April 2, 2025

OsteoRemedies, LLC
℅ Danielle Besal
Principal Consultant
MRC Global
9085 E. Mineral Circle
Suite 110
Centennial, Colorado 80112

Re: K250760
Trade/Device Name: SPECTRUM® GV Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD, MBB
Dated: March 12, 2025
Received: March 13, 2025

Dear Ms. Besal:

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: 2025.04.02 13:49:43 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250760

Device Name
SPECTRUM® GV Bone Cement

Indications for Use *(Describe)*
SPECTRUM® GV Bone Cement is indicated for the fixation of the REMEDY® & REMEDY SPECTRUM® GV Spacers, and for the fixation of prostheses to living bone in the second stage of a two-stage revision of a total joint arthroplasty after the initial infection has been cleared.

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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510(k) #: **K250760**

510(k) Summary

Prepared on: 2025-03-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	OsteoRemedies, LLC
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Applicant Contact Telephone	901.453.3141
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Correspondent Contact	Danielle Besal
Correspondent Contact Email	danielle.besal@askmrcglobal.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SPECTRUM® GV Bone Cement
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
K231556	SPECTRUM GV Bone Cement	LOD, MBB
K143100 (Reference	NP Cements Genta Bone Cement	LOD, MBB

Device Description Summary

21 CFR 807.92(a)(4)

SPECTRUM® GV Bone Cement is a radiopaque, PMMA bone cement with gentamicin and vancomycin. The bone cement is single-use and provided sterile. SPECTRUM® GV Bone Cement is a traditional bone cement in that the liquid is contained in a vial and the powder in a sachet. The two components are mixed manually immediately before use. The device is protected from bacterial adhesion due to the presence of gentamicin and vancomycin.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

SPECTRUM® GV Bone Cement is indicated for the fixation of the REMEDY® & REMEDY SPECTRUM® GV Spacers, and for the fixation of

prostheses to living bone in the second stage of a two-stage revision of a total joint arthroplasty after the initial infection has been cleared.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject SPECTRUM® GV Bone Cement is identical to the SPECTRUM® GV Bone Cement cleared in K231556 with respect to intended use, materials, design, and function. The minor difference in indications for use of the subject device versus the primary predicate K231556 is to clarify the device may be used in total joint arthroplasty as part of a two-stage revision when the initial infection has been cleared (which is identical to that of the reference device).

Technological Comparison

21 CFR 807.92(a)(6)

The technological characteristics of the subject device are unchanged versus the predicate SPECTRUM® GV Bone Cement (K231556).

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing was not required as the subject device is identical to that of the predicate.