October 12, 2023

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

Re: K232998
Trade/Device Name: Montage- XT Settable, Resorbable Hemostatic Bone Putty
Regulatory Class: Unclassified
Product Code: MTJ
Dated: September 22, 2023
Received: September 22, 2023

Dear Mr. 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,

Sara S. Thompson -S

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232998

Device Name

Montage- XT Settable, Resorbable Hemostatic Bone Putty

Indications for Use *(Describe)*

Montage-XT Settable, Resorbable Hemostatic Bone Putty is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries. Montage-XT is also indicated for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.

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

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

Date Prepared: October 12, 2023

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

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

Telephone: (855) 475 - 9175

Common Name: Calcium phosphate bone hemostasis material

Classification: Unclassified

Product Code: MTJ

Primary Predicate Device:

Orthocon, Inc.	MONTAGE Settable, Resorbable Hemostatic Bone Putty 510(k) K213418

Reference Predicate Device:

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

Indications for Use:

Montage-XT Settable, Resorbable Hemostatic Bone Putty is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries. Montage-XT is also indicated for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.

Device Description:

MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty is a sterile, biocompatible, resorbable material of putty-like consistency for use in the control of bleeding from bone surfaces. The single use MONTAGE-XT device contains two separate components of putty-like consistency comprised of 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 resorbable putty-like material that can be applied directly to bleeding bone. The resulting hardening material is primarily comprised of calcium phosphate. MONTAGE-XT must be mixed immediately prior to use.

When applied to surgically cut or traumatically broken bone, MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty achieves local control of bleeding by acting as a mechanical barrier (tamponade).

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 in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.

Substantial Equivalence and Predicate Devices:

The subject device is nearly identical to and is substantially equivalent to its previously cleared predicate, Montage. The only difference between the subject device and its predicate is the addition of a statement regarding the use of the device in sternotomy procedures.

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 Hemostatic Bone Putty 510(k) - K232998	**Orthocon, Inc. Montage Settable, Resorbable Hemostatic Bone Putty 510(k) - K213418**

Similarities and Differences

Montage-XT Settable, Resorbable Hemostatic Bone Putty is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries. Montage-XT is also indicated for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.	Montage Settable, Resorbable Hemostatic Bone Putty is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries. Montage-XT is also indicated for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.
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 bleeding bone tissue	Device is designed to be manually applied and spread onto bleeding bone tissue
Montage-XT Settable, Resorbable Hemostatic 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, Resorbable Hemostatic 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	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 (~70% by weight) of calcium phosphate similar to the mineral phase of native bone tissue.	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 (~70% by weight) 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

Technological Characteristics:

The technological characteristics of the devices are unchanged. The only change is the addition of a statement regarding the use of the devices in sternotomy procedures.

Performance Testing:

Evaluations were previously conducted to compare MONTAGE-XT Settable, Resorbable Hemostatic 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: 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 demonstrate intraoperative *in vivo* hemostasis and resistance to irrigation.

Clinical Testing

A human clinical evaluation was conducted that supports the use of Montage during sternotomy procedures. The only clinically meaningful difference between Montage and Montage-XT is the extension of working time from 2 to 4 minutes. Because the devices have nearly identical formulations and have been found to be substantially equivalent in all other respects, the clinical data obtained from a sternotomy study is relevant to Montage-XT.

Conclusion

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