June 15, 2026

Orthocon, Inc.
Alyssa Mcdermott
Sr. Director, Quality and Regulatory Affairs
700 Fairfield Ave., Suite 1
Stamford, Connecticut 06902

Re: K261265
Trade/Device Name: Permatage XT Settable Bone Putty
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl Methacrylate For Cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: April 16, 2026
Received: April 16, 2026

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 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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

YEN-CHIH LIN -S

Digitally signed by YEN-CHIH LIN -S
Date: 2026.06.15 14:40:07 -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

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.	K261265

Please provide the device trade name(s).

Permatage XT Settable Bone Putty

Please provide your Indications for Use below.

Permatage XT Settable Bone Putty is a self-setting cement indicated for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects. Permatage XT Settable Bone Putty should be used only in skeletally mature individuals.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) SUMMARY

General Company Information:

Name:	Orthocon, Inc.
Contact:	Alyssa McDermott Senior Director of Quality and Regulatory Affairs
Address:	700 Fairfield Avenue, Suite 1 Stamford, CT 06902
Telephone:	(855) 475 - 9175

Date Prepared:

June 9th, 2026

General Device Information:

Product Name:	Permatage XT Settable Bone Putty
Common Name:	Methyl Methacrylate for Cranioplasty
Classification:	Class II
Product codes:	GXP

Predicate Device:

Orthocon, Inc.	Permatage Settable Bone Putty [510(k) Number K241027]

Device Description

Permatage XT Settable Bone Putty is a sterile, biocompatible, nonabsorbable material of putty-like consistency for in the repair of cranial defects. The single use Permatage XT device contains two separate components of putty-like consistency comprised of granular calcium phosphate, paraffin oil, vitamin E acetate, a triglyceride, and a mixture of nonabsorbable, polyether-based polymers. When mixed together, the components of the Permatage XT device form a nonabsorbable cohesive, putty-like material that adheres to the bone surface and remains in place following application. The resulting hardening material is primarily calcium phosphate and nonabsorbable polymer materials. Permatage XT components must be mixed immediately prior to use.

Indications for Use

Permatage XT Settable Bone Putty is a self-setting cement indicated for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects. Permatage XT Settable Bone Putty should be used only in skeletally mature individuals.

The following table shows comparisons of characteristics of Permatage XT Settable Bone Putty and the predicate device.

	Permatage Settable Bone Putty (K241027, Primary Predicate)	Permatage XT Settable Bone Putty (K261265, Subject Device)
Indications	Permatage Settable Bone Putty is intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects.	Permatage XT Settable Bone Putty is intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects.
Product Code	Product Code GXP	Product Code GXP
Product Consistency	Permatage Settable Bone Putty is formulated as a two-part putty/putty device that forms a "settable" (hardening) material when mixed at the time of surgery. At the time of application, device is in the form of a spreadable material.	Permatage XT Settable Bone Putty is formulated as a two-part putty/putty device that forms a "settable" (hardening) material when mixed at the time of surgery. At the time of application, device is in the form of a spreadable material.
Application	Device is designed to be manually applied to the bone surface.	Device is designed to be manually applied to the bone surface.
Components	Permatage Settable Bone Putty is a sterile, biocompatible, nonabsorbable material of putty-like consistency for use in repair of cranial defects. The single use Permatage device contains two separate components of putty-like consistency comprised of granular calcium phosphate, paraffin oil, vitamin E acetate, a triglyceride, and a mixture of nonabsorbable, polyether-based polymers. When mixed together, the components of the Permatage device form a nonabsorbable cohesive putty-like material that adheres to the bone surface and remains in place following application. The resulting hardening material is primarily comprised of calcium phosphate and nonabsorbable polymer materials.	Permatage XT Settable Bone Putty is a sterile, biocompatible, nonabsorbable material of putty-like consistency for use in repair of cranial defects. The single use Permatage device contains two separate components of putty-like consistency comprised of granular calcium phosphate, paraffin oil, vitamin E acetate, a triglyceride, and a mixture of nonabsorbable, polyether-based polymers. When mixed together, the components of the Permatage XT device form a nonabsorbable cohesive putty-like material that adheres to the bone surface and remains in place following application. The resulting hardening material is primarily comprised of calcium phosphate and nonabsorbable polymer materials.
Radiopacity	Radiopaque – Contains hydroxyapatite and β-tricalcium phosphate.	Radiopaque – Contains hydroxyapatite and β-tricalcium phosphate.
Implant Life	Implanted device is nonabsorbable.	Implanted device is nonabsorbable.
Sterilization	Single-patient-use device is provided sterile by gamma irradiation.	Single-patient-use device is provided sterile by gamma irradiation.
Unit Sizes	The bone putty is available in individual sizes of up to 10cc.	The bone putty is available in individual sizes of up to 10cc.
Packaging	The putty is provided in two foil packages each within a Tyvek/LDPE pouch, within a single outer foil pouch. The outer foil pouch contains a desiccant. The pouch is heat sealed and terminally sterilized via gamma irradiation.	The putty is provided in two foil packages each within a Tyvek/LDPE pouch, within a single outer foil pouch. The outer foil pouch contains a desiccant. The pouch is heat sealed and terminally sterilized via gamma irradiation.
Mixing	Mixing for homogeneity takes 45 seconds.	Mixing for homogeneity takes 45 seconds.
Setting	Material sets within minutes following application.	Material sets within minutes following application.
Working Time	Material provides a working time of 2 minutes.	Material provides a working time of 4 minutes.
Exotherm	Device cures with no appreciable exothermic reaction.	Device cures with no appreciable exothermic reaction.

Testing Completed

Biocompatibility Testing

Biocompatibility testing was previously conducted on the primary predicate device, Permatage, 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. Because the minute adjustments made to the polymer content of the device decrease the overall polymer content and increase the calcium phosphate content, the conclusions of the predicate biocompatibility are still applicable and no additional testing is needed to support the biocompatibility of the Permatage XT Settable Bone Putty.

Bench testing

The only difference between the predicate device in K241027 and the subject device is a minute adjustment in the polymer content to extend the working time of the subject device. All other studies submitted for the predicate device in K241027 are directly applicable to the subject device, Permatage XT. Only one benchtop study was conducted to compare the extended working time via physical handling of the subject device to the predicate device, Permatage. Results confirm the extended working time of 4 minutes presented in the labeling.

Conclusions

This submission supports the position that Orthocon Permatage XT Settable Bone Putty is substantially equivalent to the predicate device.