be surgically created or osseous defects created as the result of traumatic injury to the bone. Montage Flowable is indicated only for filling bony voids or gaps that are not intrinsic to the integrity of the bony structure.

When hardened in situ, Montage Flowable may be used to augment provisional hardware (e.g., k-wires, plates and screws) and to help support bone fragments during the surgical procedure. The hardened paste acts only as a temporary support medium and is not intended to provide structural support during the healing process.

Montage Flowable can be drilled and tapped, and hardware can be placed through it at any time during the setting 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****General Company Information**

Name: Orthocon, Inc.  
Contact: Howard Schrayer  
Regulatory Affairs Consultant

Address: 700 Fairfield Avenue – Suite 1  
Stamford, CT 06902

Telephone: (609) 273 - 7350

**Date Prepared** July 11, 2023

**General Device Information**

Product Name: Montage Flowable Settable, Resorbable Bone Paste

Common Name: Resorbable calcium salt bone void filler device

Classification: Class II  
Product code: MQV, OIS  
Regulation: 21 CFR 888.3045

**Predicate Devices****Primary Predicate:**

Orthovita, Inc. HydroSet XT™  
[510(k) Number K161447]

**Reference Device:**

Orthocon, Inc. HBP6, Resorbable Hemostatic Bone Paste  
[510(k) Number K193052]

Orthocon, Inc. Montage-QS Settable, Resorbable Bone Putty  
[510(k) Number K191140]

## **Description**

Montage Flowable Settable, Resorbable Bone Paste is a sterile, biocompatible, resorbable material for use in filling bony voids or gaps in skeletal bones of the extremities. The Montage Flowable device comprises two separate components of paste-like consistency containing granular calcium phosphate, calcium stearate, vitamin E acetate, a triglyceride, polyalcohols and a mixture of a lactide-diester and polyester-based polymers. When mixed together in the applicator tip, the components of the Montage Flowable device form a cohesive paste-like material that adheres to the bone surface and remains in place following application. The resulting hardened, resorbable material is primarily calcium phosphate and is slowly resorbed and replaced with bone during the remodeling process. Montage Flowable can be drilled and tapped, and hardware can be placed through it at any time during the setting process. The performance of Montage Flowable was compared to HydroSet in a rabbit critical sized femoral defect model. At the 12-week timepoint, animal study data demonstrated new bone formation averages of 15.8% in the Montage Flowable group, 12.4% in the HydroSet predicate group, and 10% in the empty defect negative control group. Animal study data suggest that approximately 75% of implant material remained in both the Montage Flowable group and the HydroSet group at 12 weeks following implantation.

## **Intended Use (Indications)**

Orthocon MONTAGE Flowable Settable, Resorbable Bone Paste is indicated to fill bony voids or gaps in the skeletal system (i.e., extremities and pelvis). These defects may be surgically created or osseous defects created as the result of traumatic injury to the bone. Montage Flowable is indicated only for filling bony voids or gaps that are not intrinsic to the integrity of the bony structure.

When hardened in situ, Montage Flowable may be used to augment provisional hardware (e.g., k-wires, plates and screws) and to help support bone fragments during the surgical procedure. The hardened paste acts only as a temporary support medium and is not intended to provide structural support during the healing process.

Montage Flowable can be drilled and tapped, and hardware can be placed through it at any time during the setting process.

## **Purpose of Submission**

Orthocon is proposing to modify the labeling (Instructions for Use) to provide for use of Montage Flowable as a bone void filler that can be used to augment provisional hardware (e.g., k-wires, plates and screws) and to help support bone fragments during the surgical procedure.

**Substantial Equivalence**

This submission supports the position that Orthocon Montage Flowable Settable, Resorbable Bone Paste is substantially equivalent to the HydroSet XT primary predicate 510(k) - K161447.

The following table shows comparisons of the several characteristics of Montage Flowable Settable, Resorbable Bone Paste and the primary predicate device. The differences noted in the table below do not impact substantial equivalence.

**SUBSTANTIAL EQUIVALENCE INFORMATION**

**Orthocon, Inc.**  
**Montage Flowable Settable,**  
**Resorbable Bone Paste**

**Orthovita / Stryker**  
**HydroSet XT™**  
**Bone Void Filler**

**TBD**

**510(k) - K161447**

**Similarities and Differences**

Device is indicated for use as a bone graft substitute to fill voids in damaged bone that are not intrinsic to the stability of the bony structure.	Device is indicated for use as a bone graft substitute to fill voids in damaged bone that are not intrinsic to the stability of the bony structure.
Hardened device can be drilled and tapped to provide temporary support for the placement of provisional hardware during the surgical procedure.	Hardened device can provide temporary support for the placement of provisional hardware during the surgical procedure.
At the time of application, device is in the form of a paste-like material	At the time of application, device is in the form of a paste-like material
Device is designed to be manually applied or injected with a syringe and spread onto voids in bone tissue	Device is designed to be manually applied or injected with a syringe and spread onto voids in bone tissue
Montage Flowable Settable, Resorbable Bone Paste is formulated as a two-part paste/paste device that forms a “settable” (hardening) material when mixed at the time of surgery	HydroSet XT settable, resorbable bone void filler device is formulated as a two-part powder/liquid device that forms a “settable” (hardening) material when manually mixed at the time of surgery
Sterile mixture of two separate components of paste-like consistency comprised of granular calcium phosphate, (hydroxyapatite and β-tricalcium phosphate), calcium stearate, vitamin E acetate, a triglyceride, polyalcohols and a mixture of a lactide-	Sterile mixture of two separate components, a powder comprised of dicalcium phosphate dihydrate, tetracalcium phosphate and tri-sodium citrate; and a liquid comprised of sodium phosphate, polyvinylpyrrolidone and water. HydroSet XT is to be

diester and polyester-based polymers. Montage Flowable is mixed in a static mixing tip immediately prior to use. Resulting settable material from the two pastes is primarily comprised of calcium phosphate similar to the mineral phase of native bone tissue.	manually mixed immediately prior to use. Resulting settable material from the two components is primarily comprised of calcium phosphate similar to the mineral phase of native bone tissue.
Implanted device is resorbable in greater than 30 days primarily due to presence of calcium phosphate.	Implanted device is resorbable in greater than 30 days primarily due to presence of calcium phosphate.
The non-calcium salt and non-polymeric components degrade via dissolution; the polymer degrades via hydrolysis and calcium salts degrade via chemical dissolution and/or cellular removal	The non-calcium salt components degrade via dissolution and calcium salts degrade via chemical dissolution and/or cellular removal
Single-patient-use device is provided sterile by gamma irradiation	Single-patient-use device is provided sterile by gamma irradiation and ethylene oxide
The device is available for single-patient use with a single-use applicator.	The device is available for single-patient use with a single-use applicator.
The past is provided in a dual-barrel cartridge within a single outer foil pouch. The outer foil pouch contains a desiccant. The pouch is heat sealed and sterilized.	Each kit contains one liquid-filled glass syringe and one plastic bowl of powder packaged within a double pre-formed tray with a Tyvek lid.
Mixing for homogeneity is immediate.	Mixing for homogeneity takes 45 sec.
Material is settable within 10 minutes of application	Material is settable within 10 minutes of application
Device cures with no appreciable exothermic reaction.	Device cures with no appreciable exothermic reaction

## Testing Completed

### Performance Animal Testing

The performance of Montage Flowable was compared to HydroSet in a rabbit critical sized femoral defect model. Micro-CT and histopathology/histomorphometry assessments were performed on defects treated with each material to quantify device resorption and new bone formation. At the 12-week timepoint, animal study data demonstrated new bone formation averages of 15.8% in the Montage Flowable group, 12.4% in the HydroSet predicate group, and 10% in the empty defect negative control group. Clinical performance has not been evaluated.

## **Performance Data**

Testing was conducted to verify that the device may be drilled when hardened without fragmenting or being displaced. This allows use in conjunction with provisional hardware. In addition, an in vitro study was conducted to demonstrate that once placed as indicated, the device provides temporary support to a complex repair until permanent hardware fixation is accomplished.

## **Biocompatibility Testing**

Testing was conducted to evaluate the device's biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted on the final, finished, gamma-irradiation sterilized device and in accordance with the GLP requirements: cytotoxicity, irritation, sensitization, systemic toxicity, genotoxicity, local tissue toxicity, hemolysis, endotoxicity and pyrogenicity.

## **Sterility**

The gamma sterilization process has been validated to provide a SAL of  $10^{-6}$ . Each lot of finished devices is tested for bacterial endotoxin for lot release.

## **Conclusions**

The information provided establishes that the Orthocon Montage Flowable Settable, Resorbable Bone Paste performs substantially equivalent to the HydroSet predicate device for the same intended use. All results demonstrate that any differences in technology do not impact substantial equivalence.