February 2, 2022

Heraeus Medical GmbH
Ljuba Jaeckel
Regulatory Affairs Manager
Philipp-Reis-Str. 8/13
Wehrheim, Hessen 61273
Germany

Re: K213812
Trade/Device Name: PALACOS® MV pro
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD, KIH, JDZ
Dated: December 2, 2021
Received: December 7, 2021

Dear Ljuba Jaeckel:

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,

for

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative 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)*

K213812

Device Name
PALACOS® MV pro

Indications for Use *(Describe)*
PALACOS® MV pro is indicated for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living 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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Heraeus
Heraeus Medical GmbH

510(k) Summary - K213812

I. SUBMITTER

Manufacturer:	Heraeus Medical GmbH Philipp-Reis-Str. 8/13 61273 Wehrheim Germany
Contact Person:	Ljuba Jaeckel Manager Regulatory Affairs Phone: +49 6181 35-3138 Email: ljuba.jaeckel@heraeus.com
Additional Contact Person:	Alexander Peczka Senior Regulatory Affairs Manager Phone: +49 (6181) 35-2964 Email: alexander.peczka@heraeus.com

Date Prepared: December 03, 2021

II. DEVICES

Name of Device:	PALACOS® MV pro (PALACOS® MV pro 40, PALACOS® MV pro 80)
Common Name:	Polymethylmethacrylate (PMMA) bone cement
Classification Name:	Bone cement (21 CFR 888.3027)
Regulatory Class:	Class II
Product Code:	LOD
Subsequent Product Code(s):	KIH, JDZ

III. PREDICATE DEVICES

PALACOS® R pro (K210607)

IV. DEVICE DESCRIPTION

A Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market PALACOS® MV pro.

PALACOS® MV pro is a standard-setting, medium viscosity, radiopaque, poly(methyl methacrylate)-based (PMMA) bone cement, pre-filled into a mixing and application system, suitable for use with or without vacuum (ready to mix). It contains the X-ray contrast medium zirconium dioxide. To improve visibility in the surgical field, it has been colored with chlorophyll-copper-complex (E141). The bone cement consists of two components and is prepared immediately before use by mixing the polymer powder (= powder) with the monomer liquid (= liquid). A ductile dough forms that sets within a few minutes.

V. INTENDED USE

PALACOS® MV pro is a PMMA bone cement intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

VI. INDICATIONS FOR USE

PALACOS® MV pro is indicated for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device comparison demonstrated that the PALACOS® MV pro is substantially equivalent to the previously cleared PALACOS® R pro (K210607) regarding intended use, technological characteristics (device design, material and performance) as well as operating principle.

Both the subject and predicate device are PMMA bone cements that are intended for use in arthroplastic procedures. They consist of two components that are already prefilled in a mixing and application system and are prepared immediately before use by mixing the polymer powder with the monomer liquid.

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

- PMMA bone cement,
- Chemical composition,
- Sterilized with an established method (ethylene oxide) as per DIN EN ISO 11135 and DIN EN ISO 10993-7
- Mechanical characteristics as per ISO 5833 and ASTM F451,
- Mixing and application properties, and
- Clinical use of the devices including the anatomical location, duration of exposure, and intended use population.

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

- Ratio of material constituents in polymer powder differs and therefore setting time is extended.

VIII. PERFORMANCE DATA

The submitter of this Traditional 510(k) Premarket Notification is the manufacturer of the predicate device.

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

Biocompatibility testing

A biocompatibility evaluation for PALACOS® MV pro was performed on PALACOS® R (K202475), which is representative of the subject device 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"* issued on September 4th, 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
- Acute Systemic Toxicity
- Material-mediated Pyrogenicity
- Genotoxicity
- Hemocompatibility
- Implantation

The bone cements of PALACOS® MV pro and the test article are identical in their qualitative components and differ only in the slightly different quantitative compositions. The formulation change does not alter the chemical or physical properties of the medical device in its final finished form, and therefore, results from the test article can be applied to the proposed medical device in its final finished form.

In Addition, cytotoxicity testing was performed on the PALACOS MV® pro (subject device) and PALACOS® R pro (predicate device) after preparation aseptically with the mixing and application system.

The PALACOS® MV pro is categorized as: implant medical device, intended to be used for long term contact duration (> 30 d) in tissue / bone.

Accessories of PALACOS® MV pro are categorized as: implant medical device, intended to be used for limited contact duration (≤ 24 h) in tissue / bone.

Mechanical and functional testing

Mechanical tests were conducted in order to demonstrate that the PALACOS® MV pro functions as intended and is safe and effective for its intended use.

The mechanical and functional testing was performed alongside the FDA Guidance document *Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement - Guidance for Industry and FDA,* issued on July 17th, 2002. The testing according to Annex I and Annex II of prior named FDA Guidance document provided data to state the substantial equivalence of the subject device to the predicate device.

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 and PALACOS® MV pro shows equivalence to the predicate device.

Pyrogenicity

PALACOS® MV pro has been tested for the presence of bacterial endotoxins using the LAL test (known as the Limulus amebocyte lysate test) according to ANSI/AAMI ST72. The subject device meets the endotoxin limit specification of ≤ 20 EU/device and shows equivalence to the predicate device.

IX. CLINICAL TESTING

No clinical testing of the PALACOS® MV pro has been conducted.

X. CONCLUSIONS

The PALACOS® MV pro is substantially equivalent to the predicate device (PALACOS® R pro, K210607) identified in this premarket notification. Substantial equivalence has been demonstrated through a comparison of intended use, technological characteristics (device design, material and performance) as well as operating principle. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device.