February 3, 2023

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

Re: K222063
Trade/Device Name: MONTAGE Settable, Resorbable Bone Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, OIS
Dated: July 1, 2022
Received: July 13, 2022

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sara S. Thompson -S

For

Laura C. Rose, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222063

Device Name

MONTAGE Settable, Resorbable Bone Putty

Indications for Use *(Describe)*

Orthocon MONTAGE Settable, Resorbable Bone Putty 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 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 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 putty acts only as a temporary support medium and is not intended to provide structural support during the healing process.

MONTAGE 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.

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

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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 February 3, 2023

General Device Information

Product Name:	MONTAGE™ Settable, Resorbable Bone Putty
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 Devices:

Orthocon, Inc.	MONTAGE Settable, Resorbable Hemostatic Bone Putty [510(k) Number K152005]

Description

MONTAGE Settable, Resorbable Bone Putty is a sterile, biocompatible, resorbable material for use in filling bony voids or gaps in skeletal bones of the extremities. The MONTAGE device comprises two separate components of putty-like consistency containing granular calcium phosphate, calcium stearate, vitamin E acetate, a triglyceride, a polyalcohol and a mixture of a lactide-diester and polyester-based polymers. When mixed together, the components of the MONTAGE device form a cohesive putty-like material that adheres to the bone surface and remains in place following application. The resulting hardened material is primarily calcium phosphate. MONTAGE components must be mixed immediately prior to use. MONTAGE can be drilled and tapped, and hardware can be placed through it at any time during the setting process. The performance of MONTAGE 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 16.1% in the MONTAGE group, 12.4% in the HydroSet predicate group, and 10% in the empty defect negative control group. Animal study data demonstrated that approximately 70% of implant material remained in both the MONTAGE group and the predicate group at 52 weeks following implantation.

Intended Use (Indications)

Orthocon MONTAGE Settable, Resorbable Bone Putty 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 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 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 putty acts only as a temporary support medium and is not intended to provide structural support during the healing process.

MONTAGE 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 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 Settable, Resorbable Bone Putty is substantially equivalent to the HydroSet XT primary predicate 510(k) - K161447.

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

SUBSTANTIAL EQUIVALENCE INFORMATION

Orthocon, Inc. MONTAGE Settable, Resorbable Bone Putty	**Orthovita, Inc. HydroSet XT™ Bone Void Filler**
510(k) K222063	**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 putty-like material	At the time of application, device is in the form of a paste-like material
Device is designed to be manually applied 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 Settable, Resorbable Bone Putty is formulated as a two-part putty/putty device that forms a “settable” (hardening) material when manually 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 putty-like consistency comprised of granular calcium phosphate, (hydroxyapatite and β-tricalcium phosphate), calcium stearate, vitamin E acetate, triacetin, 1,4-butanediol and a mixture of a lactide-diester and polyester-based (lactide and caprolactone) absorbable polymers. MONTAGE is to be mixed immediately prior to use. Resulting settable material from the two putties is primarily comprised of calcium phosphate similar to the mineral phase of native bone tissue.	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 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 in individual and/or multi-pack patient use sizes.	The device is available in individual; and/or multi-pack patient use sizes.
Each putty is placed into a separate inner foil “blister” which are contained within a single outer foil pouch. The outer foil pouch contains a desiccant. The inner blister and outer 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 takes 45 sec.	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 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 16.1% in the MONTAGE group, 12.4% in the HydroSet predicate group, and 10% in the empty defect negative control group. Animal study data demonstrated approximately 70% of implant material remaining in both the MONTAGE group and the predicate group at 52 weeks following implantation. 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.

The biocompatibility testing was supplemented by an assessment of the potential impact of the Vitamin E acetate content of MONTAGE. This assessment included an evaluation by CDER and concluded that labeling should include a Caution statement regarding the need to monitor patients taking Vitamin E supplements who may be at risk for bleeding.

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 Settable, Resorbable Bone Putty performs substantially equivalent to the predicate device for the same intended use. All results demonstrate that any differences in technology do not impact substantial equivalence.