August 23, 2019

OsteoRemedies, LLC
% Hollace Saas Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20005

Re: K191981
Trade/Device Name: REMEDY 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 24, 2019
Received: July 24, 2019

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 (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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Laurence D. Coyne, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191981

Device Name
REMEDY Acetabular Cup

Indications for Use *(Describe)*

The REMEDY Acetabular Cup 46mm ID/54mm OD consists of an acetabular cup that 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.

The REMEDY Acetabular Cup 46mm ID/54mm OD is positioned into the acetabular cavity following removal of the existing acetabular and femoral components and radical debridement. The device must be combined with the REMEDY Hip Spacer using the REMEDY 46mm Modular Head when gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s), or the REMEDY SPECTRUM GV Hip Spacer using the REMEDY SPECTRUM GV 46mm Modular Head when gentamicin and vancomycin are the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s). The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The REMEDY Acetabular Cup 46mm ID/54mm OD is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, etc.).

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.

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510(k) Summary for REMEDY Acetabular Cup

Submitter: OsteoRemedies, LLC
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Email: info@osteoremedies.com

Official Correspondent: Ms. Hollace Saas Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
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Washington, DC 20001
Phone: (202) 552-5807
Email: hrhodes@mcra.com

Date Prepared: August 16, 2019

Trade Name: REMEDY Acetabular Cup

Common Name: Temporary acetabular cup spacer with gentamicin

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

Product Codes: KWL, KWY

Predicate Devices: REMEDY Acetabular Cup (K173967)

REMEDY SPECTRUM GV Hip Spacer (K172906)

Device Description:

The REMEDY Acetabular Cup is a temporary spacer device available in a single size, intended to be combined with either the REMEDY Hip Spacer with 46mm Modular Head or the REMEDY SPECTRUM GV Hip Spacer using its 46 mm Modular Head.

The REMEDY Acetabular Cup is a sterile, single-use device intended for temporary use (maximum 180 days) as joint replacement. The device is made of fully formed polymethylmethacrylate (PMMA), which is radio-opaque and contains gentamicin.

The REMEDY Acetabular Cup and REMEDY or REMEDY SPECTRUM GV Hip Spacers provide a functional-mechanical mode of action; the system provides patients a temporary implant allowing for a natural range of motion and partial weight-bearing during treatment. The system is designed to preserve soft tissue to prevent further complications, such as muscular contraction, and to facilitate the subsequent joint replacement procedure. The REMEDY Acetabular Cup is protected from bacterial adhesion due to the presence of gentamicin.

Indications for Use:

The REMEDY Acetabular Cup 46mm ID/54mm OD consists of an acetabular cup that 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.

The REMEDY Acetabular Cup 46mm ID/54mm OD is positioned into the acetabular cavity following removal of the existing acetabular and femoral components and radical debridement. The device must be combined with the REMEDY Hip Spacer using the REMEDY 46mm Modular Head when gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s), or the REMEDY SPECTRUM GV Hip Spacer using the REMEDY SPECTRUM GV 46mm Modular Head when gentamicin and vancomycin are the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s). The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The REMEDY Acetabular Cup 46mm ID/54mm OD is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, etc.).

Predicate Devices:

The subject REMEDY Acetabular Cup is substantially equivalent to the REMEDY Acetabular Cup (K173967) with respect to intended use, materials, design, and function. The subject device is substantially equivalent to the REMEDY SPECTRUM GV Hip Spacer (K172906) with respect to intended use, materials, antibiotics, and function.

Substantial Equivalence:

Performance testing including static and fatigue strength of the resin, range of motion, surface roughness and antibiotic release kinetics were performed on the REMEDY Acetabular Cup, and an engineering analysis of wear was performed to support its substantial equivalence. The device is tested for endotoxins using the LAL test (gel clot) in conformance with the EP current edition of the test and must meet <20 EU/device. In addition, the total amount of antibiotics when the REMEDY Acetabular Cup is mated with the REMEDY SPECTRUM GV Hip Spacer was determined to be substantially equivalent to predicate devices.