June 3, 2026

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

Re: K261439
Trade/Device Name: Permatage Flowable, Settable Hemostatic Bone Paste
Regulatory Class: Unclassified
Product Code: MTJ
Dated: April 30, 2026
Received: April 30, 2026

Dear Mr. 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), 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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2026.06.03 10:39:27 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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.	K261439

Please provide the device trade name(s).

Permatage Flowable, Settable Hemostatic Bone Paste

Please provide your Indications for Use below.

Orthocon Permatage Flowable, Settable Hemostatic Bone Paste is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.

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 – K261439
(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 June 1, 2026

General Device Information

Product Name: Permatage Flowable, Settable Hemostatic Bone Paste

Common Name: Bone Hemostat (Bone Wax)

Classification: Class II
Product codes: MTJ
Regulation: Pre-enactment

Predicate Devices:
Primary Predicate:
Orthocon, Inc. HBP7 Settable Hemostatic Bone Putty
[510(k) Number K202363]

Reference Device:

Orthocon, Inc. Permatage Flowable Settable Bone Paste
[510(k) Number K253732]

Device Description

Permatage Flowable, Settable Hemostatic Bone Paste is a sterile, biocompatible, nonabsorbable material of Paste-like consistency for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The single use Permatage device contains two separate components of paste-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, paste-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 components must be mixed immediately prior to use.

Indications for Use

Orthocon Permatage Flowable, Settable Hemostatic Bone Paste is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.

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

SUBSTANTIAL EQUIVALENCE INFORMATION

Orthocon, Inc. HBP7 Settable, Hemostatic Bone Putty 510(k) – K202363	**Orthocon, Inc. Permatage Flowable, Settable Hemostatic Bone Paste 510(k) – K261439**

Comparisons of Technological Characteristics

Orthocon HBP7 Flowable, Settable Hemostatic Bone Putty is a self-setting cement indicated for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.	Orthocon Permatage Flowable, Settable Hemostatic Bone Paste is a self-setting cement indicated for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.
Product Code MTJ	Product Code MTJ
At the time of application, device is in the form of a spreadable material.	At the time of application, device is in the form of a flowable, spreadable material.
Device is designed to be manually applied to bleeding bone.	Device is designed to be applied to bleeding bone.
HBP7 Settable Hemostatic Bone Putty is formulated as a two-part putty/putty device that forms a “settable” (hardening) material when mixed at the time of surgery.	Permatage Flowable, Settable Hemostatic Bone Paste is formulated as a two-part paste/paste device that forms a “settable” (hardening) material when mixed at the time of surgery.
HBP7 Settable Hemostatic Bone Putty is a sterile, biocompatible, nonabsorbable material of putty-like consistency for use in control of bleeding on bone surfaces. The single use 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 HBP7 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 Flowable, Settable Bone Paste is a sterile, biocompatible, nonabsorbable material of paste-like consistency for use in control of bleeding on bone surfaces. The single use device contains two separate components of paste-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 paste-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.

Radiopaque – Contains hydroxyapatite and β-tricalcium phosphate	Radiopaque – Contains hydroxyapatite and β-tricalcium phosphate
Implanted device is nonabsorbable.	Implanted device is nonabsorbable.
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 sizes of up to 10cc.	The bone paste is available in individual sizes of up to 16cc.
The putty is provided in two foil packages within a single outer foil pouch. The outer foil pouch contains a desiccant. The pouch is heat sealed and sterilized.	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.
Mixing to homogeneity takes 45 seconds	Mixing to homogeneity is immediate
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

Biocompatibility Risk Assessment

All differences between the subject device, Permatage Flowable Settable Bone Paste, the HBP7 Settable Hemostatic Bone Putty (primary predicate - K202363) and the reference device, Permatage Flowable Settable Bone Paste (K253732), were assessed with regard to the following biocompatibility endpoints: cytotoxicity, sensitization, irritation, acute systemic toxicity, material mediated pyrogenicity, subacute/subchronic toxicity, genotoxicity, implantation, neurotoxicity, hemocompatibility (indirect hemolysis), chronic toxicity, and carcinogenicity.

Performance Data

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

Bench and Animal 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
Bone Hemostasis	Measured time to hemostasis	Acceptable hemostasis equivalent to predicate
Sterilization Validation	Validated per VDmax Method and ISO 11137-1:2015 and ISO 11137-2:2015	Validation completed
Endotoxicity	USP <85> /ANSI/AAMI ST72 - < 2.15 U/device	Passes requirement Endotoxicity to be Monitored

Clinical Testing

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

Conclusions

This submission supports the position that Orthocon Permatage Flowable, Settable 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 application as Orthocon Permatage Flowable, Settable 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 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. The data presented demonstrate that the device is suitable for its indicated use. Any differences between Permatage and the predicate do not raise new concerns or risks.