February 4, 2023

Heraeus Medical GmbH
Alexander Peczka
Senior Manager Regulatory Affairs
Philipp-Reis-Str, 8/13
Wehrheim, Hessen 61273
Germany

Re: K222570
Trade/Device Name: COPAL® knee moulds
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: August 23, 2022
Received: August 23, 2022

Dear Mr. Peczka:

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,

Sara S. Thompson -S

For

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)*
K222570

Device Name
COPAL® knee moulds

Indications for Use *(Describe)*
COPAL® knee moulds are designed to prepare spacers by filling the moulds with bone cement. COPAL® knee moulds are disposable cement spacer molds indicated for use to mold a temporary total knee replacement (TKR) for skeletally mature patients undergoing a two-stage procedure due to a septic process. The molded temporary knee spacer is indicated for an implantation period of 180 days or less. Because of inherent mechanical limitations of the device material (PALACOS® R+G bone cement), the molded temporary spacer is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers) throughout the implant 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.

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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510(k) Summary - K222570

I. SUBMITTER

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Date Prepared: August, 12th 2022

II. DEVICES

Name of Device: COPAL® knee moulds
Common Name: Knee moulds
Classification Name: Knee joint polymer cemented prosthesis (21 CFR 888.3560)

Regulatory Class: Class II
Product Code: JWH
Subsequent Product Code(s): Not applicable

III. PREDICATE DEVICES

Tecres Spacer-K (K032522)

A Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market for COPAL® knee moulds

IV. DEVICE DESCRIPTION / INTENDED USE

COPAL® knee moulds are sterile single-use moulds used for the preparation of spacers that are intended as temporary knee replacements as part of two-stage septic joint prosthesis revision.

COPAL® knee moulds comprise a tibial component and a femoral component, which together form a bearing and move against one another. They can be used in both the right and the left knee joint. The spacer function provides that after removal of the prosthesis the existing joint space is retained and contraction of the musculature and the surrounding tissues is prevented.

COPAL® knee moulds are intended for single use and must not be re-used or resterilised.

VI. INDICATIONS FOR USE

COPAL® knee moulds are designed to prepare spacers by filling the moulds with bone cement. COPAL® knee moulds are disposable cement spacer molds indicated for use to mold a temporary total knee replacement (TKR) for skeletally mature patients undergoing a two-stage procedure due to a septic process. The molded temporary knee spacer is indicated for an implantation period of 180 days or less. Because of inherent mechanical limitations of the device material (PALACOS® R+G bone cement), the molded temporary spacer is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers) throughout the implant period.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The spacer molded by the Heraeus COPAL® knee moulds are substantially equivalent to the knee spacer of the cleared predicate device (K032522) with respect to the following:

The intended use is equivalent in that they are both indicated for temporary use (maximum of 180 days) as a total knee replacement (TKR) for skeletally mature patients undergoing a two-stage procedure due to a septic process. The proposed and predicate devices are intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The technological characteristics of the spacers formed by the Heraeus COPAL® knee moulds and the predicate product are identical in that they are all designed to mimic a permanent implant for a period of up to 180 days. The configurations consist of knee components that mimic the intended anatomical space. The knee spacers formed by the Heraeus COPAL® knee moulds are also used to be molded with PALACOS® R+G a PMMA antibiotic bone cement as also the predicate devices contain an antibiotic component that helps to facilitate the healing process. There are no major differences between the proposed and the predicate devices and are substantial equivalent in materials and design.

The operational characteristics of the spacers formed by the Heraeus COPAL® knee moulds are equivalent to the predicate device. The basic operational principle for the predicate device, as well

as the subject device is for temporary use (maximum of 180 days) as a TKR in skeletally mature patients undergoing a two-stage procedure due to a septic process. The method of insertion and the operative technique is identical for both subject device and predicate device.

Both Spacers provide patients, undergoing a two stage revision procedure for an infected total joint, a temporary implant to allow for partial weight bearing.

The devices also maintain a patient's soft tissue and joint space, preventing further complications such as muscular contraction. The gentamicin released from the bone cement protects the spacer from bacterial colonization.

The spacers formed by the Heraeus COPAL® knee moulds and the predicate devices are placed into the joint to maintain normal joint space and alignment. They provide patient comfort and limited mobility while the infection is being treated. The spacers formed by the COPAL® knee moulds and the predicate spacers are made with bone cement.

The proposed and predicate devices are provided in a range of sizes that are compatible with skeletally mature adults.

All of these technological characteristics are equal fit, form and function resulting in the spacers formed by the Heraeus COPAL® knee moulds are being substantially equivalent to the Tecres Spacer-K.

VIII. PERFORMANCE DATA

Testing was conducted according to the FDA recognized standards in order to demonstrate equivalence to the predicate devices.

Biocompatibility testing

A biocompatibility evaluation for COPAL® knee moulds was conducted in accordance with the 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 (FDA 2020)"* and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.
The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Material-mediated Pyrogenicity
- Acute Systemic Toxicity

COPAL® knee moulds are categorized as: externally communicating medical device with indirect / direct contact to tissue / bone for limited (≤ 24 hours) contact duration.

Mechanical and functional testing

These tests include Mechanical tests as well as Wear tests and demonstrates that spacers formed by the COPAL® knee moulds are mechanically and functionally similar to the predicate devices. The verification and validation testing performed demonstrated that COPAL® knee moulds function as intended and are safe and effective for their use.

Sterilization

Validation of the sterilization was performed in accordance to ISO 11135. The sterilization is carried out by gassing with ethylene oxide. The sterilization cycle is designed to deliver sterile units, starting with a defined bioburden and ending with a sterility assurance level (SAL) of 10^{-6}. Based on the tests performed and the results obtained, the chosen sterilization process can be considered as valid.

The COPAL® knee moulds meet the requirements of FDA Guidance document Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile (January 21, 2016).

Pyrogenicity

N/A - Pyrogenicity testing was not performed for COPAL® knee moulds because the determination of bacterial endotoxins is only required for sterile implantable medical devices that contact non-intact tissue during use or medical devices that have direct or indirect intravascular, intralymphatic, intrathecal, and/or intraocular contact.

In summary, the verification and validation testing performed demonstrate that the Heraeus COPAL® knee moulds function as intended and are safe and effective for their intended use and where appropriate were tested and found to be substantially equivalent to the predicate devices.

IX. CLINICAL TESTING

No clinical testing was performed

X. CONCLUSIONS

The spacers formed by the Heraeus COPAL® knee moulds have been shown to be substantially equivalent to the predicate devices. Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance testing. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate devices and demonstrates them to be substantial equivalent.