



Food and Drug Administration
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Silver Spring, MD 20993-0002

October 15, 2015

Orthocon Incorporated
Mr. Howard Schrayer
1 Bridge Street, Suite 121
Irvington, New York 1053

Re: K152005

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

Regulatory Class: Unclassified

Product Code: MTJ

Dated: September 14, 2015

Received: September 15, 2015

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. 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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS)

regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152005

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.

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.

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510(k) Summary

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: July 17, 2015

Device Trade Name: MONTAGE™ 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

Primary Predicate: HBP4™ Hardening, Resorbable Hemostatic Bone Putty
510(k) K141502

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.

Device Description:

MONTAGE 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 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 device form a cohesive putty-like material that adheres to the bleeding bone surface and remains in place upon application. The resulting hardened, resorbable material is primarily calcium phosphate. MONTAGE must be mixed immediately prior to use.

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

Substantial Equivalence and Predicate Device:

MONTAGE Settable, Resorbable Hemostatic Bone Putty is exactly the same device and is substantially equivalent to the previously cleared Orthocon HBP4 Hardening, Resorbable Hemostatic Bone Putty (K141502). The only difference between MONTAGE Settable, Resorbable Hemostatic Bone Putty and the predicate device is the configuration of the packaging (blister package).

Technological Characteristics:

The tables below provide comparisons of MONTAGE Settable, Resorbable Hemostatic Bone Putty with the predicate devices.

Predicate Comparison Table

Manufacturer	Orthocon, Inc.	Orthocon, Inc
Trade Name	MONTAGE Settable, Resorbable Hemostatic Bone Putty	HBP4 Hardening, Resorbable Hemostatic Bone Putty
510(k) Number	Subject Device	K141502
Type of Device/ Product Code	Bone hemostat / MTJ	Bone hemostat / MTJ
Indications for Use	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	HBP4 Hardening, 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 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.	HBP4 Hardening, 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 calcium phosphate	Radiopaque – Contains calcium 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, triacetin, 1,4-butanediol and a mixture of a lactide-diester and polyester-based (lactide and caprolactone) absorbable polymers. MONTAGE is to be mixed immediately prior to use. Resulting hardening material from the two putties is primarily comprised 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, triacetin, 1,4-butanediol and a mixture of a lactide-diester and polyester-based (lactide and caprolactone) absorbable polymers. HBP4 is to be mixed immediately prior to use. Resulting hardening material from the two putties 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 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
Packaging	Foil blister	Foil pouch

Performance Testing:

Bench testing, biocompatibility and animal functionality testing performed on the predicate HBP4™ Hardening, Resorbable Hemostatic Bone Putty demonstrate that the device is substantially equivalent to predicate devices in intended use, technological characteristics, and performance. Because this device is exactly the same formulation as the predicate device the testing is completely relevant. 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 bench studies 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, subacute systemic toxicity, chronic systemic toxicity, hemolysis, endotoxicity and pyrogenicity.

Animal Testing included animal studies to demonstrate intraoperative *in vivo* hemostasis, resistance to irrigation, and to characterize resorption time.

Conclusion

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