August 21, 2024

Orthocon, Inc.
Howard Schrayer
Regulatory Consultant
700 Fairfield Ave. - Suite 1
Stamford, Connecticut 06902

Re: K233566
Trade/Device Name: Montage-XT 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 3, 2024
Received: July 3, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2024.08.21 10:28:43 -04'00'

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

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.

Submission Number *(if known)*

K233566

Device Name

Montage-XT Settable, Resorbable Bone Putty

Indications for Use *(Describe)*

Orthocon Montage-XT 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-XT 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-XT 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-XT 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.

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
PRAStaff@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 K233566

Contact: Howard Schrayer
Orthocon, Inc.
8 Lookout
Hilton Head Island, SC 29928
Telephone: 609-273-7350
hs.ss@lucidmedical.net

Date Prepared: August 20, 2024

Device Trade Name: MONTAGE-XT™ Settable, Resorbable Bone Putty

Manufacturer: Orthocon, Inc.
700 Fairfield Avenue, Suite 1
Stamford, CT 10533

Telephone: (855) 475 - 9175

Common Name: Resorbable calcium salt bone void filler device

Classification: Class II

Product Code: MQV, OIS

Primary Predicate Device:

Orthocon, Inc.	MONTAGE® Settable, Resorbable Bone Putty 510(k) K222063

Reference Predicate Device:

Orthocon, Inc.	MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty 510(k) K220315

Indications for Use:

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

Device Description:

Montage-XT 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 single use Montage-XT device contains 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 Montage-XT 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-XT can be drilled and tapped, and hardware can be placed through it at any time during the setting process.

Montage-XT differs from Montage by allowing for an extended working time of up to 4 minutes. The performance of Montage-XT was compared to Montage in a rabbit critical sized femoral defect model. At the 12-week timepoint, animal study data demonstrated new bone formation averages of 20.4% in the Montage-XT group, 20.8% in the Montage predicate group, and less than 10% in the empty defect negative control group. Animal study data show that approximately 70% of implant material remained in both the Montage-XT group and the Montage group at 12 weeks following implantation.

Purpose of this Submission:

Montage-XT was previously cleared for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The purpose of this submission is to add an indication for Montage-XT for use as a bone void filler device.

Substantial Equivalence and Predicate Devices:

The subject device is nearly identical to and is substantially equivalent to its previously cleared primary predicate, Montage. The only difference between the subject device and its reference predicate is the addition of a statement regarding the use of the device as a bone void filler.

The following table shows comparisons of the several characteristics of Montage-XT and the primary predicate device. The differences noted in the table below do not impact substantial equivalence.

SUBSTANTIAL EQUIVALENCE INFORMATION

Orthocon, Inc. Montage-XT Settable, Resorbable Bone Putty 510(k) - 233566	**Orthocon, Inc. Montage Settable, Resorbable Bone Putty 510(k) - K222063**

Similarities and Differences

Orthocon Montage-XT 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-XT 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-XT 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-XT can be drilled and tapped, and hardware can be placed through it at any time during the setting process.	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.
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 putty-like material
Device is designed to be manually applied and spread onto bone defects	Device is designed to be manually applied and spread onto bone defects

Montage-XT Settable, Resorbable Bone Putty is formulated as a two-part putty/putty device that forms a "settable" (hardening) material when mixed at the time of surgery	Montage-XT Settable, Bone Putty is formulated as a two-part putty/putty device that forms a "settable" (hardening) material when 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, a triglyceride, a polyalcohol and a mixture of a lactide-diester and polyester-based (lactide and caprolactone) absorbable polymers. Montage-XT 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 of putty-like consistency comprised of granular calcium phosphate, (hydroxyapatite and β-tricalcium phosphate), calcium stearate, vitamin E acetate, a triglyceride, a polyalcohol 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.
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 and non-polymeric components degrade via dissolution; the polymer degrades via hydrolysis 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
The two putties are provided separately within a single outer foil pouch. The outer foil pouch contains a desiccant.	The two putties are provided separately within a single outer foil pouch. The outer foil pouch contains a desiccant.
Mixing for homogeneity takes 45 sec.	Mixing for homogeneity takes 45 sec.
Working time is 4 minutes	Working time is 2 minutes

Device cures with no appreciable exothermic reaction.	Device cures with no appreciable exothermic reaction
Device can be drilled and tapped, and hardware can be placed through it at any time during the setting process.	Device can be drilled and tapped, and hardware can be placed through it at any time during the setting process.
When hardened in situ, Montage-XT 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.	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.

Technological Characteristics:

The technological characteristics of the devices are unchanged. The only change is the addition of a statement regarding the use of Montage-XT in as a bone void filler.

Performance Testing:

The only clinically meaningful difference between Montage and Montage-XT is the extension of working time from 2 to 4 minutes. Evaluations were previously conducted to compare MONTAGE-XT Settable, Resorbable Bone Putty with the predicate device. The evaluations demonstrated that Montage-XT is substantially equivalent to the Montage predicate in intended use, technological characteristics, and performance. This testing included the following:

Bench Testing was conducted to verify the device's handling properties, to characterize the device's performance. The following bench studies were completed: pH characterization, dissolution/solubility, reaction temperature, relative stiffness, spreadability, stickiness, temperature sensitivity, electrocautery compatibility and working time. Both devices are sterilized with the same validated gamma irradiation process and both have the same established shelf-life / stability characteristics.

Biocompatibility Testing was conducted to evaluate biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted in accordance with the GLP requirements: irritation, sensitization, acute systemic toxicity, genotoxicity, implantation, systemic toxicity, hemolysis, endotoxicity and pyrogenicity.

Animal Testing included animal studies to quantify device resorption and new bone formation of Montage and Montage-XT in a rabbit critical sized femoral defect model. Because the devices have nearly identical formulations and have been found to be substantially equivalent in all other respects, the data supporting use as a bone void filler from studies of Montage is relevant to Montage-XT and was confirmed through testing of Montage-XT. Clinical performance has not been evaluated.

Conclusion

MONTAGE-XT is substantially equivalent to Montage Settable, Resorbable Bone Putty with respect to intended use, general technological characteristics, and performance.