July 18, 2019

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

Re: K191140
Trade/Device Name: MONTAGE-QS Settable, Resorbable Hemostatic Bone, HBP5, Montage Rapid Set (RS) and Montage Fast Set (FS)
Regulatory Class: Unclassified
Product Code: MTJ
Dated: April 29, 2019
Received: April 30, 2019

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,

Nina Mezu-Nwaba, PharmD., MPH. MSC. CAPT USPHS
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)*
K191140

Device Name
MONTAGE-QS Settable, Resorbable Hemostatic Bone Putty

Indications for Use *(Describe)*
MONTAGE-QS 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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510(k) Summary

Contact: Howard Schrayer
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Date Prepared: June 25, 2019

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

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

Common Name: Bone Wax

Classification: Unclassified

Product Code: MTJ

Predicate Devices
Primary Predicate:
Orthocon, Inc. MONTAGE Settable, Resorbable Hemostatic Bone Putty
510(k) K152005

Reference Device:
Orthocon, Inc. HBP4 Hardening, Resorbable Hemostatic Bone Putty
510(k) K141502

Indications for Use:

MONTAGE-QS 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-QS 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-QS *device* contains two separate components of putty-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 MONTAGE-QS 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-QS must be mixed immediately prior to use.

When applied to surgically cut or traumatically broken bone, MONTAGE-QS Settable, Resorbable Hemostatic Bone Putty 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 bone hemostasis predicate device, Montage Settable, Resorbable Hemostatic Bone Putty (K152005).

Performance Testing:

Bench testing, biocompatibility and animal functionality testing performed on MONTAGE-QS Settable, Resorbable Hemostatic Bone Putty 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 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: cytotoxicity. irritation, sensitization, acute systemic toxicity, genotoxicity, implantation, systemic toxicity, hemolysis, endotoxicity and pyrogenicity.

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

Technological Characteristics of MONTAGE-QS and the predicate Orthocon, Inc. MONTAGE Settable, Resorbable Hemostatic Bone Putty are nearly identical. MONTAGE-QS Settable, Resorbable Hemostatic Bone Putty and the referenced predicate use similar configurations and formulations (i.e., two putty materials that are mixed together at the time of use, including a calcium salt and other resorbable materials for ease of application). Both function by the same principle (i.e., mechanical tamponade). MONTAGE-QS Settable, Resorbable Hemostatic Bone Putty and the predicate are formulated from the same materials with a single exception (that accelerates setting time). Both are primarily comprised (~70% by weight) of calcium phosphate; and rely on a reaction between two packaged components to produce a putty that hardens *in situ*. These devices are resorbable devices provided sterile by gamma irradiation.

The constituents of the MONTAGE-QS Settable, Resorbable Hemostatic Bone Putty device and the predicate device formulations have been shown to be as safe as the predicate device for the intended use. The devices are provided in packages designed for individual patient use.

Conclusion

MONTAGE-QS is substantially equivalent to the previously cleared bone wax predicate device [Montage Settable, Resorbable Hemostatic Bone Putty (K152005)] with respect to intended use, general technological characteristics and performance.