May 15, 2026

Depuy Ireland UC
Megan Palumbo
Regulatory Affairs Manager
Loughbeg
Ringaskiddy, County Cork P43 ED82
Ireland

Re: K260536
Trade/Device Name: Prostalac Hip System, SmartSet V+G Dual Antibiotic Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: MBB, LOD, KWL, KWY
Dated: April 22, 2026
Received: April 22, 2026

Dear Megan Palumbo:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.05.15 16:01:34 -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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K260536 |

Please provide the device trade name(s).

Prostalac Hip System;
SmartSet V+G Dual Antibiotic Bone Cement

Please provide your Indications for Use below.

The PROSTALAC Hip System is indicated for use as a short-term total hip replacement (THR) in patients who need a two-stage procedure to treat a confirmed infection of their THR and where vancomycin combined with either tobramycin OR gentamicin are the most appropriate antibiotics for treatment of the infection based on the susceptibility pattern of the infecting microorganism(s).

SmartSet V+G Dual Antibiotic Bone Cement is intended for use with the DePuy Prostalac Hip System. The SmartSet V+G Dual Antibiotic Bone Cement is indicated for the formation and fixation of the DePuy Prostalac Hip System to the host bone.

| | |
|---|---|
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) |
| Please select the age group(s) for which the device(s) is to be used. | ☐ Neonates/Newborns (Birth to < 29 days old)<br>☐ Infants (29 days old to < 2 years old)<br>☐ Children (2 years old to < 12 years old)<br>☐ Adolescents (12 years old to < 22 years old)<br>☒ Adults (22 years old and greater) |

# K260536 – 510(k) Summary

**I. Submitter**

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork
P43 ED82
Ireland

Contact: Megan Palumbo
Phone: (774) 282-0281
Email: MPalumb1@its.jnj.com

Date of Submission: February 13, 2026

**II. Device**

| | |
|---|---|
| **Device Proprietary Name** | Prostalac Hip System<br><br>SmartSet V+G Dual Antibiotic Bone Cement |
| **Common Name** | Temporary total hip replacement prosthesis<br><br>Bone Cement, Antibiotic<br>Polymethylmethacrylate (PMMA) bone cement |
| **Product Code and CFR Reference** | MBB – 21CFR 888.3027<br>LOD – 21CFR 888.3027<br>KWL – 21CFR 888.3360<br>KWY – 21CFR 888.3390 |
| **Regulatory Classification** | II |

**III. Predicate and Reference Devices**

**Predicate**
DePuy Prostalac Hip System (H000004 – March 19, 2001)
For use with SmartSet MV Bone Cement (K081155)

**Reference**
Biomet, Inc. StageOne Select Hip Cement Spacer Molds (K222760)
For use with Refobacin Bone Cement R (K171540)

Spectrum GV Bone Cement (K172906)

**IV. Device Description**

- **Prostalac Hip System**

The **Prost**hesis of **A**ntibiotic-**L**oaded **A**crylic **C**ement, also known as the PROSTALAC Hip System, is comprised of a core femoral implant, a modular femoral ball head, a one-piece, ultrahigh molecular weight polyethylene (UHMWPE) acetabular component, and a polymethylmethacrylate (PMMA) stem centering device. To form the implantable spacer, the system is used in conjunction with either the SmartSet MV Bone Cement (PMMA) mixed intraoperatively with tobramycin sulfate and vancomycin hydrochloride antibiotics or the proposed subject device, SmartSet V+G Dual Antibiotic Bone Cement. The SmartSet V+G Dual Antibiotic Bone Cement is supplied with vancomycin hydrochloride and gentamicin sulfate pre-blended into the powder and does not require the admixing of additional antibiotics prior to use.

The Prostalac Hip System is available in a range of femoral implant sizes intended to accommodate the patient population.

- **SmartSet V+G Dual Antibiotic Bone Cement**

SmartSet V+G Dual Antibiotic Bone Cement is a self-curing, radiopaque, polymethyl methacrylate-based cement, which contains 1.0g of active gentamicin and 1.9g of active vancomycin in 40g of bone cement powder, which is used for the formation and fixation of the DePuy Prostalac Hip Temporary Prosthesis System to the host bone.

Bone cements do not have intrinsic adhesive properties, however they instead rely on a close mechanical interlock between the irregular bone surface and the prosthesis.

The bone cement is supplied as a conventional two-component system, consisting of separate, sterile liquid and powder components, which are mixed together at the point of use to produce the bone cement.

The liquid component is sterilized by membrane filtration and aseptically filled into a sterile glass ampule. The ampule is contained within a sealed blister pack, which is sterilized using ethylene oxide. The powder component is contained in a primary paper-polyester pouch, within a secondary paper-polyester peelable pouch and is sterilized by gamma radiation. The sterile powder component is supplied within an outer, protective, non-sterile, laminated foil pouch.

The cement powder and liquid components can be mixed using a bowl mixing system and following the instructions in the Surgical Technique guide which

details the use of the cement for the formation and fixation of the DePuy Prostalac Hip System.

**V. Indications for Use**

The Indications for Use statement in the proposed device Instructions for Use is as follows:

- **Prostalac Hip System**

*The PROSTALAC Hip System is indicated for use as a short-term total hip replacement (THR) in patients who need a two-stage procedure to treat a confirmed infection of their THR and where* ***vancomycin combined with either tobramycin OR gentamicin*** *are the most appropriate antibiotics for treatment of the infection based on the susceptibility pattern of the infecting microorganism(s).*

- **SmartSet V+G Dual Antibiotic Bone Cement**

*SmartSet V+G Dual Antibiotic Bone Cement is intended for use with the DePuy Prostalac Hip System. The SmartSet V+G Dual Antibiotic Bone Cement is indicated for the formation and fixation of the DePuy Prostalac Hip System to the host bone.*

**VI. Comparison to Predicate and Reference Devices**

The subject device, the DePuy Prostalac Hip System for use with the SmartSet V+G Dual Antibiotic Bone Cement, is substantially equivalent to the predicate device, the DePuy Prostalac Hip System for use with the SmartSet MV Bone Cement.

In fact, the components of the Prostalac Hip System will remain unchanged and identical to the existing product in intended use, technological characteristics and clinical utility. The only change being proposed to the Prostalac Hip System is that it will be indicated for use with the subject bone cement, which is sold pre-blended with antibiotics, rather than requiring the end user to hand-blend the antibiotics intraoperatively.

The predicate and reference devices have the same intended use, technological properties, patient population, intended user, and function. Each system provides a range of sizes to suit the appropriate patient population.

**Substantial Equivalence Overview**

The SmartSet V+G Dual Antibiotic Bone Cement is similar to the predicate and references devices with respect to the following:

- The Predicate Prostalac Hip System is indicated for use with an antibiotic cement formulation containing a combination of vancomycin and an aminoglycoside.
- The Subject device contains the same two antibiotics as the reference Unite Plus Bone Cement.
- The main cement components of the predicate and reference devices are similar
- Similar mechanical performance characteristics, and
- Similar *in vitro* elution profiles

There are differences between the SmartSet V+G Dual Antibiotic Bone cement and the predicate device however, these differences do not impact the substantial equivalence determination:

- The SmartSet V+G Dual Antibiotic bone cement comes pre-blended with antibiotics whereas the predicate Prostalac Hip system currently specifies that the antibiotic cement formulation is prepared intraoperatively.
- The SmartSet V+G Dual Antibiotic Bone Cement contains vancomycin and gentamicin whereas the Prostalac predicate contains vancomycin and tobramycin.

**Performance Testing Overview**

Performance data for the SmartSet V+G Dual Antibiotic Bone Cement, the predicate and reference devices demonstrate their substantial equivalence. The following testing was performed:

- Chemical and physical properties of the cement
- Antibiotic elution kinetics
- Zone of inhibition testing
- Biocompatibility data
- Sterilization, pyrogenicity, endotoxin, and shelf life testing

**Table 1** below provides a comparison between the subject devices, the predicate devices, and reference devices.

| **Table 1: Properties of the Proposed, Predicate and Reference Devices** | | | | | |
|---|---|---|---|---|---|
| | **Subject Device**<br>(This submission)<br><br>Prostalac Hip Temporary Prosthesis System<br><br>*For Use With*<br>SmartSet V+G Dual Antibiotic Bone Cement | **Predicate Device**<br>(H000004, K081155)<br><br>Prostalac Hip Temporary Prosthesis System<br><br>*For Use With*<br>SmartSet MV Bone Cement | **Reference Device**<br>(K222760, K150850)<br><br>Zimmer Biomet StageOne Select Hip Cement Spacer Molds<br><br>*For Use With*<br>Refobacin Bone Cement R | **Reference Device**<br>(K172906)<br><br>Spectrum GV Bone Cement<br><br>*(Originally Cleared under the name,*<br>*"Unite Plus Bone Cement")* | **Comments on Equivalency** |
| **FDA Product Code** | MBB, LOD, KWL, KWY | MBB, LOD, KWL, KWY | MBB, KWL, KWY | MBB | **Equivalent** |
| **Classification** | 21CFR 888.3027<br>21CFR 888.3360<br>21CFR 888.3390 | 21CFR 888.3027<br>21CFR 888.3360<br>21CFR 888.3390 | 21CFR 888.3027<br>21CFR 888.3360<br>21CFR 888.3390 | 21CFR 888.3027 | **Equivalent** |
| **Classification Name** | Bone Cement, Antibiotic Polymethylmethacrylate (PMMA) bone cement<br><br>For Use with:<br>Hip joint femoral (hemi-hip) metallic/metal/polymer cemented or uncemented prosthesis. | Bone Cement, Antibiotic Polymethylmethacrylate (PMMA) bone cement<br><br>For Use with:<br>Hip joint femoral (hemi-hip) metallic/metal/polymer cemented or uncemented prosthesis. | Bone Cement, Antibiotic Polymethylmethacrylate (PMMA) bone cement<br><br>For Use with:<br>Hip joint femoral (hemi-hip) metallic/metal/polymer cemented or uncemented prosthesis. | Bone Cement, Antibiotic Polymethylmethacrylate (PMMA) bone cement | **Equivalent** |
| **Intended Use – Hip System** | This device is indicated for use as a short-term total hip replacement (THR) in patients who need a two-stage procedure to treat a confirmed infection of their THR. | This device is indicated for use as a short-term total hip replacement (THR) in patients who need a two-stage procedure to treat a confirmed infection of their THR. | StageOne antibiotic bone cement spacers are intended for use in patients undergoing a two-stage revision procedure due to prosthetic joint infection. | Not Applicable | **Equivalent** |
| **Intended Use – Bone Cement** | Bone Cement intended for the formation and fixation of a spacer device to the host bone. | Bone Cement intended for the formation and fixation of a spacer device to the host bone. | Bone Cement intended for the formation and fixation of a spacer device to the host bone. | Bone Cement is intended for the fixation of a spacer device to the host bone.<br><br>*This reference device is not intended for the formation of the | **Equivalent** |

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| | | | | temporary hip prosthesis, as the subject, predicate and other reference devices are. | |
| **Indications for Use – Hip System** | The PROSTALAC Hip System is indicated for use as a short-term total hip replacement (THR) in patients who need a two-stage procedure to treat a confirmed infection of their THR and where vancomycin combined with either tobramycin OR gentamicin are the most appropriate antibiotics for treatment of the infection based on the susceptibility pattern of the infecting microorganism(s). | The PROSTALAC Hip System is indicated for use as a short-term total hip replacement (THR) in patients who need a two-stage procedure to treat a confirmed infection of their THR and where vancomycin and tobramycin are the most appropriate antibiotics for treatment of the infection based on the susceptibility pattern of the infecting microorganism(s). | StageOne™ Select Hip Cement Spacer Molds with stainless steel reinforcement stems, adapters and inserts are indicated for use to mold a temporary hemi-hip replacement for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary prosthesis is molded using Refobacin Bone Cement R, assembled and inserted into the femoral medullary canal and acetabular cavity following removal of the existing femoral and acetabular replacement implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).<br><br>The hemi-hip prosthesis made from the StageOne™ Select Cement Spacer Molds is not intended for use more than 180 days, at which time it must be explanted and permanent devices implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.).<br><br>Due to the inherent mechanical limitations of the hemi-hip prosthesis material (Refobacin Bone Cement R), the temporary hemi-hip prosthesis is only indicated for patients who will consistently use traditional | The REMEDY PLUS Hip Spacer, which consists of a modular head and stem, 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 and vancomycin are the most appropriate antibiotics based on the susceptibility pattern of the infecting micro-organism(s).<br><br>The head and stem components are inserted into the acetabular cavity and femoral medullary canal, respectively, following removal of the existing acetabular and femoral components and radical debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).<br><br>The REMEDY PLUS Hip 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.). | **Substantially Equivalent** |

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| | | | mobility assist devices (e.g. crutches, walkers) throughout the implant period. | | |
| **Indications for Use – Bone Cement** | SmartSet V+G Dual Antibiotic Bone Cement is intended for use with the DePuy Prostalac Hip System. The SmartSet V+G Dual Antibiotic Bone Cement is indicated for the formation and fixation of the DePuy Prostalac Hip System to the host bone. | SmartSet MV Bone Cement is indicated for the fixation of prostheses to living bone in orthopaedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, and revision of previous arthroplasty.<br><br>The bone cement is indicated for use in children only in the case of limb preservation where no other procedure is likely to give a good chance of successful treatment.<br><br>The bone cement should be used with an appropriate prosthesis. | Refobacin® Bone Cement R is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared. | The UNITE PLUS Bone Cement is intended for the fixation of a REMEDY PLUS spacer device to the host bone. | **Substantially Equivalent** |
| **Single Use** | Yes | Yes | Yes | Yes | **Equivalent** |
| **Sterilization Method** | **Hip System**<br>Gamma Irradiation<br><br>**Cement**<br>Liquid Component:<br>Aseptic Processing Techniques<br><br>Glass Ampule: EO<br><br>Powder Component:<br>Gamma irradiation | **Hip System**<br>Gamma Irradiation<br><br>**Cement**<br>Liquid Component:<br>Aseptic Processing Techniques<br><br>Glass Ampule: EO<br><br>Powder Component: EO | **Hip System**<br>Gamma Irradiation<br><br>**Cement**<br>Liquid Component:<br>Aseptic Processing Techniques<br><br>Glass Ampule: EO<br><br>Powder Component: EO | **Cement**<br>Liquid Component:<br>Aseptic Processing Techniques<br><br>Glass Ampule: EO<br><br>Powder Component: Gamma Irradiation | **Substantially Equivalent**<br><br>All components of each device are provided sterile, using an FDA Established Category A. |
| **Packaging Components** | **Hip System**<br>Sterile peel pouch | **Hip System**<br>Sterile peel pouch | Packaging configuration is the same. Specifications, including packaging materials, are | Packaging configuration is the same. Specifications, including packaging materials, are | **Substantially Equivalent** |

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| | **Cement**<br>Powder: Paper-polyester primary sterile pouch, peelable non-sterile secondary paper-polyester pouch, followed by a foil sterile pouch for protection against moisture.<br><br>Liquid: Sterile ampule placed in a blister with Tyvek lid. | **Cement**<br>Powder: Paper-polyester primary sterile pouch, peelable non-sterile secondary paper-polyester pouch, followed by a foil sterile pouch for protection against moisture.<br><br>Liquid: Sterile ampule placed in a blister with Tyvek lid. | unknown as they are proprietary to the device Legal Manufacturer. | unknown as they are proprietary to the device Legal Manufacturer. | |
| ***BONE CEMENT ATTRIBUTES*** | | | | | |
| **Quantity of Active vancomycin per 40g powder pack of bone cement** | vancomycin– 1.9g | vancomycin– 1.0g<br><br>(added intraoperatively at cement mixing stage) | N/A | vancomycin– 1.0g | **Substantially Equivalent**<br><br>Bench elution testing has been conducted, which has demonstrated that the antibiotic elution profiles of the predicate and subject devises are substantially equivalent. |
| **Quantity of active aminoglycoside antibiotic per 40g powder pack of bone cement** | gentamicin– 1.0g | tobramycin–3.6g<br><br>(added intraoperatively at cement mixing stage) | gentamicin– 0.5g | gentamicin – 1.0g | **Substantially Equivalent**<br><br>Bench elution testing has been conducted, which has demonstrated that the antibiotic elution profiles of the predicate and subject devises are substantially equivalent. |
| **Non-Medicinal Cement Ingredients** | **Powder:**<br>Methyl Methacrylate/ Methyl Acrylate Copolymer<br>Zirconium Dioxide<br>Benzoyl Peroxide<br><br>**Liquid:**<br>Methyl methacrylate<br>N,N dimethyl-p-toluidine<br>Hydroquinone | **Powder:**<br>Polymethylmethacrylate<br>Zirconium Dioxide<br>Benzoyl Peroxide<br><br>**Liquid:**<br>Methyl methacrylate<br>N,N dimethyl-p-toluidine<br>Hydroquinone | **Powder:**<br>Poly (methyl acrylate, methyl methacrylate)<br>Zirconium dioxide Benzoyl peroxide<br><br>**Liquid:**<br>Methyl methacrylate<br>N,N-dimethyl-p-toluidine<br>Hydroquinone Chlorophyll (colorant)* | **Powder:**<br>Polymethylmethacrylate<br>Barium Sulphate**<br>Benzoyl Peroxide<br><br>**Liquid:**<br>Monomethylmethacrylate***<br>N,N dimethyl-p-toluidine<br>Hydroquinone | **Substantially Equivalent**<br><br>*The use of Chlorophyll as a colorant in the reference device, Refobacin Bone Cement R, provides no physiological effect.<br><br>**The reference device, Spectrum GV Bone Cement, contains Barium Sulphate, rather than Zirconium Dioxide as the radiopaque component of the powdered cement. The use |

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| | | | | | of Barium Sulphate or Zirconium Dioxide is considered equivalent for the purpose it serves.<br><br>***The reference device, Spectrum GV Bone Cement, contains Monomethylmethacrylate, which is an alternative chemical name for methyl methacrylate. This is the monomer which polymerizes to cause the cement to form a solid mass during curing. There are no differences between the predicate and proposed liquid components. |

**VII. Performance Data**

The following performance data has been provided in support of the substantial equivalence determination. All testing was performed on final sterile devices.

**Bench Testing**

Performance bench testing was conducted in alignment with FDA's guidance, *Polymethylmethacrylate (PMMA) Bone Cement – Class II Special Controls Guidance Document for Industry and FDA* issued July 17, 2002, and internal requirements.

| Performance Bench Test Results |
|---|
| **Test** |
| Benzoyl Peroxide Content |
| Ignition Residue |
| Gentamicin Assay |
| Vancomycin Assay |
| Uniformity of Barium Sulphate/ Zirconium Dioxide Dispersion in Radiopaque Bone Cements |
| Dough, Handling and Setting Time (ISO 5833:2002) |
| Method for Determination of Flexural Modulus and Flexural Strength (ISO 5833:2002) |
| Compressive Strength (ISO 5833:2002) |
| Exothermic Temperature and Setting Time (ISO 5833:2002) |
| Sieve Test for Powder Agglomeration in PBGMV, PBGHV and SmartSet GHV Gentamicin Bone Cement |
| Determination of Residual Methyl methacrylate in Cured Bone Cement |
| Method for Determination of Intrusion of Liquid -Powder Mixture of Cement (ISO 5833:2002) |
| Appearance of Bone Cement Powder and Liquid (ISO 5833:2002) |
| Human Factors Simulated Use of Prostalac Hip System made with SmartSet V+G Dual Antibiotic Bone Cement |
| Tensile Strength (ASTM D638-14) |
| Shear Strength Testing (ASTM D732-17) |
| Fatigue Testing (ASTM F2118-14) |
| Stem Fatigue of Spacers (ISO 7206-4) |
| Fracture Toughness Testing (ASTM D5045-14) |
| Compressive Creep Testing (ASTM D2990-17) |
| Report on the effect of storage in PBS over time on mechanical properties of various bone cement types |
| Zone of Inhibition Testing |
| Quantification of Antibacterial Efficacy Testing of SmartSet V+G Dual Antibiotic Bone Cement |
| Elution Profile of Vancomycin & Gentamicin from SmartSet V+G & Spectrum GV Bone Cement Discs |
| Elution Profile of Vancomycin Hydrochloride, Gentamicin Sulfate, Tobramycin Sulfate from the Prostalac Hip System formed with Dual Antibiotic Bone Cement, predicate and comparator devices |

**Magnetic Resonance Imaging**
The Prostalac Hip System is considered *MR-Conditional*. An MRI Safety Evaluation has been completed for all commercially available DePuy Synthes Hip Implants in accordance with ASTM F2503-23 (Standard practice for marking medical devices and other items for safety in the magnetic resonance environment) and FDA's guidance, *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, issued on May 20, 2021.

The SmartSet V+G Dual Antibiotic Bone Cement is considered *MR-Safe*. An MRI Safety Evaluation has been conducted in accordance with ASTM F2503-13 and FDA's guidance, *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, issued on May 20, 2021.

**Sterilization**
The Prostalac Hip System implantable components are sterilized by gamma irradiation. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of $10^{-6}$ in accordance with ISO 11137-1:2025 and ISO 11137-2:2013 + AMD1:2022, *Sterilization of health care products – Radiation*.

The Prostalac Hip System is provided with non-sterile instrumentation intended to assist in the fabrication and implantation of the prosthesis. These instruments are provided non-sterile, intended for processing by the customer prior to each use.

The SmartSet V+G Dual Antibiotic Bone Cement is sterilized using the following techniques:

1) Powder Component – Sterilized via a validated gamma irradiation sterilization cycle. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of $10^{-6}$ in accordance with 11137-1:2025 and ISO 11137-2:2013 + AMD1:2022, *Sterilization of health care products – Radiation*.

2) Liquid Component: Sterilized using terminal filtration, then aseptically filled into sterile glass ampules.

3) Glass Ampule (holds liquid): Sterilized via a validated Ethylene Oxide sterilization cycle. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of $10^{-6}$ in accordance with ISO 11135: 2014 +A1:2019, *Sterilization of health care products – Ethylene Oxide*.

**Shelf-Life Testing**
Shelf-life testing was conducted in accordance with DePuy's internal requirements.

The Prostalac Hip System implantable components were the subject of real-time aging studies, which established that the device and packaging remain functional and maintain sterility for up to 10 years.

The SmartSet V+G Dual Antibiotic Bone Cement was subjected to real time aging studies, which established that the device and packaging remain functional and maintain sterility for up to 3 years (36 months).

**Biocompatibility Testing**

The Prostalac Hip System implantable components have been assessed for biocompatibility and have been available in the US market for over 25 years.

The SmartSet V+G Dual Antibiotic Bone Cement was the subject of biocompatibility testing conducted in accordance with ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, and FDA's guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* issued September 2020.

| **Biocompatibility Test Results** |
|---|
| **Test** |
| MTT Cytotoxicity Testing per ISO ISO 10993-5: 2009 |
| ISO Guinea Pig Maximization Sensitization Test ISO 10993-10: 2010 |
| ISO Intracutaneous Study in Rabbits ISO 10993-10: 2010 |
| Genotoxicity – Bacterial Reverse Mutation Assay/Ames Test (OECD 471) per ISO 10993-3 |
| Genotoxicity – *in vitro* mouse lymphoma (OECD 476) per ISO 10993-3: 2014 |
| Pyrogenicity – Material Mediated in rabbits per ISO 10993-11: 2017 |
| Femoral Implantation in rabbits per ISO 10993-6: 2016 |
| Extractables and Leachables Testing per ISO 10993-18: 2020 and Toxicological Risk Assessment per ISO 10993-17:2002 |
| Methyl Methacrylate Monomer Release Study per ASTM F451 and Toxicological Risk Assessment per ISO 10993-17: 2002 |

**Performance Testing - Animal Studies**
No animal studies were performed for performance testing, as appropriate verification and validation of the new device was achieved based on the comparison to the predicate device and from the results of the bench testing and biocompatibility testing.

**Performance Testing - Clinical Studies**
No clinical studies were performed for performance testing, as appropriate verification and validation of the new device was achieved based on the comparison to the predicate device and from the results of the bench testing and biocompatibility testing.

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**VIII. Conclusion**

Based upon the intended use, design, function, materials, comparison to the predicate device, and testing conducted, it is concluded that the subject device, the Prostalac Hip System for use with the SmartSet V+G Dual Antibiotic Bone Cement, is substantially equivalent to the predicate devices, and therefore does not raise new issues of safety and effectiveness.