January 2, 2026

ORTHOCON, Inc.
% Alyssa McDermott
Sr. Director, Quality and Regulatory Affairs
Abyrx, Inc.
700 Fairfield Avenue, Suite 1
Stamford, Connecticut 06902

Re: K253854
Trade/Device Name: MONTAGE XT Cranial Cement
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl Methacrylate for Cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: October 27, 2025
Received: December 3, 2025

Dear Alyssa McDermott:

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 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.

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,

XIAOLIN
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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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253854

Please provide the device trade name(s).

MONTAGE XT Cranial Cement

Please provide your Indications for Use below.

MONTAGE XT Cranial Cement 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 25 cm^2. MONTAGE XT Cranial Cement should be used only in skeletally mature individuals.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

General Company Information

Name: Orthocon, Inc.
Contact: Alyssa McDermott
Sr. Director of Quality and Regulatory Affairs

Address: 700 Fairfield Avenue – Suite 1
Stamford, CT 10533

Telephone: (855) 475 - 9175

Date Prepared December 29, 2025

General Device Information

Product Name: MONTAGE XT™ Cranial Cement

Common Name: Calcium Phosphate Cranial Cement

Classification: Class II

Product codes: GXP

Regulation: 21 CFR 882.5300

Primary Predicate Device

Orthocon Montage™ Settable Resorbable Bone Putty
[510(k) Number K221933]

Reference Predicate Device:

Orthocon, Inc. MONTAGE-XT Settable, Resorbable Bone Putty
[510(k) K233566]

Device Description

MONTAGE XT Cranial Cement is a sterile, biocompatible, resorbable material for use in repair of cranial defects. The MONTAGE XT Cranial Cement comprises of two separate components of putty consistency containing granular calcium phosphate, calcium stearate, vitamin E acetate, a triglyceride, a polyalcohol and a mixture of lactide-diester and polyester-based polymers. When mixed together, the components of the MONTAGE XT Cranial Cement form a putty-like material. The resulting hardened, resorbable material is primarily calcium phosphate and is slowly resorbed during the remodeling process. Montage XT components must be mixed immediately prior to use.

Indications for Use

MONTAGE XT Cranial Cement 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 25 cm^2. MONTAGE XT Cranial Cement should be used only in skeletally mature individuals.

The following table shows comparisons of characteristics of the MONTAGE XT Cranial Cement and the predicate device.

SUBSTANTIAL EQUIVALENCE INFORMATION

Comparisons of Technological Characteristics

MONTAGE XT Cranial Cement K253854	**Montage Settable, Resorbable Bone Putty Predicate 510(k) – K221933**
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 25 cm^2.	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 25 cm^2.
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 putty-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 XT Cranial Cement is formulated as a two-part putty/putty device that forms a "settable" (hardening) material when manually mixed at the time of surgery.	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.
Sterile mixture of two separate components of putty-like consistency comprised of granular calcium phosphate, calcium stearate, vitamin E acetate, a triglyceride, polyalcohols and a mixture of lactide-diester and polyester-based polymers. The MONTAGE XT Cranial Cement 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 of putty-like consistency comprised of granular calcium phosphate, calcium stearate, vitamin E acetate, a triglyceride, polyalcohols and a mixture of lactide-diester and polyester-based polymers. Montage is to be 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.
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.
Single-patient-use device is provided sterile by gamma irradiation.	Single-patient-use device is provided sterile by gamma irradiation.
The bone putty is available in individual and/or multi-pack patient use sizes.	The bone putty is available in individual and/or multi-pack patient use sizes.
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 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.
Mixing for homogeneity takes 45 seconds.	Mixing for homogeneity takes 45 seconds.
Material is settable following application.	Material is settable following application.
Material provides a working time of 4 minutes.	Material provides a working time of 2 minutes.
Device cures with no appreciable exothermic reaction.	Device cures with no appreciable exothermic reaction

Testing Completed

Biocompatibility Testing

Testing was previously conducted under K221933 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 Montage device and in accordance with the good laboratory practice (GLP) requirements: cytotoxicity, irritation, sensitization, systemic toxicity, genotoxicity, local tissue toxicity, hemolysis, pyrogenicity and neurotoxicity; please see Montage Settable Resorbable Bone Putty 510(k) Number K221933. Based on a risk assessment, no additional testing is needed to support the biocompatibility of the MONTAGE XT Cranial Cement.

In Vivo Testing

The MONTAGE-XT Settable, Resorbable Bone Putty was compared to the predicate Montage in a rabbit critical size defect model under K233566 and was found to be substantially equivalent to Montage when used as a bone void filler device. Based on a risk assessment, no additional testing is needed to support the safety and performance of the MONTAGE XT Cranial Cement.

Performance Data

Testing was previously conducted under K220315 to confirm working time of 4 min and equivalent device performance. Based on a risk assessment, no additional testing is needed to support the safety and performance of the MONTAGE XT Cranial Cement.

Clinical Testing

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

Conclusion

This submission supports the position that the Orthocon MONTAGE XT Cranial Cement is substantially equivalent to the predicate device.