March 23, 2022

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

Re: K220492
Trade/Device Name: COPAL® exchange G hip spacer
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWY, KWL
Dated: February 14, 2022
Received: February 22, 2022

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 (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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Laura C. Rose, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220492

Device Name
COPAL® exchange G hip spacer

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.

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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"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."

7 510(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 Additional Email: Regulatory_HM@heraeus.com

Date Prepared: March 21, 2022

II. DEVICES

Name of Device:	COPAL® exchange G hip spacer
Device Common Name:	KWL: Prosthesis, Hip, Hemi-, Femoral, Metal KWY: Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented
Regulation Description:	KWL: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis KWY: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulation Number:	KWL: 21 CFR 888.3360 KWY: 21 CFR 888.3390
Regulatory Class:	Class II
Product Code(s):	KWL, KWY

III. PREDICATE DEVICES

COPAL® exchange G hip and knee spacers (K191016)

IV. DEVICE DESCRIPTION

A Special 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 K191016. The change includes a modified dimension of COPAL® exchange G hip spacer.

The intended use and indications for use of existing COPAL® exchange G hip spacer previously cleared in K191016 remain unchanged.

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).

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device comparison demonstrated that COPAL® exchange G hip spacer is substantially equivalent to the previously cleared COPAL® exchange G hip spacer (K191016) regarding intended use, indications for use, technological characteristics (design features, material, and performance) as well as operating principle.

At a high level, the subject device and predicate devices are based on the following same technological elements:

- Temporary joint prostheses
- Preformed PMMA hip spacer containing gentamicin with an inner stainless-steel core
- Spacer design (diameter and shape)

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

- Spacer design (length)

VII. PERFORMANCE DATA

The submitter of this Special 510(k) is the manufacturer of the predicate device.

A risk analysis was performed as per DIN EN ISO 14971 to assess the impact of the modification on the device. The records of risk analysis process are retained in design history file. The evaluation demonstrated that the subject device did not present a new worst case and that the same verification and validation methods were applied to the subject device in comparison to the previously cleared predicate device (K191016). The risk analysis demonstrated that the subject device is as safe and effective as the predicate device.

The fatigue performance testing as per ISO 7206-6 was performed to address the modified dimension of COPAL® exchange G hip spacer. The same protocol as the original submission was used for collecting and assessing the data. The acceptance criteria were not altered from those used for the original device. COPAL® exchange G hip spacer meets endotoxin limits. It has been indicated that the subject device is as safe and effective as the predicate device.

VIII. CLINICAL TESTING

No clinical testing of COPAL® exchange G hip spacer has been conducted.

IX. CONCLUSION

COPAL® exchange G hip spacer is substantially equivalent to the predicate device (COPAL® exchange G hip spacer (K191016)) identified in this premarket notification