October 2, 2024

OsteoRemedies, LLC
℅ Michael Coladonato
Associate Director, Regulatory Affairs
MCRA LLC
803 7th Street NW, Third Floor
Washington, District of Columbia 20001

Re: K242377
Trade/Device Name: REMEDY Stemmed Knee Spacer System with All-Poly Tibial Component
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: August 9, 2024
Received: August 9, 2024

Dear Michael Coladonato:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSE MUIR -S
Digitally signed by JESSE MUIR -S
Date: 2024.10.02 11:27:08 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242377

Device Name

REMEDY Stemmed Knee Spacer System with All-Poly Tibial Component

Indications for Use *(Describe)*

The REMEDY Stemmed Knee Spacer, which consists of 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 where gentamicin is the most appropriate antibiotic based on the susceptibility of the infecting micro-organism(s).

The REMEDY Stemmed Femoral Component can be used with a PMMA Tibial Component or an All-Poly tibial component. 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). Stem Extensions may be used with the Femoral and Tibial components. Moreover, if necessary, the Tibial Component could be coupled with the 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 device is intended for use with antibiotic (gentamicin) bone cement.

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, 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.

Administrative Documentation

510(k) Summary

Device Trade Name: REMEDY Stemmed Knee Spacer System with All-Poly Tibial Component

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, 3rd Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: September 24, 2024

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

Class: II

Product Codes: JWH

Primary Predicate: REMEDY Knee Spacer Family (K183017 and K223650)

Indications For Use:
The REMEDY Stemmed Knee Spacer, which consists of 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 where gentamicin is the most appropriate antibiotic based on the susceptibility of the infecting micro-organism(s).

The REMEDY Stemmed Femoral Component can be used with a PMMA Tibial Component or an All-Poly tibial component. 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). Stem Extensions may be used with the Femoral and Tibial components. Moreover, if necessary, the Tibial Component could be coupled with the 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 device is intended for use with antibiotic (gentamicin) bone cement.

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, 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.

Device Description:
The OsteoRemedies' REMEDY Stemmed Knee Spacer (K183017, K223650) 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 REMEDY Stemmed Knee Spacer is a temporary knee spacer device consisting of independent components (femoral component, tibial component and stem extension components) that can be combined with each other and the optional insert wedge depending on the anatomy of the patient. All components are manufactured from PMMA with gentamicin; the stems are structurally reinforced with a stainless steel core.

The subject REMEDY All-Poly Tibial Component is intended to be a line extension to the REMEDY Stemmed Knee Spacer (K183017, and K223650). The REMEDY All-Poly Tibial Component may be used in lieu of the currently cleared PMMA tibial component.

Predicate Devices:
OsteoRemedies submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the REMEDY Stemmed Knee Spacer System with All-Poly Tibial Component is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

- **Primary Predicate:** REMEDY Stemmed Knee Spacer Family (K183017, K223650)

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 11138. Sterilization as validated with a sterility assurance level of 10^{-6}. The shelf life of the device was established through real time and accelerated aging studies.

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:

- Fatigue Testing
- 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 cited in the table above 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.