January 5, 2023

OsteoRemedies, LLC
℅ Hollace Saas Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
803 7th Street NW
Third Floor
Washington, District of Columbia 20001

Re: K223650
Trade/Device Name: REMEDY Stemmed Knee Spacer
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: December 5, 2022
Received: December 6, 2022

Dear Ms. 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 (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,

Sara S. Thompson -S

For

Laura C. Rose, 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)*

K223650

Device Name

REMEDY Stemmed Knee Spacer

Indications for Use *(Describe)*

The REMEDY Stemmed Knee Spacer, which consists of a modular femoral, tibial and stem extension components, is indicated for temporary use (maximum 180 days) as an adjunct to total knee replacement (TKR) in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s).

The device is applied on the femoral condyles (femoral component) and on the tibial plate (tibial component) following removal of the existing implant and radical debridement. The use of the stem extension component is optional to replace the space occupied by the previous femoral and/or tibial stem (dead space management). Moreover, if necessary, the tibial component could be coupled with the OsteoRemedies REMEDY Tibial Insert Wedge when a large tibial defect is present.

The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The REMEDY Stemmed Knee Spacer 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, fusion etc.). Because of the inherent mechanical limitations of the device materials (gentamicin/polymethylmethacrylate), the device is only indicated for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers, canes) throughout the implantation period, allowing basic joint mobility.

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:
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Official Correspondent:
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Phone: (202) 552-5807
hrhodes@mcra.com

Date Prepared: January 3, 2023

Trade Name: REMEDY Stemmed Knee Spacer

Common Name: Temporary Knee Spacer with Gentamicin

Classification: Class II
21 CFR 888.3560, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Product Code: JWH

Predicate Device: REMEDY Stemmed Knee Spacer (K183017)

Device Description:

The REMEDY Stemmed Knee Spacer System is a temporary knee spacer system consisting of femoral, tibial, and tibial wedge components, and stem extensions which can be combined to address dead space management following explantation of an infected total knee arthroplasty device. These components are available in different sizes to generally

match the sizes of the explanted components and to accommodate variations in patient anatomy.

The stem extension components can be coupled with the femoral and tibial implant components to address dead space management in the femoral and tibial intramedullary canals following removal of infected stemmed prostheses.

The components of the REMEDY Stemmed Knee Spacer System are sterile, single-use devices intended for temporary use (maximum 180 days) as joint replacement. The components are made of fully formed polymethylmethacrylate (PMMA), which is radiopaque and contains gentamicin. The stem components have a stainless steel core.

The REMEDY Stemmed Knee Spacer System provides patients a temporary complete knee implant that allows for a natural range of motion and partial weight-bearing during treatment of the infection, and preserves the soft tissue to prevent further complications, such as muscular contraction, to facilitate the subsequent joint replacement procedure after systemic treatment of the underlying infection. The components of the REMEDY Stemmed Knee Spacer System are protected from bacterial adhesion due to the presence of gentamicin.

Indications for Use:

The REMEDY Stemmed Knee Spacer, which consists of a modular femoral, tibial and stem extension components, is indicated for temporary use (maximum 180 days) as an adjunct to total knee replacement (TKR) in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s).

The device is applied on the femoral condyles (femoral component) and on the tibial plate (tibial component) following removal of the existing implant and radical debridement. The use of the stem extension component is optional to replace the space occupied by the previous femoral and/or tibial stem (dead space management). Moreover, if necessary, the tibial component could be coupled with the OsteoRemedies REMEDY Tibial Insert Wedge when a large tibial defect is present.

The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The REMEDY Stemmed Knee Spacer 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, fusion etc.). Because of the inherent mechanical limitations of the device materials (gentamicin/polymethylmethacrylate), the device is only indicated for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers, canes) throughout the implantation period, allowing basic joint mobility.

Substantial Equivalence:

The REMEDY Stemmed Knee Spacer share many of the same technological characteristics compared to the predicate REMEDY Stemmed Knee Spacer, including important considerations such as the same materials, same PMMA bone cement formulation including antibiotic concentration, and mechanical performance. An overview of these technological characteristics is shown in the table below.

Characteristics	REMEDY Stemmed Knee Spacer (Subject Device)	REMEDY Stemmed Knee Spacer (Predicate Device)
Materials	Polymethylmethacrylate (PMMA) Barium Sulphate Gentamicin Sulphate	Polymethylmethacrylate (PMMA) Barium Sulphate Gentamicin Sulphate
Antibiotic	Gentamicin Sulphate	Gentamicin Sulphate
Single Use Device	Yes	Yes
Provided Sterile	Yes	Yes
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}
Shelf-Life	45 Months	45 Months
Design	Femoral component, tibial component, stem extension components, tibial wedge components	Femoral component, tibial component, stem extension components, tibial wedge components
Stem Extension Dimensions	Femoral component: Small, Medium, Large, X-Large Tibial component: Small, Medium, Large Stem extension component: 100mm, 150mm, 175mm, 230mm	Femoral component: Small, Medium, Large, X-Large Tibial component: Small, Medium, Large Stem extension component: 100mm, 175mm

Performance Data:

Sterilization and Shelf Life:

The devices are sterilized using standard methods and the sterilization cycles have been validated following international standards. The shelf life of the devices has been established through stability studies. The sterilization validation complies with: UNI EN ISO 11135:2014; EC 1-2011 UNI EN ISO 11737-1:2006, UNI EN ISO 11737- 2:2010, UNI EN ISO 10993-7:2009, UNI EN 556-1:2002, EP current Edition. The sterilization cycle was validated to a sterility assurance level of 10-6. The shelf life of the REMEDY Stemmed Knee Spacer was established through realtime and accelerated aging studies. All demonstrate a shelf life of 45 months.

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 of Subject REMEDY Stemmed Knee Spacer:

- Antibiotic elution testing
- Fatigue behavior of the stem extensions,
- Interconnection strength

The performance data demonstrate that the Remedy Stemmed Knee Spacer is substantially equivalent to the predicate devices.