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

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

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.

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
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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Suite 120
Memphis, TN 38138

1.2 Official Correspondent

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Regulatory Affairs Consultants
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Fairfax, Virginia 20031

Telephone: (703) 307-2921
Fax: (703) 242-1117
E-mail: dnh@mandellhorwitzconsulting.com

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), Equinoxe 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 radiopaque 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

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>OsteoRemedies LLC Remedy® Shoulder Spacer</th>
<th>Tecres SpA InterSpace Shoulder K060535 and K112983</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Components</td>
<td>Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Barium Sulphate</td>
<td>Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Barium Sulphate</td>
<td>Same</td>
</tr>
<tr>
<td>Other components</td>
<td>Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone</td>
<td>Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone</td>
<td>Same</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>Gentamicin Sulphate</td>
<td>Gentamicin Sulphate</td>
<td>Same</td>
</tr>
<tr>
<td>Inner core</td>
<td>Stainless Steel (AISI 316 ESR)</td>
<td>Stainless Steel (AISI 316 ESR)</td>
<td>Same</td>
</tr>
<tr>
<td>Design (shape)</td>
<td>Head + Stem (separated)</td>
<td>Head + Stem (monoblock)</td>
<td>Different</td>
</tr>
<tr>
<td>Modularity</td>
<td>3 heads, 3 stems, offset adjustment</td>
<td>None</td>
<td>Different</td>
</tr>
<tr>
<td>Head Size</td>
<td>Ø: 40 – 45 – 50 mm</td>
<td>Ø: 41 – 46 mm</td>
<td>Different</td>
</tr>
<tr>
<td>Stem Size</td>
<td>L: 101 mm Ø: 7 mm L: 116 mm Ø: 10.5 mm L: 131 mm Ø: 14 mm</td>
<td>L: 99 mm Ø: 7 mm L: 125 mm Ø: 11 mm</td>
<td>Different</td>
</tr>
<tr>
<td>Stem-neck angle</td>
<td>130°</td>
<td>130°</td>
<td>Same</td>
</tr>
<tr>
<td>X-ray visibility</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>Single-use device</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>Provided Sterile</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>Ethylene Oxide</td>
<td>Ethylene Oxide</td>
<td>Same</td>
</tr>
<tr>
<td>Sterility Assurance Level (SAL) – Powder</td>
<td>10⁻⁶</td>
<td>10⁻⁶</td>
<td>Same</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>5 years</td>
<td>5 years</td>
<td>Same</td>
</tr>
</tbody>
</table>

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.