July 24, 2026

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

Re: K262290
Trade/Device Name: REMEDY POLY+PLUS SNAP FIT Acetabular Cup
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: July 6, 2026
Received: July 6, 2026

Dear Ms. 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 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: 2026.07.24 10:46:09 -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.	K262290

Please provide the device trade name(s).

REMEDY POLY+PLUS SNAP FIT Acetabular Cup

Please provide your Indications for Use below.

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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

Device Trade Name: OsteoRemedies Hip Spacer System:
- REMEDY POLY+PLUS SNAP FIT Acetabular Cup

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

Prepared by: MCRA, LLC
803 7th Street, NW, 4th Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: July 6, 2026

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

Class: II

Product Codes: KWL, KWY

Subject, Predicate, & Reference Devices:

Subject Device	REMEDY POLY+PLUS SNAP FIT Acetabular Cup
Predicate Device	REMEDY POLY+PLUS Acetabular Cup (K253675)
Reference Device	DePuy Prostalac Hip System (H000004, converted to a 510(k) in February 2003)

The subject REMEDY POLY+PLUS SNAP FIT Acetabular Cup (i.e., 40mm and 44mm constrained acetabular cup manufactured from crosslinked, Vitamin E UHMWPE) is 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 component met the pre-determined acceptance criteria for the verification activities.

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, K253675) 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 SNAP FIT Acetabular Cups are intended to be a line extension to the REMEDY Hip Spacer and REMEDY SPECTRUM GV Hip Spacer families (K112470, K172906, K191981, K192995, K253675).

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 was validated with a sterility assurance level of 10^{-6}.

Package integrity testing was performed per ISO 11607-1, ISO 11607-2, ASTM F1886, ASTM F88, ASTM D4196, and label legibility inspection.

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:

- Range of Motion
- Wear Performance
- Insertion Force (head into cup)
- Lever Out Moment (head from cup)
- Antibiotic Content of the System

Comparison of Technological Similarities and Differences:

The REMEDY POLY+PLUS SNAP FIT Acetabular Cup has the same indications and is made of the same material as the REMEDY POLY+PLUS Acetabular Cup (K253675). Both cups are intended to be mated with the REMEDY CoCr Modular Femoral Head and a REMEDY or REMEDY SPECTRUM GV Hip Stem.

The subject device differs from the predicate REMEDY POLY+PLUS Acetabular Cup in that it employs a snap fit with the femoral head while the predicate cup has a semi-constrained design. In addition, the subject cup is available in inner diameters of 40mm and 44mm while the predicate cup is available in inner diameters of 40mm, 44mm, and 46mm.

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.