July 25, 2019

OsteoRemedies LLC
% Diane Horwitz
Regulatory Affairs Consultant
Mandell Horwitz Consultants LLC
2995 Steven Martin Drive
Fairfax, Virginia 20031

Re: K183017
Trade/Device Name: Remedy® Femoral Component 84mm, 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: June 26, 2019
Received: June 26, 2019

Dear Ms. Horwitz:

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,

Laurence D. Coyne -S

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)*
K183017

Device Name
Remedy® Femoral Component 84mm

Indications for Use *(Describe)*
The Remedy Knee Spacer, which consists of a Femoral Component, a Tibial Component and a Tibial Insert, 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 Tibial Insert is optional, 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 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)*
K183017

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 OF SAFETY AND EFFECTIVENESS

1 GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

OsteoRemedies LLC
6800 Poplar Avenue
Suite 120
Memphis, TN 38138

1.2 Official Correspondent

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Regulatory Affairs Consultant
Mandell Horwitz Consultants, LLC
5 Lake Como Court
Greenville, South Carolina 29609

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1.3 Devices Subject of this 510(k)

Remedy® Stemmed Knee Spacer
Remedy® Femoral Component 84mm (Extra-Large)

1.4 Date of Preparation

July 24, 2019

2 NAME OF THE DEVICE AND CLASSIFICATION INFORMATION

2.1 Trade/Proprietary Name

Remedy® Stemmed Knee Spacer
Remedy® Femoral Component 84mm

2.2 Common/Usual Name

Temporary Knee Spacer with Gentamicin

2.3 Classification Information

Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Classification Regulation:	888.3560
Class:	II
Product Code(s):	JWH – prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
Panel:	Orthopaedic

3 PREDICATE DEVICES

The predicate devices are as follows:

- Remedy® Knee Spacer which was cleared originally through 510(k) application K112470.

In addition, the Remedy Stemmed Knee Spacer and the Remedy Femoral Component 84mm (Extra-Large) have also been compared to the following device for certain technological characteristics:

- InterSpace Knee which was cleared through 510(k) application K181732.

4 DEVICE DESCRIPTION

The Remedy® Knee Spacer, cleared via K112470, is a temporary knee spacer device consisting of independent components (femoral component, tibial component and insert wedge) that can be combined one with each other depending on the anatomy of the patient. The cleared femoral components are available in three sizes (54mm, 64mm and 74mm). With this 510(k) submission, OsteoRemedies is adding the additional 84mm size (extra-large) to the FDA cleared range of Remedy Femoral Component.

The 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 one with each other depending on the anatomy of the patient. These components are available in different sizes to further accommodate variations in patient anatomy.

The Stem Extension Implant components can be coupled with both the femoral and the tibial components, as they are intended to be used, if necessary, to replace the space occupied by the previous femoral and/or tibial stem. The Remedy Stemmed Tibial component could also be coupled, if necessary, with the commercially marketed Remedy Tibial Insert Wedge (K112470), when a large tibial defect is present.

The Remedy Femoral Component 84mm and the Remedy Stemmed Knee Spacer are sterile, single-use devices intended for temporary use (maximum 180 days) as joint replacement. The devices are made of fully formed polymethylmethacrylate (PMMA), which is radio-opaque

and contains gentamicin. The mass used to fill the molds (the unformed PMMA resin) is prepared from powder and liquid components. The liquid component consists of methylmethacrylate (MMA), N, N dimethyl-p-toluidine and hydroquinone; the powder component consists of PMMA, barium sulphate, benzoyl peroxide and gentamicin sulphate. The stem components also present an inner core of Stainless Steel (AISI 316 ESR).

The devices (which consists of the combination of single components) provide 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 devices are protected from bacterial adhesion due to the presence of gentamicin, similar to other spacers devices made with PMMA with antibiotics currently on the US market.

5 INDICATIONS FOR USE

Remedy® Femoral Component 84mm (Extra-Large)

The Remedy Knee Spacer, which consists of a Femoral Component, a Tibial Component and a Tibial Insert, 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 Tibial Insert is optional, 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 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.

Remedy® Stemmed Knee Spacer

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.

6 COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICES

The Remedy® Stemmed Knee Spacer, the Remedy® Femoral Component 84mm and the predicate device, the Remedy® Knee Spacer, are intended to be used in the same surgical procedure (two-stage revision procedure) in the same target patient population and have the same primary function of providing patients a temporary knee implant to allow for a natural range of motion and partial weight bearing. Thus, the Remedy® Femoral Component 84mm and the Remedy® Stemmed Knee Spacer have the same intended use as the predicate device. The Remedy® Stemmed Knee Spacer and the Remedy® Femoral Component 84mm also share the same intended use as the Tecres InterSpace Knee for the same reasons.

7 COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Remedy® Femoral Component 84mm (Extra-Large)

The Remedy® Femoral Component 84mm shares many of the same technological characteristics with the predicate Remedy® Knee Spacer, including important considerations such as the same materials, same PMMA bone cement formulation including antibiotic concentration, and mechanical performances. The technological characteristics are the same between the proposed device and the predicate device (see Table 1). The Remedy® Femoral Component 84mm results in four available sizes for the spacer device similar to the Tecres InterSpace Knee in terms of available sizes.

Table 1: Summary of Technological Characteristics between the Remedy® Femoral Component 84mm and the Remedy® Femoral Component 54mm, 64mm, 74mm

Characteristics	OsteoRemedies LLC Remedy® Femoral Component 84mm (subject device)	OsteoRemedies LLC Remedy® Femoral Component 54mm, 64mm, 74mm (Predicate Device, K112470)	Comparison
Main Material Components	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Barium Sulphate	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Barium Sulphate	Same
Other Material Components	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Same
Antibiotic	Gentamicin Sulphate	Gentamicin Sulphate	Same
Modularity	Femoral Component Tibial Component Tibial Insert Wedge (optional)	Femoral Component Tibial Component Tibial Insert Wedge (optional)	Same
Femoral Component Sizes	84mm	54mm, 64mm, 74mm	Different
X-ray Visibility	Yes	Yes	Same
Single-use Device	Yes	Yes	Same
Provided Sterile	Yes	Yes	Same
Spacer Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sterility Assurance Level (SAL) – Powder	10^{-6}	10^{-6}	Same
Shelf Life	45 months	60 months	Different

Remedy® Stemmed Knee Spacer

The Remedy® Stemmed Knee Spacer shares many of the same technological characteristics compared to the predicate Remedy® Knee Spacer, including important considerations such as the same materials, same PMMA bone cement formulation including antibiotic concentration, and mechanical performances. The technological characteristics are the same between the proposed device and the predicate device (see Table 2).

Table 2: Summary of Technological Characteristics between the Remedy® Stemmed Knee Spacer and the Predicate Device, the Remedy® Knee Spacer

Characteristics	OsteoRemedies LLC Remedy® Stemmed Knee Spacer (Subject Device)	OsteoRemedies LLC Remedy Knee Spacer (Predicate Device, K112470)	Comparison
Main Material Components	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Barium Sulphate	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Barium Sulphate	Same
Other Material Components	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Same
Antibiotic	Gentamicin Sulphate	Gentamicin Sulphate	Same
Inner core	Stem Extension: Stainless Steel (AISI 316 ESR)	None	Different
Design (shape)	Femoral Component Tibial Component Stem Extension Components (optional)	Femoral Component Tibial Component Tibial Insert Wedge (optional)	Different
Modularity and Sizes	Femoral Component: 4 sizes Tibial Component: 3 sizes Stem Extension Component: 2 sizes	Femoral Component: 4 sizes* Tibial Component: 3 sizes Tibial Insert Wedge: 3 sizes	Different
X-ray Visibility	Yes	Yes	Same
Single-use Device	Yes	Yes	Same
Provided Sterile	Yes	Yes	Same
Spacer Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sterility Assurance Level (SAL) – Powder	10^{-6}	10^{-6}	Same
Shelf Life	45 months	60 months	Different

*Includes the 84mm size requested for clearance in this submission.

8 PERFORMANCE DATA

This 510(k) notification provided performance data to establish the substantial equivalence of the Remedy® Femoral Component 84mm and of the Remedy® Stemmed Knee Spacer to the predicate device. The following is a summary of the 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 Femoral Component 84mm and of the Remedy Stemmed Knee Spacer was established through real-time 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 on the Remedy Femoral Component 84mm: Performance testing was performed to characterize the Remedy Femoral Component 84mm in comparison to the predicate Remedy Knee Spacer.

This testing included the evaluation of:

- the static performances of the resin (ISO 5833),
- the fatigue performances of the resin (ASTM F2118),
- the surface roughness (ISO 4287),
- the range of motion (ASTM F2083),
- the device wear (ISO 14243-1), and
- the antibiotic (gentamicin) elution testing.

The performance data demonstrate that the Remedy Femoral Component 84mm is substantially equivalent to the predicate device.

Performance Testing on the Remedy Stemmed Knee Spacer: Performance testing was performed to characterize the Remedy Stemmed Knee Spacer in comparison to the predicate Remedy Knee Spacer.

This testing included the evaluation of

- the static performances of the resin (ISO 5833),
- the fatigue performances of the resin (ASTM F2118),
- the surface roughness (ISO 4287),
- the tibial tray fatigue behavior (ASTM F1800),
- the fatigue behavior of the stem extensions,
- the range of motion (ASTM F2083),
- the device wear (ISO 14243-1), and
- the antibiotic (gentamicin) elution testing.

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