February 15, 2024

Heraeus Medical GmbH
Heike Gustke
Senior Manager Regulatory Affairs
Philipp-Reis-Str. 8-13
Wehrheim, Hessen 61273
Germany

Re: K234028
Trade/Device Name: COPAL® exchange G hip spacer; COPAL® G+V
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, MBB
Dated: December 18, 2023
Received: December 20, 2023

Dear Heike Gustke:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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: 2024.02.15 21:13:38 -05'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234028

Device Name

COPAL® exchange G hip spacer;
COPAL® G+V

Indications for Use *(Describe)*

COPAL® exchange G hip spacer (polymethylmethacrylate / gentamicin) is indicated for temporary use (maximum of 180 days) as a total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process. The device is inserted into the femoral medullary canal and acetabular cavity following removal of the existing implant and radical debridement. The device is assigned to be used in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection). COPAL® exchange G 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.). COPAL® exchange G hip spacer is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

COPAL® G+V (gentamicin and vancomycin) is a PMMA bone cement intended for fixation of COPAL® exchange G hip spacer to the host bone.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

Heraeus

Heraeus Medical GmbH

510(k) Summary

I. SUBMITTER

Manufacturer:	Heraeus Medical GmbH Philipp-Reis-Str. 8/13 61273 Wehrheim Germany
Contact Person:	Dr. Heike Gustke Senior Manager Regulatory Affairs Phone: +49 (6181) 35-2942 Email: heike.gustke@heraeus.com
Date Prepared:	February 12, 2024

II. DEVICES

Name of Device(s):	COPAL® exchange G hip spacer, COPAL® G+V
Device Common Name:	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis Polymethylmethacrylate (PMMA) bone cement
Regulation Number:	21CFR 888.3360 21CFR 888.3390 21CFR 888.3027
Device Class:	Class 2
Product Code:	KWL
Associated Product Code(s):	KWY, MBB

III. PREDICATE DEVICES

Primary Predicate:	REMEDY PLUS Hip Spacer, UNITE PLUS Bone Cement (K172906)
Reference Device:	COPAL® exchange G hip spacer (K220492)

IV. DEVICE DESCRIPTION

A Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance for a modification to the existing COPAL® exchange G hip spacer previously cleared in K220492. The change includes the addition of bone cement COPAL® G+V to fixation of COPAL® exchange G hip spacer to the host bone.

COPAL® exchange G hip spacer is a temporary hip spacer implant as part of two-stage septic endoprosthesis revision based on bone cement. COPAL® exchange G hip spacer contains gentamicin. Gentamicin reduces the risk for bacterial colonization of the device and is released into the fluid surrounding the joint. COPAL® exchange G hip spacer is intended for single-use and is supplied sterile.

COPAL® exchange G hip spacer is made of fully formed polymethylmethacrylate (radiopaque PMMA with gentamicin) and contains an inner stainless steel (AISI 316L) reinforcing structure. The mass used in the filling of the molds (the PMMA unformed resin) is prepared from a powder component and a liquid component. It contains the X-ray contrast medium calcium carbonate. To improve visibility in the surgical field, it has been colored with chlorophyll-copper-complex (E141).

COPAL® exchange G hip spacer will be used with COPAL® exchange G hip trials (510(k) exempt devices).

COPAL® G+V is a standard-setting, high-viscosity, radiopaque, poly(methyl methacrylate)-based (PMMA) bone cement, containing gentamicin and vancomycin, designed for fixation of COPAL® exchange G hip spacer to the host bone. COPAL® G+V is intended for single-use and is supplied sterile.

V. INDICATIONS FOR USE

COPAL® exchange G hip spacer

COPAL® exchange G hip spacer (polymethylmethacrylate / gentamicin) is indicated for temporary use (maximum of 180 days) as a total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process. The device is inserted into the femoral medullary canal and acetabular cavity following removal of the existing implant and radical debridement. The device is assigned to be used in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection). COPAL® exchange G 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.). COPAL® exchange G hip spacer is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

COPAL® G+V

COPAL® G+V (gentamicin and vancomycin) is a PMMA bone cement intended for fixation of COPAL® exchange G hip spacer to the host bone.

The subject device (COPAL® exchange G hip spacer, COPAL® G+V) has the same intended use and indications for use in comparison to the predicate device (REMEDY PLUS Hip Spacer, UNITE PLUS Bone Cement). The hip spacer is designed for the first stage of a two-stage revision arthroplasty procedure to temporarily (max. 180 days) replace an implant due to an infection of the implant site in the same patient population.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device (COPAL® exchange G hip spacer, COPAL® G+V) and the predicate device (REMEDY PLUS Hip Spacer, UNITE PLUS Bone Cement) have the same technological characteristics (design features (hip spacer with PMMA bone cement), performance, and operational principle). At a high level, the subject device and predicate device are based on the following same technological elements:

Hip spacer

- Temporary joint prostheses,
- Preformed antibiotic-loaded PMMA cement spacer with an inner stainless-steel core,
- Design (length, diameter, and shape), and
- Fixation with PMMA bone cements.

PMMA bone cement

- Constituents including antibiotics (gentamicin and vancomycin),
- Designed for fixation of hip spacer to the host bone,
- Biocompatibility of materials, and
- Performance characteristics.

The following technological differences exist between the subject and predicate devices:

Hip spacer

- COPAL® exchange G hip spacer contains gentamicin and the REMEDY PLUS Hip Spacer contains gentamicin and vancomycin.
- COPAL® exchange G hip spacer can be fixed with PALACOS® bone cement.

PMMA bone cement

- Different radio-opacifier and concentrations of antibiotics.

VII. PERFORMANCE DATA

Summary of non-clinical tests

The compatibility extension does not modify the design, material, function, manufacturing, packaging, and sterilization of existing COPAL® exchange G hip spacer. Therefore, the reference device COPAL® exchange G hip spacer (previously cleared in K220492) was used to support the biocompatibility, performance, manufacturing, packaging, sterilization, and shelf-life of the hip spacer portion of the 510(k) submission. The non-clinical tests reviewed as part of K191016 and K220492 remain unchanged.

The following performance data were provided in support of the substantial equivalence determination:

Mechanical testing

Mechanical testing was performed to characterize the PMMA bone cements and to assess the compatibility to hip spacer:

- ISO 5833 testing of PMMA bone cements
- Antibiotic elution kinetic of PMMA bone cements
- Safety and effectiveness assessment of PMMA bone cements
- Compatibility assessment of COPAL® exchange G hip spacer with the PMMA bone cements
- Safety and compatibility of PMMA bone cement in the MR environment.

Clinical evaluation

A clinical evaluation was performed to analyze the existing clinical data of predicate device and legally marketed U.S. devices and to evaluate whether there is sufficient clinical evidence to confirm the clinical safety and performance when using COPAL® exchange G hip spacer with COPAL® G+V according to the manufacturer's instructions for use. It has been demonstrated that the subject device COPAL® exchange G hip spacer in compatibility with COPAL® G+V bone cement performs as intended if used as intended by the manufacturer and no unknown complications that have not yet been described in the instructions for use were found.

Biocompatibility testing

The biocompatibility evaluation of COPAL® G+V was performed according to FDA guidance document "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and recognized consensus standard ISO 10993-1. The battery of testing included the following tests:

- Chemical characterization as per ISO 10993-18
- Toxicological assessment as per ISO 10993-17
- Cytotoxicity as per ISO 10993-5
- Sensitization as per ISO 10993-10
- Intracutaneous irritation as per ISO 10993-10
- Systemic toxicity as per ISO 10993-11
- Implantation as per ISO 10993-6
- Hemocompatibility as per ISO 10993-4 and ASTM F756
- Genotoxicity as per ISO 10993-3

It has been demonstrated that the materials of COPAL® G+V are biological safe, and suitable for their intended use.

Packaging, Sterilization and Shelf Life

COPAL® G+V is sterilized using well established sterilization methods and the validations have been performed following international standards and FDA guidance document "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile". The compatibility between the packaging material and the sterilization process is ensured and the packaging preserves the functionality and safety of COPAL® G+V throughout its declared shelf-life. COPAL® G+V meets endotoxin limits.

The non-clinical tests demonstrated that the subject device is substantially equivalent to the predicate device.

Summary of clinical tests

No clinical tests were performed to demonstrate substantial equivalence.

VIII. CONCLUSION

There have been no modifications made to the intended use, design, biocompatibility, materials, sterilization, or packaging of the existing COPAL® exchange G hip spacer. Non-clinical tests have been demonstrated that COPAL® G+V is intended for fixation of COPAL® exchange G hip spacer to the host bone.

COPAL® exchange G hip spacer and COPAL® G+V are substantially equivalent to the predicate device (REMEDY PLUS Hip Spacer, UNITE PLUS Bone Cement (K172906)) identified in this premarket notification.