January 13, 2023

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

Re: K221933
Trade/Device Name: MONTAGE Settable, Resorbable Bone Putty
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl Methacrylate For Cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: December 14, 2022
Received: December 14, 2022

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2023.01.13 13:22:26 -05'00'

Adam Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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and Neurodiagnostic Devices
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and Physical Medicine Devices
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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)*
K221933

Device Name
MONTAGE Settable, Resorbable Bone Putty

Indications for Use *(Describe)*

Orthocon MONTAGE Settable, Resorbable Bone Putty 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 Settable, Resorbable Bone Putty 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.

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510(k) SUMMARY

General Company Information

Name: Orthocon, Inc.

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

Telephone: (855) 475 - 9175

Contact: Howard Schrayer
Date Prepared January 12, 2023

General Device Information

Product Name: MONTAGE Settable, Resorbable Bone Putty

Common Name: Calcium Phosphate Cement

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

Predicate Device

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

Device Description

MONTAGE Settable, Resorbable Bone Putty is a sterile, biocompatible, resorbable material for use in repair of cranial defects. The MONTAGE device comprises two separate components of putty 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 putty-like material. The resulting hardened, resorbable material is primarily calcium phosphate. MONTAGE components must be mixed immediately prior to use.

Indications for Use

Orthocon MONTAGE Settable, Resorbable Bone Putty 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 Settable, Resorbable Bone Putty should be used only in skeletally mature individuals.

The following table shows comparisons of characteristics of MONTAGE Settable, Resorbable Bone Putty and the predicate device.

SUBSTANTIAL EQUIVALENCE INFORMATION

Orthocon, Inc. MONTAGE Settable, Resorbable Bone Putty 510(k) – 221933	**Stryker Injectable Cement HydroSet 510(k) - K060763**

Comparisons of Technological Characteristics

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 putty-like material	At the time of application, device is in the form of a paste-like material
Device is designed to be manually applied to the cranial defect	Device is designed to be manually applied to the cranial defect
MONTAGE Settable, Resorbable Bone Putty is formulated as a two-part putty/putty device that forms a “settable” (hardening) material when manually 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 manually 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, 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 settable material from the two putties is primarily comprised of calcium phosphate .	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.

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 5cc (approximately 10 grams).	The device is available in individual; and/or multi-pack patient use sizes of 3, 5, 10 and 15cc.
Each putty is placed into a separate inner foil “blister” which are contained within a single outer foil pouch. The outer foil pouch contains a desiccant. The inner blister and outer pouch are 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 takes 45 sec.	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 2 minutes.	Material provides a working time of 2 minutes.
Device cures with no appreciable exothermic reaction.	Device cures with no appreciable exothermic reaction

Performance Data

Biocompatibility Testing

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-irradiation sterilized device and in accordance with the GLP requirements: cytotoxicity, irritation, sensitization, systemic toxicity, genotoxicity, local tissue toxicity, hemolysis, pyrogenicity and neurotoxicity.

Bench Testing

Test	Description	Conclusions
Visual Inspection	Evaluated putty component color using a 3-point scale	Putty color and handling met specification
Putty Handling	Evaluated putty stickiness to gloves using a 3-point scale	
Putty Stiffness	Measured putty stiffness using a Penetrometer	Putty stiffness met specification
Putty Vitamin E Acetate Concentration	Solvent extraction and chemical analysis	Putty vitamin E acetate concentration met specification
Hand Mixing Time	Evaluated hand-mixing time using a 2-point scale	Mixing time, stickiness, and mixability met specification
Hand Mixing Stickiness	Evaluated stickiness to gloves using a 3-point scale	
Mixability	Evaluated mixability using a 2-point scale	
Device Stiffness	Measured device stiffness using a Penetrometer	Device stiffness met specification
Package Gross Leak	Bubble emission leak test	All test articles passed
Temperature Sensitivity	Determined maximum temperature increase observed during mixing	Acceptable maximum temperature increase following hand-mixing
Water Uptake, Swelling and Dissolution	Measured volume and mass changes during 72 hours in phosphate buffered saline, pH 7.4, at 37°C	Acceptable water uptake, swelling and dissolution

In-Vivo Testing

In-vivo animal testing was used to demonstrate substantial equivalence of MONTAGE Settable, Resorbable Bone Putty in the repair of a critical sized cranial bone defect of New Zealand White rabbits compared to the predicate device. Substantial equivalence was assessed from histopathologic evaluation and histomorphometric measurements of implant absorption over time.

Clinical Testing

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

Conclusions

This submission supports the position that Orthocon MONTAGE Settable, Resorbable Bone Putty is substantially equivalent to the predicate device.

The information provided establishes that similar legally marketed devices have been used for the same clinical applications as Orthocon MONTAGE Settable, Resorbable Bone Putty 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.