March 11, 2022

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

Re: K220315
Trade/Device Name: MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty
Regulatory Class: Unclassified
Product Code: MTJ
Dated: February 2, 2022
Received: February 3, 2022

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 (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,

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

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)*
K220315

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.

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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Exhibit E - 510(k) Summary
510(k) K220315

Contact: Howard Schrayer
Orthocon, Inc.
1 Bridge Street, Suite 121
Irvington, NY 10533
Telephone: 914-357-2600
Fax: 914-231-7884
hs.ss@verizon.net

Date Prepared: March 8, 2022

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

Manufacturer: Orthocon, Inc.
1 Bridge Street, Suite 121
Irvington, NY 10533

Common Name: Calcium phosphate bone hemostasis material

Classification: Unclassified

Product Code: MTJ

Predicate Device:

Orthocon, Inc. MONTAGE Settable, Resorbable Hemostatic Bone Putty
510(k) K141502 and K152005

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.

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).

Substantial Equivalence and Predicate Devices:

The purpose of this submission is to obtain clearance for a version of the device with extended working time. MONTAGE-XT was shown to be substantially equivalent to previously cleared bone hemostasis devices including Montage, Resorbable Hemostatic Bone Putty (K141502 and K152005).

The table below provides a comparison of MONTAGE-XT and the predicate Montage device.

Predicate Comparison Table

Manufacturer	Orthocon, Inc.	Orthocon, Inc.
Trade Name	MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty	MONTAGE Settable, Resorbable Hemostatic Bone Putty
510(k) Number	Subject Device	K141502 and K152005
Product Code	MTJ	MTJ
Indications for Use	MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty is indicated in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade	MONTAGE Settable, Resorbable Hemostatic Bone Putty is indicated in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade
Intended Use	Bone hemostasis	Bone hemostasis
Mechanism of Action	Mechanical tamponade that occludes vascular openings in damaged bone	Mechanical tamponade that occludes vascular openings in damaged bone
Form of Device	MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty is formulated as a two-part putty/putty device that forms a “settable” (hardening) putty when manually mixed at the time of surgery.	MONTAGE Settable, Resorbable Hemostatic Bone Putty is formulated as a two-part putty/putty device that forms a “settable” (hardening) putty when manually mixed at the time of surgery.

Radiopacity	Radiopaque – Contains hydroxyapatite and β-tricalcium phosphate	Radiopaque – Contains hydroxyapatite and β-tricalcium phosphate
Materials	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 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.	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 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.
Resorbable	Yes	Yes

Resorption Time	Greater than 30 days primarily due to presence of calcium phosphate.	Greater than 30 days primarily due to presence of calcium phosphate
Method of Application	Manually applied and spread onto bone tissue	Manually applied and spread onto bone tissue
Degradation Process	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
Sterility	Provided sterile for single use by gamma irradiation	Provided sterile for single use by gamma irradiation
Settability	Sets following application	Sets following application
Working Time	Working time up to 4 minutes	Working time up to 2 minutes

Performance Testing:

Evaluations performed to compare MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty with the predicate device demonstrate that the device is substantially equivalent to predicate devices 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.

Biocompatibility Testing was conducted on a representative device 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.

Conclusion

MONTAGE-XT is substantially equivalent to previously cleared bone hemostasis devices with respect to intended use, general technological characteristics and performance.