December 5, 2024

Heraeus Medical GmbH
Sarah Kopischke
Manager Regulatory Affairs
Philipp-Reis-Str. 8/13
Wehrheim, Hessen 61273
Germany

Re: K241674
Trade/Device Name: Osteopal® V
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD, NDN
Dated: June 11, 2024
Received: June 11, 2024

Dear Sarah Kopischke:

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 quality systems (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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2024.12.05 12:09:20 -05'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair & Trauma Devices
OHT6: Office of Orthopedic 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)*

K241674

Device Name

OSTEOPAL® V

Indications for Use *(Describe)*

OSTEOPAL® V bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Manufacturer: Heraeus Medical GmbH
Philipp-Reis-Str. 8/13
61273 Wehrheim
Germany

Contact Person: Dr. Sarah Kopischke
Manager Regulatory Affairs
Phone: +49 (6181) 959-259
Email: Sarah.kopischke@heraeus.com

Date Prepared: December 4, 2024

II. DEVICES

Name of Device(s):	OSTEOPAL® V
Device Common Name:	Polymethylmethacrylate (PMMA) bone cement
Regulation Number:	21CFR 888.3027
Device Class:	Class 2
Primary Product Code:	LOD
Associated Product Code(s):	NDN

III. PREDICATE DEVICES

Primary Predicate: OSTEOPAL® V (K050085)

IV. DEVICE DESCRIPTION

A Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance for modifications to the existing OSTEOPAL® V polymethylmethacrylate (PMMA) bone cement previously cleared in K050085.

The modifications include the cumulative effect of changes regarding sterility, shelf-life and manufacturing as well as the addition of MR safety information, the specification extension of benzoyl peroxide and labeling changes.

OSTEOPAL® V is a PMMA bone cement for use in vertebroplasty or kyphoplasty. It is formed from powder and liquid by exothermic polymerization.

V. INDICATIONS FOR USE

OSTEOPAL® V bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.

The subject device (OSTEOPAL® V) has the same intended use and indications for use in comparison to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device comparison demonstrated that OSTEOPAL® V is substantial equivalent to the cited predicate device in terms of operating principle and technological characteristics (design features, material, and performance). At a high level, the subject device and predicate device are based on the following same technological elements:

- PMMA bone cements,
- Same raw materials,
- Biocompatibility of materials,
- Physical and chemical characterization,
- Mechanical performance characteristics,
- Packaging including stability and integrity,
- Sterilized with an established method (ethylene oxide) and
- Designed for use in vertebroplasty or kyphoplasty procedures.

The following technological differences exist between the subject and predicate devices:

- Cumulative effect of changes regarding sterility / shelf-life and manufacturing,
- Specification extension of benzoyl peroxide,
- Addition of MR safety information, and
- Labeling changes.

VII. PERFORMANCE DATA

Summary of non-clinical tests

A risk-based assessment was performed as per DIN EN ISO 14971 to evaluate the impact of the modifications regarding sterility, shelf-life and manufacturing as well as the specification extension of benzoyl peroxide on the device. The evaluation demonstrated that no new risks were identified, and the existing risks were not significantly modified. Subsequent mechanical testing (as per ISO 5833 and ASTM F451) and stability testing were performed and the initially cleared acceptance criteria were fulfilled. It has been indicated that the subject device is as safe and effective as the predicate device.

Furthermore, a scientifically based rationale has been prepared to designate the bone cement as “MR Safe”. OSTEOPAL® V is composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic and pose no known hazards in all MR environments.

The labeling changes regarding contraindications, adverse events and residual risks, warnings, and precautions were assessed in the clinical evaluation and a risk-based assessment. It has been demonstrated that OSTEOPAL® V performs as intended if used as intended by the manufacturer and no unknown complications that have not yet been described in the instructions for use were found.

Summary of clinical tests

No clinical tests were performed to demonstrate substantial equivalence.

VIII. CONCLUSION

OSTEOPAL® V is substantially equivalent to the predicate device (OSTEOPAL® V (K050085)) identified in this premarket notification.