February 22, 2018

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

Re: K173967
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, KWZ
Dated: December 28, 2017
Received: December 29, 2017

Dear Dr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K173967

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, and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s).

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 REMEDY® Hip Spacer using REMEDY® Modular Head 46 mm. 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.

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

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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
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1.3 510(k) Number and Devices Subject of this 510(k)

K173967
Remedy® Acetabular Cup

1.4 Date of Preparation

February 4, 2018

2 NAME OF THE DEVICE AND CLASSIFICATION INFORMATION

2.1 Trade/Proprietary Name

Remedy® Acetabular Cup

2.2 Common/Usual Name

Temporary Acetabular Cup Spacer with Gentamicin

2.3 Classification Information

Classification Name:	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis	Hip joint metal/polymer constrained cemented or uncemented prothesis

Classification Regulation:	888.3360	888.3310
Class:	II	II
Product Code(s):	KWL - Prosthesis, Hip, Hemi-, Femoral, Metal KWY - Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented or Uncemented	KWZ – Prosthesis, Hip, Constrained or Uncemented, Metal/Polymer
Panel:	Orthopaedic	Orthopaedic

3 PREDICATE DEVICE

The predicate device is as follows:

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

4 DEVICE DESCRIPTION

The Remedy® Acetabular Cup is a temporary spacer device available in a single size, intended to be combined with Remedy Hip Spacer using Remedy® Modular Head 46 mm.

The Remedy® Acetabular Cup is 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 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 Remedy® Hip Spacer and Acetabular Cup 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, similar to other spacers devices made from antibiotic loaded PMMA currently on the US market.

5 INDICATIONS FOR USE

Below is the indication 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, and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s).*

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 REMEDY® Hip Spacer using REMEDY® Modular Head 46 mm. 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.).

6 COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICE

The Remedy® Acetabular Cup and the predicate device are intended to be used in the same surgical procedure (two-stage revision procedure) in the same target patient population, and provide the same primary function of providing patients a temporary hip implant to allow for a natural range of motion and partial weight bearing. Thus, the Remedy® Acetabular Cup has the same intended use as the predicate device.

7 COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Remedy® Acetabular Cup shares many of the same technological characteristics compared to the predicate Remedy® Hip 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).

Table 1: Summary of Technological Characteristics between the Remedy® Acetabular Cup and the Predicate Device, the Remedy® Hip Spacer

Characteristics	**OsteoRemedies LLC Remedy® Acetabular Cup – Subject Device**	**OsteoRemedies LLC Remedy® Hip 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	None	Stainless Steel (AISI 316 ESR)	Different
Design (shape)	Cup	Head + Stem	Different
Modularity and Sizes	None – 1 size for cup to match 46 mm head	3 heads, 3 stems, offset adjustment	Different
Articulating Surfaces	PMMA (Remedy acetabular cup) PMMA (Remedy hip spacer)	Patient Bone - PMMA (Remedy hip spacer)	Different
X-ray Visibility	Yes	Yes	Same

Characteristics	OsteoRemedies LLC Remedy® Acetabular Cup – Subject Device	OsteoRemedies LLC Remedy® Hip Spacer – Predicate Device (K112470)	Comparison
Single-use Device	Yes	Yes	Same
Provided Sterile	Yes	Yes	Same
Spacer Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Shelf Life	5 years	5 years	Same

The Remedy® Acetabular Cup and the predicate device, the Remedy® Hip Spacer, are intended to be used together to form a total hip implant; this is analogous to the Prostalac Hip System by DePuy Orthopedics, which served as a reference device for this design feature. Both provide total hip temporary spacers with antibiotic-loaded PMMA cement.

8 PERFORMANCE DATA

This 510(k) notification provided performance data to establish the substantial equivalence of the Remedy® Acetabular Cup 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 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.

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: Performance testing was performed to characterize the Remedy Acetabular Cup. This testing included the evaluation of the static and fatigue performances, the surface roughness, the device wear and the antibiotic (gentamicin) elution testing.

The performance data demonstrate that the new device is substantially equivalent to the predicate device.