March 27, 2020

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

Re: K193052
Trade/Device Name: HBP6 Settable, Resorbable Hemostatic Bone Paste
Regulatory Class: Unclassified
Product Code: MTJ
Dated: February 26, 2020
Received: February 27, 2020

Dear Mr. 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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193052

Device Name
HBP6 Settable, Resorbable Hemostatic Bone Paste

Indications for Use *(Describe)*
The HBP6 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

K193052

Contact: Howard Schrayer
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hs.ss@lucidmedical.net

Date Prepared: March 23, 2020

Device Trade Name: HBP6 Settable, Resorbable Hemostatic Bone Paste

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

Common Name: Bone Wax

Classification: Unclassified

Product Code: MTJ

Predicate Devices

Orthocon, Inc. MONTAGE-QS Settable, Resorbable Hemostatic Bone Putty
510(k) K191140

Indications for Use:

The HBP6 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:

The HBP6 Settable, Resorbable Hemostatic Bone Paste is a sterile, biocompatible, resorbable material for use in the control of bleeding from bone surfaces. The single use HBP6 device contains two separate components of paste-like consistency comprised of granular calcium phosphate, calcium stearate, vitamin E acetate, a triglyceride, polyalcohols and a mixture of a lactide-diester and polyester-based polymers. When mixed together, the components of the HBP6 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. HBP6 is mixed immediately prior to use.

When applied to surgically cut or traumatically broken bone, HBP6 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 previously cleared bone hemostasis predicate device, Montage-QS Settable, Resorbable Hemostatic Bone Putty (K191140).

Technological Characteristics:

The table below compares the technological characteristics of HBP6 and the predicate.

Predicate Comparison Table

Manufacturer	Orthocon, Inc.	Orthocon, Inc.
Trade Name	HBP6 Settable, Resorbable Hemostatic Bone Paste	MONTAGE-QS™ Settable, Resorbable Hemostatic Bone Putty
510(k) Number	K193052	K191140
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-QS™ 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	HBP6 Settable, Resorbable Hemostatic Bone Paste is formulated as a two-part paste/paste device that forms a “settable” (hardening) paste when manually mixed at the time of surgery.	MONTAGE-QS™ Settable, Resorbable Hemostatic Bone Putty is formulated as a two-part putty/putty device that forms a “settable” (hardening) putty when mixed at the time of surgery.

Radiopacity	Radiopaque – Contains hydroxyapatite and β-tricalcium phosphate	Radiopaque – Contains hydroxyapatite and β-tricalcium phosphate
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 putty-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. MONTAGE-QS is to be mixed immediately prior to use. Resulting settable device 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 with delivery instrument 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
Set Time	Sets within 5-minutes of application	Sets within 5-minutes of application

Performance Testing:

Bench testing, biocompatibility and animal functionality testing performed on the predicate and HBP6 Settable, Resorbable Hemostatic Bone Paste demonstrate that the device is substantially equivalent to the predicate device 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.

Conclusion

HBP6 is substantially equivalent to the predicate MONTAGE-QS Settable Hemostatic Bone Putty with respect to intended use, general technological characteristics and performance.