July 11, 2023

Orthocon, Inc.
% Howard Schrayer
Consultant
Orthocon, Inc
700 Fairfield Ave – Suite 1
Stamford, CT 06902

Re: K231386
Trade/Device Name: Montage XRO Settable, Resorbable Hemostatic Bone Paste
Regulatory Class: Unclassified
Product Code: MTJ
Dated: May 12, 2023
Received: May 12, 2023

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 (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,

Jesse Muir -S

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.

510(k) Number *(if known)*
K231386

Device Name
Montage Flowable XRO Settable, Resorbable Hemostatic Bone Paste

Indications for Use *(Describe)*
Montage Flowable XRO Settable, Resorbable Hemostatic Bone Paste 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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510(k) Summary

Contact:
Howard Schrayer
Orthocon, Inc.
700 Fairfield Avenue - Suite 1
Stamford, CT 06902 USA
Telephone: 609-273-7350
hs.ss@lucidmedical.net

Date Prepared: May 12, 2023

Device Trade Name: Montage Flowable XRO Settable, Resorbable Hemostatic Bone Paste

Manufacturer:
Orthocon, Inc.
700 Fairfield Avenue - Suite 1
Stamford, CT 06902 USA

Common Name: Calcium phosphate bone hemostasis material

Classification: Unclassified

Product Code: MTJ

Predicate Devices:
Primary Predicate:

Orthocon, Inc.
HBP6 Settable, Resorbable Hemostatic Bone Putty
510(k) K193052

Reference Device:

Synthes, Inc.
Norian® XR (Extra Radiopaque) Calcium Phosphate Bone Void Filler
510(k) K023862

Indications for Use:

Montage Flowable XRO Settable, Resorbable Hemostatic Bone Paste is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.

Device Description:

Montage Flowable XRO Settable, Resorbable Hemostatic Bone Paste is a sterile, biocompatible, resorbable material for use in the control of bleeding from bone surfaces. The single use device contains two separate components of paste-like consistency comprised of granular calcium phosphate, calcium stearate, vitamin E acetate, a triglyceride, polyalcohols, a mixture of a lactide-diester and polyester-based polymers and barium sulfate. When mixed together, the components of the device form a resorbable paste-like material that can be applied directly to bleeding bone by means of a single-use applicator (delivery device). The resulting hardening paste is primarily comprised of calcium phosphate. Montage Flowable XRO is mixed immediately prior to use.

When applied to surgically cut or traumatically broken bone, Montage Flowable XRO Settable, Resorbable Hemostatic Bone Paste achieves local control of bleeding by acting as a mechanical barrier (tamponade).

Substantial Equivalence and Predicate Devices:

The device was shown to be substantially equivalent to the previously cleared, predicate, HBP6 Settable, Resorbable Hemostatic Bone Putty (K193052).

The following table shows comparisons of the several characteristics of Montage Flowable XRO Settable, Resorbable Bone Paste and the primary predicate device. The differences noted in the table below do not impact substantial equivalence.

Predicate Comparison Table

Manufacturer	Orthocon, Inc. Predicate Device	Orthocon, Inc. Subject Device
Trade Name	HBP6 Settable, Resorbable Hemostatic Bone Paste	Montage Flowable XRO Settable, Resorbable Hemostatic Bone Paste
510(k) Number	K193052	TBD
Type of Device/ Product Code	Bone wax / MTJ	Bone wax / MTJ

Indications for Use	HBP6 Settable, Resorbable Hemostatic Bone Paste is indicated in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade	Montage Flowable XRO Settable, Resorbable Hemostatic Bone Paste 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	HBP6 Settable, Resorbable Hemostatic Bone Paste is formulated as a two-part paste/paste device that forms a "settable" (hardening) paste when mixed at the time of surgery.	Montage Flowable XRO Settable, Resorbable Hemostatic Bone Paste is formulated as a two-part paste/paste device that forms a "settable" (hardening) paste when mixed at the time of surgery.
Radiopacity	Radiopaque – Contains hydroxyapatite and β-tricalcium phosphate	Radiopaque – Contains hydroxyapatite, β-tricalcium phosphate and barium sulfate
Composition	Sterile mixture of two separate components of paste-like consistency comprised of granular calcium phosphate, (hydroxyapatite and β- tricalcium phosphate), calcium stearate, vitamin E acetate, triacetin, 1,4-butanediol, triethanolamine and a mixture of a lactide-diester and polyester-based (lactide and caprolactone) absorbable polymers. HBP6 is to be mixed immediately prior to use. Resulting settable device from the two pastes is primarily comprised of calcium phosphate similar to the mineral phase of native bone tissue.	Sterile mixture of two separate components of paste-like consistency comprised of granular calcium phosphate, (hydroxyapatite and β-tricalcium phosphate), calcium stearate, vitamin E acetate, triacetin, 1,4-butanediol, triethanolamine, a mixture of a lactide-diester and polyester-based (lactide and caprolactone) absorbable polymers and barium sulfate. Montage Flowable XRO is to be mixed immediately prior to use. Resulting settable device from the two pastes is primarily comprised 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 with delivery instrument and spread onto bone tissue	Manually applied with delivery instrument 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 the calcium salts and barium sulfate 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
MRI Safety	Device is safe in the MRI environment	Device is safe in the MRI environment

Performance Testing:

Bench testing, biocompatibility and animal functionality testing performed on the predicate and Montage Flowable XRO Settable, Resorbable Hemostatic Bone Paste 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 over a range of temperatures and to evaluate the device's dissolution properties. The following evaluations were completed: relative stiffness, spreadability, stickiness, temperature sensitivity, electrocautery compatibility, dissolution and swelling.

Biocompatibility Testing was conducted to evaluate the device's biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted on the final, finished, gamma-irradiated sterile device in accordance with the GLP requirements: irritation, sensitization, acute systemic toxicity, genotoxicity, implantation, systemic toxicity, hemolysis, endotoxicity and pyrogenicity.

Animal Testing included studies to demonstrate intraoperative *in vivo* hemostasis and resistance to irrigation.

Sterility

The gamma sterilization process has been validated to provide a SAL of 10^{-6}. Each lot of finished devices is tested for bacterial endotoxin for lot release.

Conclusion

Montage Flowable XRO is substantially equivalent to the predicate HBP6 Settable Hemostatic Bone Putty and previously cleared bone hemostasis devices with respect to intended use, general technological characteristics and performance.