August 30, 2023

Orthocon, Inc.
Howard Schrayer
Official Correspondent
1 Bridge Street, Suite 121
Irvington, New York 10533

Re: K213418
Trade/Device Name: MONTAGE Settable, Resorbable Hemostatic Bone Putty
Regulation Number: 21 CFR
Regulation Name:
Regulatory Class: Class II
Product Code: MTJ
Dated: October 19, 2021
Received: October 20, 2021

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,

David Krause -S

David Krause, Ph.D.
Deputy Director
OHT4: Office of Surgical
and Infection Control 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)*
K213418

Device Name
MONTAGE Settable, Resorbable Hemostatic Bone Putty

Indications for Use *(Describe)*
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 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.
700 Fairfield Avenue, Suite 1
Stamford, CT 06902
hs.ss@lucidmedical.net

Date Prepared: August 29, 2023

Device Trade Name: MONTAGE™ Settable, Resorbable Hemostatic Bone Putty

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

Telephone: (855) 475 - 9175

Common Name: Calcium phosphate bone hemostasis material

Classification: Unclassified

Product Code: MTJ

Primary Predicate: MONTAGE Settable, Resorbable Hemostatic Bone Putty
510(k) K152005

Reference Predicate: Hemasorb Resorbable Hemostatic Bone Putty
510(k) K111575

Indications for Use:

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 is also indicated for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.

Device Description:

MONTAGE Settable, Resorbable Hemostatic Bone Putty is a sterile, biocompatible, resorbable material for use in the control of bleeding from bone surfaces. The MONTAGE 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 device form a cohesive putty-like material that adheres to the bleeding bone surface and remains in place following application. The resulting hardened, resorbable material is primarily calcium phosphate. MONTAGE components must be mixed immediately prior to use. When applied to surgically cut or traumatically broken bone, MONTAGE Settable, Resorbable Hemostatic Bone Putty achieves local control of bleeding by acting as a mechanical barrier (tamponade).

Substantial Equivalence and Predicate Device:

The subject device is exactly the same device and is substantially equivalent to its previously cleared predicate and to the Hemasorb reference predicate. 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.

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:

Studies have been conducted which demonstrate that Montage can achieve hemostasis and allows for acceptable bone remodeling. Montage has been previously tested to demonstrate biocompatibility through an appropriate series of studies as required for compliance with ISO 10993. Montage has been evaluated for handling characteristics and shelf-life / stability. Each lot is evaluated for endotoxicity. The device is provided sterile with a Sterility Assurance Level (SAL) of 10^{-6}. The studies demonstrate that the pre-established performance criteria were met using the well-established internal protocols.

Clinical Testing

A human clinical evaluation was conducted that supports the use of Montage during sternotomy procedures.

Conclusion

The subject device is substantially equivalent to the above-referenced (previously cleared) predicate devices with respect to intended use, general technological characteristics and performance.