



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Osteoremedies LLC
% Diane M. Horwitz, Ph.D., RAC
Regulatory Affairs Consultant
Mandell Horwitz Consultants, LLC
2995 Steven Martin Drive
Fairfax, Virginia 22031

December 30, 2015

Re: K152267

Trade/Device Name: Remedy® Shoulder Spacer
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, MBB
Dated: November 17, 2015
Received: November 17, 2015

Dear Dr. Horwitz:

This letter corrects our substantially equivalent letter of December 15, 2015.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K152267

Device Name
Remedy® Shoulder Spacer

Indications for Use (Describe)

The Remedy® Shoulder Spacer, which consists of a modular head and stem, is indicated for temporary use (maximum 180 days) as an adjunct to total or hemi-shoulder replacement 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-organisms.

The head and stem components are inserted into the glenoidal cavity and humeral medullary canal, respectively, following removal of the existing prosthetic components and radical debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The Remedy® Shoulder 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.).

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.

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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
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Memphis, TN 38138

1.2 Official Correspondent

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1.3 Devices Subject of this 510(k)

Remedy[®] Shoulder Spacer

1.4 Date of Preparation

October 25, 2015

2 NAME OF THE DEVICE AND CLASSIFICATION INFORMATION

2.1 Trade/Proprietary Name

Remedy[®] Shoulder Spacer, K152267

2.2 Common/Usual Name

Modular temporary shoulder prosthesis with gentamicin

2.3 Classification Information

Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Classification Regulation:	888.3660
Regulatory Class:	II
Product Code:	KWS – prosthesis, shoulder, semi-constrained, metal/polymer cemented
Panel:	Orthopedic

Because the Remedy[®] Shoulder Spacers are made from antibiotic containing bone cement, they may also be classified as Class II medical device within the generic type of device known as:

Classification Name: Polymethylmethacrylate (PMMA) Bone Cement

Classification Regulation: 21 CFR § 888.3027

Regulatory Class: Class II

Product Code: MBB – Bone cement, antibiotic

Panel: Orthopedic

3 PREDICATE DEVICE

The predicate device is as follows:

- Tecres' InterSpace Shoulder, which was cleared through 510(k) application K060535 and K112983.

The following reference devices were considered in analysis of the technological characteristics of the Remedy[®] Shoulder Spacer.

- Reference devices for discussion of sizes and shapes: StageOne Shoulder Cement Spacer Molds (K131135), Equinox Shoulder System (K042021, K061454, K140063), Solar Total Shoulder System (K040432), and Univers II Total Shoulder System (K071032, K103466).
- Reference devices for evaluation of surface roughness: Tecres InterSpace Knee (K062273 and K062274) and OsteoRemedies Knee Modular Spacer (K112470).

4 DEVICE DESCRIPTION

The Remedy[®] Shoulder Spacer is a sterile, single-use device intended for temporary use (maximum 180 days) as shoulder replacement.

The Remedy[®] Shoulder Spacer is composed of two components (a head and a stem) that are intended to be used together to form a temporary shoulder spacer; the components are available in a range of sizes.

The device is made of fully formed polymethylmethacrylate (PMMA), which is radio-opaque and contains gentamicin. The stem component has also an inner stainless steel reinforcing structure.

The Remedy[®] Shoulder Spacer provides a functional-mechanical mode of action; it provides patients a temporary implant allowing for a natural range of motion and partial weight-bearing during treatment. It is designed to preserve soft tissue to prevent further complications, such as muscular contraction, and to facilitate the subsequent joint replacement procedure.

5 INDICATIONS FOR USE

Below is the indication for use.

The Remedy[®] Shoulder Spacer, which consists of a modular head and stem, is indicated for temporary use (maximum 180 days) as an adjunct to total or hemi-shoulder replacement 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-organisms.

The head and stem components are inserted into the glenoidal cavity and humeral medullary canal, respectively, following removal of the existing prosthetic components and radical debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The Remedy[®] Shoulder 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.).

6 COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICE

The Remedy[®] Shoulder Spacer 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 shoulder implant to allow for a natural range of motion and partial weight bearing. Thus, the Remedy[®] Shoulder Spacer has the same intended use as the predicate device.

7 COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Remedy[®] Shoulder Spacer share many similar technological characteristics compared to the predicate Tecres' Interspace Shoulder, including important considerations such as the same materials, and mechanical and chemical-physical performances. Both devices share the same tissue contact and duration of contact. Both are provided preformed to the user, sterile and for single-use. Nonetheless, there are differences in the design due to the modularity of the Remedy[®] Shoulder Spacer and the sizes of the devices. Indeed, the head and the stem components of the Remedy[®] Shoulder Spacer are provided separate in order to combine them at the time of use to achieve the final configuration and fit better the patient's anatomy. The sizes of the components have been chosen in order to cover most of shoulder prostheses configurations currently available on the US market (see list of reference devices for variations in sizes and shapes of shoulder prostheses). These comparisons are summarized in Table 1 on the following page.

Table 1: Comparison of the Technological Characteristics with the Predicate Device

Characteristics	OsteoRemedies LLC Remedy® Shoulder Spacer	Tecres SpA InterSpace Shoulder K060535 and K112983	Comparison
Main Components	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Barium Sulphate	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Barium Sulphate	Same
Other components	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Same
Antibiotics	Gentamicin Sulphate	Gentamicin Sulphate	Same
Inner core	Stainless Steel (AISI 316 ESR)	Stainless Steel (AISI 316 ESR)	Same
Design (shape)	Head + Stem (separated)	Head + Stem (monoblock)	Different
Modularity	3 heads, 3 stems, offset adjustment	None	Different
Head Size	Ø: 40 – 45 – 50 mm	Ø: 41 – 46 mm	Different
Stem Size	L: 101 mm Ø: 7 mm L: 116 mm Ø: 10.5 mm L: 131 mm Ø: 14 mm	L: 99 mm Ø: 7 mm L: 125 mm Ø: 11 mm	Different
Stem-neck angle	130°	130°	Same
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	5 years	5 years	Same

8 PERFORMANCE DATA

This 510(k) submission provided performance data to establish the substantial equivalence of the new line of shoulder spacers 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.

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” have been taken into account to evaluate the biocompatibility of the device materials.

Performance Testing: Performance testing was performed to characterize the Remedy[®] Shoulder Spacer. This testing included the evaluation of the static and fatigue performances, the surface roughness, the disassembling and the antibiotic (gentamicin) elution testing.

The performance data demonstrate that the new devices are substantially equivalent to the predicate device Tecres' Interspace Shoulder.