April 15, 2026

Biomet France
Vanessa Gautier
Regulatory Affairs Specialist
Plateau De Lautagne
Valence, 26000
France

Re: K254107
Trade/Device Name: Refobacin Bone Cement R (110034355)
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD, MBB
Dated: December 15, 2025
Received: December 19, 2025

Dear Vanessa Gautier:

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: 2026.04.15 14:23:40 -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.	**K254107**

Please provide the device trade name(s).

Refobacin Bone Cement R (110034355)

Please provide your Indications for Use below.

Refobacin Bone Cement R is indicated to be used for stable anchoring of suitable joint prostheses to the bone, in hip and knee revision arthroplasty operations when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection, also in case an infection with gentamicin-sensitive strains is a potential risk.
Refobacin Bone Cement R is indicated to be used in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

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)

510(k) #: **K254107**

510(k) Summary

Prepared on: 2026-03-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Biomet France
Applicant Address	Plateau de Lautagne Valence 26000 France
Applicant Contact Telephone	+33658480323
Applicant Contact	Ms. Vanessa Gautier
Applicant Contact Email	vanessa.gautier@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Refobacin Bone Cement R (110034355)
Common Name	Polymethylmethacrylate (PMMA) bone cement
Classification Name	Bone Cement
Regulation Number	888.3027
Product Code(s)	LOD, MBB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K171540	Refobacin Bone Cement R	MBB

Device Description Summary

21 CFR 807.92(a)(4)

Refobacin Bone Cement R (RBCR) is a fast-setting acrylic polymer, containing gentamicin sulfate (GMS), for use in hip and knee arthroplasty operations.

Bone cement consists of a powder and a liquid. The mixing of these two components initially produces a paste, which is used to anchor the prosthesis to the bone.

The hardened bone cement allows stable fixation of the prosthesis and transfers stresses associated with movement to the bone via the large interface.

Insoluble zirconium dioxide is included in the cement powder as an X-ray contrast medium. The chlorophyll additive serves as optical marking of the bone cement at the site of the operation.

The GMS content is designed to protect against infections caused by bacterial invasion of the prosthesis and the surrounding tissue by gentamicin-sensitive strains.

The purpose of the current 510(k) notification is to introduce a new source of GMS to secure the supply chain and ensure a double-sourcing for the manufacturing of Refobacin Bone Cement R.
Indeed, the GMS antibiotic particles used in the Refobacin Bone Cement R are larger than the particles of the raw material delivered by the by the vendor who performs the synthesis of gentamicin. As the use of larger particles enhances the gentamicin release from the bone cement, an additional processing step of precipitation is necessary.

Furthermore, the labeling of the subject device will be updated. These labeling changes are not related to the new vendor of GMS.

Please note that this 510(k) notification will cover only one RBCR item (110034355) following the discontinuation of the other RBCR items since the last clearance (110034356, 110034357 and 110034358).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Refobacin Bone Cement R is indicated to be used for stable anchoring of suitable joint prostheses to the bone, in hip and knee revision arthroplasty operations when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection, also in case an infection with gentamicin-sensitive strains is a potential risk.
Refobacin Bone Cement R is indicated to be used in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has similar Indications for Use as the predicate Refobacin® Bone Cement R device. The indications have been limited to hips and knees arthroplasty procedures which are within the currently cleared indications. Indeed, the device was cleared for use in hips, knees and other joints arthroplasty, while the subject device is intended to be marketed for only two of those indications.

Technological Comparison

21 CFR 807.92(a)(6)

The rationale for substantial equivalence is based on consideration of the following characteristics:

- Indications for use: Similar to predicate device
- Other clinical characteristics: Similar to predicate device
- Labeling: Different from predicate device
- Technical/design characteristics: Similar to predicate device
- Biological characteristics/materials: Similar to predicate device
- Manufacturing process: Similar to predicate device
- Sterilization: Identical to predicate device
- Packaging: Similar to predicate device

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing on Refobacin Bone Cement R has been performed during the design and development of the subject device based on the user needs and risk analysis and the impacts that this new source of gentamicin sulfate may have on the final product specifications. A demonstration that the subject device meets the same product specifications as the predicate device has been conducted.

The complete list of non-clinical testing that has been performed (including the new studies performed for the proposed change) is provided below:
- Incipient Break & Assembly
- Creep properties
- Fatigue properties / Fatigue performance
- Fracture Toughness
- Porosity
- Radiopacity
- Shear strength
- Tensile Properties
- Volume variation of bone cement upon Polymerization
- Use of antibiotics in bone cement
- Literature Review of compatibility between bone cement and surgical devices
- Literature review on the effect of cement multilayer on the mantle's mechanical properties
- Shelf-life verification of bone cement R
- Study of temperature excursion on Cement Pack
- Shelf-life verification of bone cement R – Copo E
- Design verification of Monomer/Cement powder ratio by handling and setting assessment
- Performance testing between bone cement and disposable mixing Bowl with Spatula
- Mechanical and behavioral properties as a function of mixing options
- RBCR containing Gentamicin Sulfate from Corden Pharma at industrial scale
- Dough extrusion
- Design Verification of RBCR blended with Osartis Gentamicin Sulfate raw material
- Fatigue performance - RBCR powder containing Gentamicin from Merck Vs Osartis
- Molecular weight

- Zone of inhibition of RBCR with Osartis gentamicin sulfate
- Antibiotic release
- Bibliographic evaluation of Swelling
- MR Safety
- Summative Evaluation - EU MDR Labeling
- Summative Evaluation - RBCR

The results obtained from the various studies demonstrate that both the subject device and the predicate device comply with all requirements, which confirms that this change does not impact the claimed product performances, ensuring product quality and patient safety.

Not applicable

The reports provided demonstrate the proposed subcontractor for gentamicin sulfate particle size enlargement for Refobacin Bone Cement R devices meets FDA requirements and the finished device will perform as intended. Therefore, Biomet France concludes that the device is substantially equivalent to the predicate device.