January 10, 2020

OsteoRemedies, LLC
% Hollace Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
1050 K Street NW
Suite 1000
Washington, District of Columbia 20001

Re: K192995
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: December 10, 2019
Received: December 11, 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); 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,

Laura C. Rose, Ph.D.
Acting 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)*
K192995

Device Name
OsteoRemedies Hip Spacer System

Indications for Use *(Describe)*

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.).

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.

510(k) Summary

Submitter: OsteoRemedies, LLC
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Official Correspondent: Ms. Hollace Saas Rhodes
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Washington, DC 20001
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Date Prepared: January 10, 2020

Trade Names: OsteoRemedies Hip Spacer System:

- REMEDY® Modular Head 40mm,
- REMEDY SPECTRUM® GV Modular Femoral Head – 40mm,
- REMEDY® Acetabular Cup 40mm ID/48mm OD

Common Name: Temporary femoral head and acetabular cup spacer with antibiotic

Classification: Class II

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

Product Codes: KWL, KWY

Subject & Predicate Devices:

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

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.

Device Description:

The OsteoRemedies Hip Spacer System is a modular temporary spacer device inclusive of femoral stems, femoral heads, and acetabular cups. The OsteoRemedies Hip Spacer System is sterile and single-use, intended for temporary use (maximum 180 days) for joint replacement. This submission expands the existing system to include additional sizes of the acetabular cup and femoral head. The system components are made of fully formed polymethylmethacrylate (PMMA) with gentamicin (REMEDY®) and gentamicin with vancomycin (REMEDY SPECTRUM® GV).

The OsteoRemedies Hip Spacer System provides 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® components are protected from bacterial adhesion due to the presence of gentamicin. The REMEDY SPECTRUM® GV components are protected from bacterial adhesion due to the presence of gentamicin and vancomycin.

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.).

Performance Testing:

The following testing was performed on the predicate devices and is applicable to the subject components of the OsteoRemedies Hip Spacer System:

- Stem fatigue per ISO 7206-4
- Neck fatigue per ISO 7206-6

- Femoral head/stem disassembly based on ISO 7206-13
- Chemical and physical properties of cement
- Antibiotic elution kinetics
- Clinical data
- Biocompatibility data
- Sterilization, pyrogenicity, bacterial endotoxin, and shelf life testing

Substantial Equivalence:

Analyses of static and fatigue strength of the resin, fatigue strength of the head/stem construct, range of motion, risk of dislocation, surface roughness, and wear were performed on the XS REMEDY Head, XS REMEDY SPECTRUM GV Head, and XS REMEDY Acetabular Cup to support their substantial equivalence. In addition, the extra-small head and cup components contain less antibiotics than larger, previously cleared components of the OsteoRemedies Hip Spacer System.