



December 23, 2025

OsteoRemedies, LLC  
% Hollace Saas Rhodes  
Vice President, Orthopedic Regulatory Affairs  
MCRA, LLC  
803 7th St. NW, 4th Floor  
Washington, District of Columbia 20001

Re: K253675

Trade/Device Name: OsteoRemedies Hip Spacer System  
Regulation Number: 21 CFR 888.3360  
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Cemented Or Uncemented Prosthesis  
Regulatory Class: Class II  
Product Code: KWL, KWY  
Dated: November 21, 2025  
Received: November 21, 2025

Dear Hollace Saas 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.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Robert M.  
Stefani -S**

Digitally signed by Robert  
M. Stefani -S  
Date: 2025.12.23 13:43:02  
-05'00'

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

# 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.

K253675

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Please provide the device trade name(s).

?

OsteoRemedies Hip Spacer System

Please provide your Indications for Use below.

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The OsteoRemedies Hip Spacer System consists of modular heads and stems, and optional acetabular cups. The REMEDY® components of the OsteoRemedies Hip Spacer System include gentamicin and the REMEDY SPECTRUM® GV components include gentamicin and vancomycin.

The OsteoRemedies Hip Spacer System is indicated for temporary use (maximum 180 days) as an adjunct to total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin or gentamicin/vancomycin are the most appropriate antibiotics based on the susceptibility pattern of the infecting micro-organism(s).

Following removal of the existing femoral and acetabular components and radical debridement, the head and stem components are inserted into the femoral medullary canal and can mate directly with the native acetabulum or an acetabular component which is placed in the acetabular cavity. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The OsteoRemedies Hip Spacer System is not intended for use for more than 180 days, at which time all components must be explanted, and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.).

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](#))

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### *510(k) Summary*

**Device Trade Name:** OsteoRemedies Hip Spacer System:  
 - REMEDY POLY+PLUS Acetabular Cup  
 - REMEDY CoCr Modular Femoral Head

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

**Prepared by:** MCRA, LLC  
 803 7<sup>th</sup> Street, NW, 4<sup>th</sup> Floor  
 Washington, DC 20001  
 Office: 202.552.5800

**Date Prepared:** December 19, 2025

**Classifications:** 21 CFR 888.3360, Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

**Class:** II

**Product Codes:** KWL, KWY

**Subject & Predicate Devices:**

Subject Devices	Predicate Devices
REMEDY POLY+PLUS Acetabular Cup	REMEDY Acetabular Cup (K192995, K191981 and K173967)
REMEDY CoCr Modular Femoral Head	REMEDY Hip Spacer (K112470) – Originally cleared under the trade name, 2GC Hip/Knee Modular Spacer REMEDY SPECTRUM GV Hip Spacer (K172906) – Originally cleared under the trade name, REMEDY PLUS Hip Spacer XS REMEDY and REMEDY SPECTRUM GV Modular Heads

The subject devices are substantially equivalent to the previously cleared components of the OsteoRemedies Hip Spacer System with respect to intended use, materials, design, and function. The information summarized in the Design Control Activities Summary demonstrates that the subject components met the pre-determined acceptance criteria for the verification activities.

**Reference Device:**

DePuy Prostalac Hip System (H000004, converted to a 510(k) in February 2003)

**Indications For Use:**

The OsteoRemedies Hip Spacer System consists of modular heads and stems, and optional acetabular cups. The REMEDY® components of the OsteoRemedies Hip Spacer System include gentamicin and the REMEDY SPECTRUM® GV components include gentamicin and vancomycin.

The OsteoRemedies Hip Spacer System is indicated for temporary use (maximum 180 days) as an adjunct to total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin or gentamicin/vancomycin are the most appropriate antibiotics based on the susceptibility pattern of the infecting micro-organism(s).

Following removal of the existing femoral and acetabular components and radical debridement, the head and stem components are inserted into the femoral medullary canal and can mate directly with the native acetabulum or an acetabular component which is placed in the acetabular cavity. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The OsteoRemedies Hip Spacer System is not intended for use for more than 180 days, at which time all components must be explanted, and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.).

**Device Description:**

The OsteoRemedies' REMEDY Hip Spacer and REMEDY SPECTRUM GV Hip Spacer families (K112470, K172906, K191981, K192995) are legally marketed devices that are used in skeletally mature patients undergoing a two-stage procedure due to a septic process.

The 510(k)-cleared Hip Spacer is a temporary hip spacer device consisting of independent components (femoral stem, head, and cup components). All hip spacer constructs include component(s) manufactured from PMMA with gentamicin (REMEDY Hip Spacers) or PMMA with gentamicin and vancomycin (REMEDY SPECTRUM GV Hip Spacers); the stems are structurally reinforced with a stainless steel core.

The subject REMEDY POLY+PLUS Acetabular Cup and REMEDY CoCr Modular Femoral Head Components are intended to be a line extension to the REMEDY Hip Spacer and REMEDY SPECTRUM GV Hip Spacer families (K112470, K172906, K191981, K192995).

**Performance Testing Summary:**

*Sterilization and Shelf-Life:*

The devices are sterilized using standard methods and the sterilization cycles have been validated following international standards. The shelf life has been established through

stability studies. The sterilization validation complies with ISO 11135, ISO 11137, ISO 11138. Sterilization as validated with a sterility assurance level of  $10^{-6}$ .

*Biocompatibility*

Biocompatibility evaluation has been performed to show the device materials are safe, biocompatible and suitable for their intended use. Both ISO 10993 and FDA Draft Guidance “Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process” have been taken into account to evaluate the biocompatibility of the device materials.

*Performance Testing:*

The following performance characteristics of the device have been assessed:

- Wear Characteristics
- Elution Profile of the System
- Range of Motion Assessment
- Interconnection Assessment

**Substantial Equivalence:**

The subject devices were demonstrated to be substantially equivalent to the predicates with respect to indications, design materials, function, manufacturing, and performance.

**Conclusion:**

Based on the information provided within this 510(k), the subject device is determined to be substantially equivalent to the predicate devices.