December 5, 2024

Orthocon Inc.
% Mehdi Kazemzadeh-Narbat
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW, Floor 3
Washington, District of Columbia 20001

Re: K243526
Trade/Device Name: MONTAGE Settable, Resorbable Bone Putty
MONTAGE-QS Settable, Resorbable Bone Putty
MONTAGE Flowable Settable, Resorbable Bone Paste
MONTAGE-XT Settable, Resorbable Hemostatic 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: November 12, 2024
Received: November 14, 2024

Dear Dr. Kazemzadeh-Narbat:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Robert M. Stefani -S
2024.12.05 11:21:38 -05'00'

For: 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243526

Device Name

MONTAGE Settable, Resorbable Bone Putty
MONTAGE-QS Settable, Resorbable Bone Putty
MONTAGE Flowable Settable, Resorbable Bone Paste
MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty

Indications for Use *(Describe)*

MONTAGE Settable, Resorbable Bone Putty:
Orthocon MONTAGE Settable, Resorbable Bone Putty is indicated to fill bony voids or gaps in the skeletal system (i.e., extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or 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., kwires, 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.

MONTAGE-QS Settable, Resorbable Bone Putty:
Orthocon Montage-QS Settable, Resorbable Bone Putty is indicated to fill bony voids or gaps in the skeletal system (i.e., extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of traumatic injury to the bone. Montage-QS 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-QS 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-QS can be drilled and tapped, and hardware can be placed through it at any time during the setting process.

MONTAGE Flowable Settable, Resorbable Bone Paste:
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 osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or 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.

MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty:
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 osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or 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

Manufacturer: Orthocon, Inc.
700 Fairfield Avenue, Suite 1
Stamford, CT 06902
Phone: 855.475.9175

Contact: Mehdi Kazemzadeh-Narbat
Director, Regulatory Affairs
803 7th Street NW, Floor 3
Washington, DC 20001
Office: 202.552.6011
Email: mkazemzadeh@mcra.com

Prepared By: MCRA LLC
Mehdi Kazemzadeh-Narbat
Director, Regulatory Affairs
803 7th Street NW, Floor 3
Washington, DC 20001
Office: 202.552.6011
Email: mkazemzadeh@mcra.com

Date Prepared: November 27th, 2024

Device Trade Name:

MONTAGE Settable, Resorbable Bone Putty

MONTAGE-QS Settable, Resorbable Bone Putty

MONTAGE Flowable Settable, Resorbable Bone Paste

MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty

Device Common Name: Resorbable calcium salt bone void filler device

Classification: 21 CFR 888.3045

Class II

Product Codes: MQV, OIS

Indications for Use:

"Orthocon MONTAGE Settable, Resorbable Bone Putty is indicated to fill bony voids or gaps in the skeletal system (i.e. extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or 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., kwires, 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."

"Orthocon Montage-QS Settable, Resorbable Bone Putty is indicated to fill bony voids or gaps in the skeletal system (i.e., extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of traumatic injury to the bone. Montage-QS 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-QS 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-QS can be drilled and tapped, and hardware can be placed through it at any time during the setting process."

"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 osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or 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."

"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 osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or 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."

Primary Predicate Device:

PRO-DENSE® Bone Graft Substitute (K113871)

Additional Predicate Device:

Bonalive Orthopedics granules (K231528)

Reference Devices:

MONTAGE Settable, Resorbable Bone Putty (K222063)
MONTAGE-QS Settable, Resorbable Bone Putty (K231903)
MONTAGE Flowable Settable, Resorbable Bone Paste (K231270)
MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty (K233566)

Device Description:
The devices are sterile, biocompatible, resorbable material for use in filling bony voids or gaps in skeletal bones of the extremities. Each device comprises two separate components of putty-like

consistency containing granular calcium phosphate, calcium stearate, vitamin E acetate, a triglyceride, polyalcohol(s) and a mixture of a lactide-diester and polyester-based polymers. When mixed together, the components of each device form a cohesive material that adheres to the bone surface and remains in place following application. The resulting hardened material is primarily calcium phosphate. The 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.

Purpose of this Submission:
The purpose of this Special 510(k) is to expand the indications for use statement (IFUS) of the K222063, K231903, K231270, and K233566 to include the statement "benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old)" to the current IFUS. Besides the addition of this statement, there is no other change to the devices.

Substantial Equivalence and Predicate Devices:
The subject device is similar to the primary predicate and additional predicate bone void filler devices in terms of expanded indications for use statement, intended use, and forms and is identical to its reference devices in terms of materials, manufacturing process, sterilization, and packaging process. Any difference between the subject device and the predicate and reference devices have been addressed through risk assessment, and no new verification testing was required to mitigate the potential risks. All the pre-clinical, and clinical testing conducted to support the previous 510(k) clearances are applicable to the subject device.

Conclusion:

Montage Settable, Resorbable Bone Putty, Montage-QS Settable, Resorbable Bone Putty, Montage-XT Settable, Resorbable Bone Putty, and Montage Flowable Settable, Resorbable Bone Paste are substantially equivalent to its predicates with respect to intended use, technological characteristics, and performance.