December 20, 2023

OsteoRemedies, LLC
% Hollace Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
803 7th Steet NW
Washington, District of Columbia 20001

Re: K231556
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: November 22, 2023
Received: November 22, 2023

Dear Hollace Rhodes:

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.

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,

Sara S. Thompson -S

For

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.*

Submission Number *(if known)*

K231556

Device Name

SPECTRUM® GV Bone Cement

Indications for Use *(Describe)*

SPECTRUM® GV Bone Cement is indicated for the fixation of a REMEDY SPECTRUM® GV Spacer, and for the fixation of prostheses to living bone in the second stage of a two-stage revision of a total hip 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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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*

**Submitter:** OsteoRemedies, LLC
6800 Poplar Avenue, #120
Germantown, TN 38138
Phone: (901) 453-3141
Email: info@osteoremedies.com

**Official Correspondent:** Ms. Hollace Saas Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
803 7th Street, NW, Third Floor
Washington, DC 20001
Phone: (202) 552-5807
hrhodes@mcra.com

**Date Prepared:** December 13, 2023

**Trade Name:** SPECTRUM® GV Bone Cement

**Common Name:** PMMA bone cement with antibiotic for orthopedics

**Classification:** Class II
21 CFR 888.3027, Polymethylmethacrylate (PMMA) bone cement

**Product Codes:** LOD, MBB

**Predicate Device:** SPECTRUM® GV Bone Cement (K172906)

**Reference Device:** NP Cements Genta Bone Cement (K143100)

**Device Description:**

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.

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

**Substantial Equivalence:**
The subject SPECTRUM® GV Bone Cement is substantially equivalent to the SPECTRUM® GV Bone Cement (UNITE PLUS Bone Cement) cleared in K172906 with respect to intended use, materials, design, and function. The device description and performance testing demonstrate that the subject SPECTRUM® GV Bone Cement is substantially equivalent to the identified predicate device.

**Performance Testing of Subject SPECTRUM® GV Bone Cement:**
The following tests have been performed on SPECTRUM® GV Bone Cement.

- Mechanical Testing
    - Dough Time and Setting Time
    - Intrusion Testing
    - Viscosity Testing
    - Chemical Composition
    - Physical Properties
    - Stability Testing
    - Thermal Properties
- Elution Testing
- Biocompatibility Testing
- Sterilization, pyrogenicity, bacterial endotoxin, and shelf life testing