November 18, 2024

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

Re: K243506
Trade/Device Name: Montage-XT Settable Bone Putty
Regulatory Class: Unclassified
Product Code: MTJ, MQV, OIS
Dated: November 11, 2024
Received: November 12, 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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2024.11.18 15:54:55 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243506

Device Name

Montage-XT Settable Bone Putty

Indications for Use *(Describe)*

Montage-XT Settable Bone Putty is indicated for use on the sternum in cardiothoracic surgery following sternotomy to control bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade, as well as to fill bony voids or gaps in the sternum. When hardened in situ, Montage-XT may be used on the sternum to augment hardware to help support bone during the cardiothoracic surgical procedure.

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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510(k) Summary

Manufacturer: Orthocon, Inc.
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Prepared By: MCRA LLC
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Date Prepared: November 11, 2024

Device Trade Name: Montage-XT Settable Bone Putty

Device Common Name: Resorbable calcium salt bone void filler device

Classification: 21 CFR 888.3045

Class II

Product Codes: MQV, OIS, MTJ

Indications for Use:
Montage-XT Settable Bone Putty is indicated for use on the sternum in cardiothoracic surgery following sternotomy to control bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade, as well as to fill bony voids or gaps in the sternum. When hardened in situ, Montage-XT may be used on the sternum to augment hardware to help support bone during the cardiothoracic surgical procedure.

Primary Predicate Device:

Orthocon, Inc. MONTAGE Settable Bone Putty 510(k) K242050

Additional Predicate Devices:

Orthocon, Inc. MONTAGE-XT Settable, Resorbable Bone Putty 510(k) K233566

Orthocon, Inc. MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty 510(k) K232998

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

Device Description:

MONTAGE-XT Settable Bone Putty is a sterile, biocompatible, resorbable material for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy and filling bony voids or gaps in the sternum. The MONTAGE-XT 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-XT 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-XT components must be mixed immediately prior to use. The device serves multiple clinical functions simultaneously that are integral to recovery after cardiac surgery.

Purpose of this Submission:

The purpose of this Special 510(k) is to consolidate the Montage-XT Settable Bone Putty's indications for use (i.e., hemostasis, augmentation of cerclage wire stabilization/closure, and bone void filler) into a single indications for use statement (IFUS).

Substantial Equivalence and Predicate Devices:
The subject device is identical to its predicates in terms of materials, manufacturing process, sterilization, and packaging process. There is no difference between the subject device and the predicates. All the pre-clinical, and clinical testing conducted to support the previous 510(k) clearances are applicable to the subject device. The only modification proposed in this Special 510(k) is the consolidation of Indications for Use of previous 510(k) clearances.

Conclusion:

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