February 16, 2024

Orthocon, Inc.
Howard Schrayer
Regulatory Consultant
8 Lookout
Hilton Head Island, South Carolina 29928

Re: K232771
Trade/Device Name: Montage Flowable Settable, Resorbable Bone Paste
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl Methacrylate For Cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: January 16, 2024
Received: January 16, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2024.02.16 14:38:47 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K232771

Device Name
Montage Flowable Settable, Resorbable Bone Paste

Indications for Use *(Describe)*
Orthocon Montage Flowable Settable, Resorbable Bone Paste is a self-setting calcium phosphate cement indicated for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects with a surface area no larger than 25cm2. Montage Flowable Settable, Resorbable Bone Paste should be used only in skeletally mature individuals.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff

510(k) SUMMARY
(Per 21 CFR 807.92)

General Company Information

Name: Orthocon, Inc.
Contact: Howard Schrayer
Regulatory Affairs Consultant

Address: 700 Fairfield Avenue, Suite 1
Stamford, CT 06902

Telephone: (855) 475 - 9175

Date Prepared February 14, 2024

General Device Information

Product Name: Montage Flowable™ Settable Resorbable Bone Paste

Common Name: Calcium Phosphate Cement

Classification: Class II
Product codes: GXP
Regulation: 21 CFR 882.5300

Predicate Devices:
Primary Predicate:

Stryker	HydroSet Injectable Cement [510(k) Number K060763]

Reference Devices:

Orthocon, Inc.	HBP6 Flowable Settable, Resorbable Hemostatic Bone Paste Montage® Flowable Settable, Resorbable Bone Paste [510(k) Number K193052 and K231270]
Orthocon, Inc.	Montage® Settable, Resorbable Bone Putty [510(k) Number K221933]
Orthocon, Inc.	Montage-QS Settable, Resorbable Bone Putty [510(k) Number K191140 and K231903]

Device Description

Montage Flowable Settable, Resorbable Bone Paste is a sterile, biocompatible, resorbable material for use in repair of cranial defects. The Montage Flowable device comprises two separate components of putty consistency containing 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 Flowable device form a cohesive putty-like material that adheres to the bone surface and remains in

place following application. The resulting hardened, resorbable material is primarily calcium phosphate. Montage Flowable components must be mixed immediately prior to use.

Indications for Use

Orthocon Montage Flowable Settable, Resorbable Bone Paste is a self-setting calcium phosphate cement indicated for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects with a surface area no larger than 25cm^2. Montage Flowable Settable, Resorbable Bone Paste should be used only in skeletally mature individuals.

The following table shows comparisons of characteristics of Montage Flowable Settable, Resorbable Bone Paste and the predicate device.

SUBSTANTIAL EQUIVALENCE INFORMATION

Comparisons of Technological Characteristics

Orthocon, Inc. Montage Flowable Settable, Resorbable Bone Paste 510(k) – K232771	**Stryker Injectable Cement HydroSet 510(k) - K060763**
Device is intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects with a surface area no larger than 25cm^2.	Stryker® Injectable Cement is intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects.
At the time of application, device is in the form of a paste-like material	At the time of application, device is in the form of a paste-like material
Device is designed to be applied to the cranial defect with a manually operated dispenser	Device is designed to be applied to the cranial defect with a manually operated dispenser
Montage Flowable Settable, Resorbable Bone Paste is formulated as a two-part paste/paste device that forms a “settable” (hardening) material when mixed at the time of surgery	Stryker Injectable cement is formulated as a two-part powder/liquid device that forms a “settable” (hardening) material when mixed at the time of surgery
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, polyalcohols and a mixture of a lactide-diester and polyester-based (lactide and caprolactone) absorbable polymers. Montage Flowable is to be	Sterile mixture of two separate components, a powder comprised of dicalcium phosphate dihydrate, tetracalcium phosphate and tri-sodium citrate; and a liquid comprised of sodium phosphate, polyvinylpyrrolidone and water. Stryker Injectable Cement is to be manually mixed immediately prior to use. Resulting settable material from the two components is primarily comprised of calcium phosphate.

mixed immediately prior to use. Resulting settable material from the two putties is primarily comprised of calcium phosphate.	
Implanted device is resorbable in greater than 30 days primarily due to presence of calcium phosphate.	Implanted device is resorbable in greater than 30 days primarily due to presence of calcium phosphate.
Single-patient-use device is provided sterile by gamma irradiation	Single-patient-use device is provided sterile by gamma irradiation and ethylene oxide
The bone putty is available in individual and/or multi-pack patient use sizes of up to 8cc.	The device is available in individual; and/or multi-pack patient use sizes of 3, 5, 10 and 15cc.
The paste is provided in a dual-barrel cartridge within a single outer foil pouch. The outer foil pouch contains a desiccant. The pouch is heat sealed and sterilized.	Each kit contains one liquid-filled glass syringe and one plastic bowl of powder packaged within a double pre-formed tray with a Tyvek lid.
Mixing for homogeneity is immediate	Mixing for homogeneity takes 45 sec.
Material is settable within 10 minutes of application	Material is settable within 10 minutes of application
Material provides a working time of 5 minutes.	Material provides a working time of 5 minutes.
Device cures with no appreciable exothermic reaction.	Device cures with no appreciable exothermic reaction

Testing Completed

Biocompatibility Testing

Testing was conducted to evaluate biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted on the final, finished, gamma-irradiation sterilized device and in accordance with the GLP requirements: cytotoxicity, irritation, sensitization, systemic toxicity, genotoxicity, local tissue toxicity, hemolysis, pyrogenicity and neurotoxicity.

Performance Data

Performance testing included a series of laboratory evaluations and in vivo testing. These evaluations are summarized below.

Bench Testing

Test	Description	Conclusions
Visual Inspection	Evaluated paste color using a reference scale	Paste color met specification
Paste Stiffness	Evaluated paste stiffness using a reference scale	Paste stiffness met specification
Package Leak Test	Bubble emission leak test	All test articles passed
Temperature Sensitivity	Acceptable maximum temperature increase observed	Acceptable maximum temperature increase observed
Water Uptake, Swelling and Dissolution	Measured volume and mass changes over time	Acceptable water uptake, swelling and dissolution

In-Vivo Testing

In-vivo animal testing was used to demonstrate substantial equivalence of Montage Flowable Settable, Resorbable Bone Paste in the repair of a critical sized cranial bone defect in an animal model compared to the predicate device. Substantial equivalence was assessed from histopathologic evaluation.

Clinical Testing

No clinical studies have been conducted in support of this 510(k).

Conclusions

This submission supports the position that Orthocon Montage Flowable Settable, Resorbable Bone Paste is substantially equivalent to the predicate device.

The information provided establishes that similar legally marketed devices, including the primary predicate, have been used for the same clinical applications as Orthocon Montage Flowable Settable, Resorbable Bone Paste and that Substantial Equivalence to the predicate device has been established. Each of the tests conducted passed the requirements as stated in the protocols and in recognized standards. The data presented demonstrate that the device is suitable for its indicated use. The materials from which the Orthocon device is fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines. Any differences between Montage Flowable and the predicate do not raise new concerns or risks.