September 17, 2018

Heraeus Medical GmbH
Ute Greiner
Head of Regulatory Affairs
Philipp-Reis-Straße 8/13
Wehrheim, Germany 61273

Re: K182260
Trade/Device Name: PALACOS® MV
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: LOD
Dated: August 17, 2018
Received: August 21, 2018

Dear Ute Greiner:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182260

Device Name
PALACOS® MV

Indications for Use *(Describe)*
PALACOS ® MV is 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.

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.

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Heraeus Medical GmbH
61273 Wehrheim, Germany

PALACOS® MV

Radiopaque bone cement

510(k) Summary - K182260

Date of summary	August 17th, 2018
Device trade name	PALACOS® MV (previously named PALAMED®)
Common name	PMMA Bone Cement
Classification	PMMA Bone Cement : Class II Special Controls per 21 CFR 888.3027
Classification name	Polymethylmethacrylate (PMMA) bone cement
Device product code	LOD
Identification of the marketed device to which equivalence is claimed	Palamed®, K030904 (now named PALACOS® MV)
Contact person	Ute Greiner Phone: + 49 (0) 6181.35-2808 Fax: + 49 (0) 6181.35-2947 Regulatory_HM@heraeus.com
Description of the device	PALACOS® MV is an acrylic bone cement for use in orthopedic surgery. It is formed from powder and liquid by exothermic polymerization. It secures the fixation of the grafted artificial joint, improving the transfer of forces at the interface implant - bone. It is currently marketed in a 44 g packaging size in the United States.
Indications for use	PALACOS® MV is 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.
Comparison of technological characteristics	Bone cement is derived by mixing a powder component and a monomer liquid. The only difference between the subject and predicate device is the modification of the lower specification limit of the

Heraeus Medical GmbH
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PALACOS® MV

Radiopaque bone cement

510(k) Summary - K182260

	benzoyl peroxide (BPO) content in the powder component of the finished device.
Discussion of preclinical tests	The doughing time, maximum temperature, setting time, intrusion, compressive strength, bending modulus and 4-point bending strength of PALACOS® MV with a lower specification limit of benzoyl peroxide (BPO) content was characterized per ISO 5833. In addition, impact and bending strength were measured according to Dynstat test method. Stability/shelf life data were also compared between the subject and predicate devices. Bacterial endotoxin have been evaluated using bacterial endotoxin test method (LAL test; known as the Limulus amebocyte lysate test), in accordance with the ANSI/AAMI ST72:2011. Test results met the endotoxin limits for the BET: 20 endotoxin units (EU)/Device.
Clinical performance data	No clinical data was provided.
Conclusions from preclinical and clinical data	PALACOS® MV with a lower limit of benzoyl peroxide (BPO) content is substantially equivalent to the Palamed® predicate device and meets ISO 5833 and Heraeus final test requirements
Applicant's name and address	Heraeus Medical GmbH Philipp-Reis-Straße 8/13 61273 Wehrheim Germany