March 16, 2026

Orthocon, Inc.
Howard Schrayer
Regulatory Consultant
700 Fairfield Ave. - Suite 1
Stamford, Connecticut 06902

Re: K253447
Trade/Device Name: Montage Flowable Settable, Resorbable Bone Paste (Burr Hole Cover)
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: February 11, 2026
Received: February 11, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.03.16 13:56:34 -04'00'

for Jaime Raben, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K253447

Device Name

Montage Flowable Settable, Resorbable Bone Paste (Burr Hole Cover)

Indications for Use *(Describe)*

Orthocon Montage Flowable Settable, Resorbable Bone Paste is a self-setting cement indicated for fixation of bone flaps following craniotomy. 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.

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510(k) SUMMARY
(Per 21 CFR 807.92)
K253447

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 March 14, 2026

General Device Information

Product Name: Montage® Flowable Settable Resorbable Bone Paste (Burr Hole Cover)

Common Name: Burr Hole Cover

Classification: Class II
Product codes: GXR
Regulation: 21 CFR 882.5250

Predicate Devices:
Primary Predicate:
OSSDSIGN — Cranioplug
[510(k) Number K181539]

Reference Devices:

Orthocon, Inc. — Montage Flowable Settable, Resorbable Bone Paste
510(k) Number K232771

Orthocon, Inc. — HBP6 Flowable Settable, Resorbable Hemostatic Bone Paste
Montage® Flowable Settable, Resorbable Bone Paste
[510(k) Numbers K193052 and K231270]

Orthocon, Inc. — Montage-QS Settable, Resorbable Bone Putty
[510(k) Numbers K191140 and K231903]

Device Description

Montage Flowable Settable, Resorbable Bone Paste is a sterile, biocompatible, resorbable material for fixation of bone flaps following craniotomy. The Montage Flowable device comprises two separate components of paste-like 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 in the applicator tip, the components of the Montage Flowable device form a cohesive paste-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 cement indicated for fixation of bone flaps following craniotomy. 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

Comparison	Orthocon, Inc. Montage Flowable Settable, Resorbable Bone Paste 510(k) – K253447	OSSDSIGN Cranioplug 510(k) – K181539	Comment
Comparisons of Technological Characteristics			
Indication for Use	Orthocon Montage Flowable Settable, Resorbable Bone Paste is a self-setting cement indicated for fixation of bone flaps following craniotomy. Montage Flowable Settable, Resorbable Bone Paste should be used only in skeletally mature individuals.	OSSDSIGN Cranioplug is an implant intended to cover and plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery. These osseous defects are surgically created and are not intrinsic to the stability of the bony structure. The ceramic component of Cranioplug resorbs and is replaced with bone during the healing process. Cranioplug is indicated for use in adults and adolescents age 12 and older.	Indications are equivalent and consistent with the regulation 21 CFR 882.5250
Product Code	Product Code GXR	Product Code GXR	Identical
How Applied	Device is designed to be applied to the cranial defect with a manually operated dispenser.	Device is designed to be manually applied to the cranial defect with retaining mesh and screws.	Delivery to the cranium of both devices is managed by surgeon.

Mode of Action	Montage Flowable Settable, Resorbable Bone Paste is formulated as a two-part paste/paste device that forms a “settable” (hardening) calcium phosphate-based material when mixed at the time of surgery. The paste interdigitates with bone and is self-retaining when hardened.	Cranioplug is provided as a two-part system. Preformed calcium phosphate-based plugs are combined with a titanium mesh. The device is available in 11 and 14mm sizes with either 2 or 6 titanium fixation arms that are secured with screws placed in the cranium.	Montage Flowable is applied as a formable paste and Cranioplug is provided in a fixed range of sizes. Both provide suitable mechanical fixation of cranial bone as demonstrated through testing.
Composition	Sterile mixture of two separate components of paste-like consistency comprised primarily of proprietary calcium phosphate-based material.	The Cranioplug plug is formed from a proprietary calcium phosphate-based material. The titanium mesh is “Grade 2” titanium.	Both devices contain a calcium phosphate component. Cranioplug also contains titanium. All materials have been shown to be biocompatible.
Resorption Time	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 and titanium is nonabsorbable.	Calcium phosphate material in both devices resorbs in greater than 30 days.
Resorbability	The non-calcium salt and non-polymeric components resorb in the body.	The calcium salts resorb. The titanium remains as a permanent implant.	Resorption of the calcium phosphate component is the same.
Sterility	Single-patient-use device is provided sterile by gamma irradiation.	Single-patient-use device is provided sterile.	Equivalent. Both devices are provided sterile.
Unit Size	The bone paste is available in individual and/or multi-pack patient use sizes of up to 8cc.	The device is available in 11 and 14mm sizes. Multi-component kits are provided.	Equivalent. Both are provided in sufficient quantity to allow for a single procedure

Packaging	The paste is provided in a dual-barrel cartridge within a sterile barrier package.	Cranioplug is packaged within a sterile barrier package.	Equivalent. Both are provided in a sterile barrier.
Mechanical Stability	Device is fixed in position following delivery.	Device mechanically fixed in position following delivery.	Equivalent. Both provide suitable mechanical fixation of cranial bone, as demonstrated through testing.
Fixation Means	Flowable paste mechanically interdigitates with bone to provide fixation.	Pre-formed resorbable plugs provide mechanical fixation.	Equivalent. Both provide suitable mechanical fixation of cranial bone, as demonstrated through testing.

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
Cranial flap fixation	Evaluation of applied force required to displace cranial flap	Force required exceeds force required to displace flaps fixed with metallic hardware

Performance Testing

Prior in-vivo animal testing was used to demonstrate safety and suitability of Montage Flowable Settable, Resorbable Bone Paste for use in the repair of critical sized cranial bone defects. Additional ex-vivo cadaver testing was used to demonstrate cranial flap fixation performance and substantial equivalence to the predicate.

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.