November 23, 2020

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

Re: K202475
Trade/Device Name: PALACOS® R, PALACOS® R pro, PALACOS® R+G, PALACOS® R+G pro, PALACOS® MV+G
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: LOD, MBB, KIH, JDZ
Dated: August 14, 2020
Received: August 28, 2020

Dear Dr. Hermanns:

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

Heraeus
Heraeus Medical GmbH

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)*
K202475

Device Name
PALACOS® R

Indications for Use *(Describe)*
PALACOS® R 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.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K202475

Device Name
PALACOS® R pro

Indications for Use *(Describe)*
PALACOS® R 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)

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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)*
K202475

Device Name
PALACOS® R+G

Indications for Use *(Describe)*
PALACOS® R+G is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202475

Device Name
PALACOS® R+G pro

Indications for Use *(Describe)*
PALACOS® R+G pro is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

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)

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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)*
K202475

Device Name
PALACOS® MV+G

Indications for Use *(Describe)*
PALACOS® MV+G is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

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)

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7 510(k) Summary

I. SUBMITTER

Manufacturer: Heraeus Medical GmbH
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Date Prepared: November 9, 2020

II. DEVICES

Name of Device: PALACOS® R
PALACOS® R pro
PALACOS® R+G
PALACOS® R+G pro
PALACOS® MV+G

Common Name: Polymethylmethacrylate (PMMA) bone cement

Classification Name: Bone cement (21 CFR 888.3027):
PALACOS® R pro, PALACOS® R
Bone cement, antibiotic (21 CFR 888.3027):
PALACOS® R+G pro, PALACOS® R+G, PALACOS® MV+G

Regulatory Class: Class II

Product Code: LOD
PALACOS® R pro, PALACOS® R

	MBB
	PALACOS® R+G pro, PALACOS® R+G, PALACOS® MV+G
Subsequent Product Code(s):	KIH, JDZ

III. PREDICATE DEVICES

PALACOS® R (K030902)

PALACOS® R pro (K150119)

PALACOS® G (K031673)

PALACOS® R+G pro (K142157)

PALAMED G (K050855)

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

A bundled Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance for modifications to PALACOS® R, PALACOS® R pro, PALACOS® R+G, PALACOS® R+G pro, and PALACOS® MV+G previously cleared in K030902, K150119, K031673, K142157 and K050855.

Modifications include changes of instructions for use (IFU) and labels as well as the addition of MRI safety information.

This submission encompasses multiple devices that have similar intended use and indications for use as well as rely on similar data.

PALACOS® bone cements without Gentamicin

PALACOS® R and PALACOS® R pro are polymethylmethacrylate (PMMA) bone cements:

- PALACOS® R: is a standard-setting, high-viscosity, PMMA-based bone cement for orthopaedic surgery,
- PALACOS® R pro: is a PMMA based PALACOS® R bone cement, packed in a closed mixing and application system ready for processing (ready-to-mix)

The bone cements consist of two components, a monomer liquid and a polymer powder. The liquid component contains the monomer, accelerator, and a stabilizer. The powder contains the polymer, X-Ray-opacifier, and initiator. They are intended for single-use and are provided sterile (ethylene oxide and sterile filtration).

PALACOS® bone cements with Gentamicin

PALACOS® R+G, PALACOS® R+G pro and PALACOS® MV+G are PMMA bone cements, containing the antibiotic Gentamicin:

- PALACOS® R+G (previously cleared under the name PALACOS® G): is a standard-setting, high-viscosity, PMMA-based bone cement for orthopaedic surgery,

- PALACOS® R+G pro is a PMMA based PALACOS® R+G bone cement, packed in a closed mixing and application system ready for processing (ready-to-mix) and
- PALACOS® MV+G (previously cleared under the name PALAMED G) is a standard-setting, medium-viscosity, radiopaque, poly(methyl methacrylate)-based bone cement for orthopaedic surgery.

The bone cements consist of two components, a monomer liquid and a polymer powder. The liquid component contains the monomer, accelerator, and a stabilizer. The powder contains the polymer, X-Ray-opacifier, initiator and the antibiotic Gentamicin. They are intended for single-use and are provided sterile (ethylene oxide and sterile filtration).

V. INTENDED USE

PALACOS® R

PALACOS® R 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.

PALACOS® R pro

PALACOS® R 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.

PALACOS® R+G

PALACOS® R+G 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.

PALACOS® R+G pro

PALACOS® R+G 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.

PALACOS® MV+G

PALACOS® MV+G 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® R

PALACOS® R 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.

PALACOS® R pro

PALACOS® R 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.

PALACOS® R+G

PALACOS® R+G is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

PALACOS® R+G pro

PALACOS® R+G pro is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

PALACOS® MV+G

PALACOS® MV+G is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

PALACOS® R

Device comparison demonstrated that the PALACOS® R is substantially equivalent to the previously cleared PALACOS® R (K030902) regarding intended use, technological characteristics (device design, material and performance) as well as operating principle. 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 11135-1 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.

PALACOS® R pro

Device comparison demonstrated that the PALACOS® R pro is substantially equivalent to the previously cleared PALACOS® R pro (K150119) regarding intended use, technological characteristics (device design, material and performance) as well as operating principle. 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 11135-1 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.

PALACOS® R+G

Device comparison demonstrated that the PALACOS® R+G is substantially equivalent to the previously cleared PALACOS® G (K031673) regarding intended use, technological characteristics (device design, material and performance) as well as operating principle. 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 11135-1 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.

PALACOS® R+G pro

Device comparison demonstrated that the PALACOS® R+G pro is substantially equivalent to the previously cleared PALACOS® R+G pro (K142157) regarding intended use, technological characteristics (device design, material and performance) as well as operating principle. 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 11135-1 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.

PALACOS® MV+G

Device comparison demonstrated that the PALACOS® MV+G is substantially equivalent to the previously cleared PALAMED® G (K050855) regarding intended use, technological characteristics (device design, material and performance) as well as operating principle. 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 11135-1 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

VIII. PERFORMANCE DATA

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

PALACOS® bone cements without Gentamicin

A risk-based assessment was performed as per DIN EN ISO 14971 to evaluate the impact of the modifications to the labelling of the PALACOS® R and PALACOS® R pro. The modified IFUs do not alter the previously validated packaging or sterilization data as well as the existing results of non-clinical performance testing and biocompatibility in accordance with the FDA Class II Special Controls Guidance Document 'PMMA Bone Cement'. The risk-based assessment concludes that the IFU changes do not significantly affect the device's risk profile because no new risks or significantly modified existing risks are identified. A scientifically based rationale has been prepared to designate the bone cements as "MR Safe". PALACOS® R and PALACOS® R pro are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic and pose no known hazards in all MR environments. Shelf life and pyrogenicity of PALACOS® R and PALACOS® R pro remain unchanged and testing are intended to be leveraged from their previous clearances in accordance with 21 CFR 807.92(b)(1). It has been demonstrated that the subject devices are as safe and effective as the predicate devices (K150119, K030902).

PALACOS® bone cements with Gentamicin

A risk-based assessment was performed as per DIN EN ISO 14971 to evaluate the impact of the modifications to the labelling of the PALACOS® R+G, PALACOS® R+G pro and PALACOS® MV+G. The modified IFUs do not alter the previously validated packaging or sterilization data as well as the existing results of non-clinical performance testing and biocompatibility in accordance with the Class II Special Controls Guidance Document 'PMMA Bone Cement'. The risk-based assessment concludes that the IFU changes do not significantly affect the device's risk profile because no new risks or significantly modified existing risks are identified. A scientifically based rationale has been prepared to designate the bone cements as "MR Safe". PALACOS® R+G, PALACOS® R+G pro and PALACOS® MV+G are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic and pose no known hazards in all MR environments. Shelf life and pyrogenicity of PALACOS® R+G, PALACOS® R+G pro and PALACOS® MV+G pro remain unchanged and testing are intended to be leveraged from their previous clearances in accordance with 21 CFR 807.92(b)(1). It has been demonstrated that the subject devices are as safe and effective as the predicate devices (K031673, K142157, K050855).

IX. CLINICAL TESTING

PALACOS® R

No clinical testing of the PALACOS® R has been conducted.

PALACOS® R pro

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

PALACOS® R+G

No clinical testing of the PALACOS® R+G has been conducted.

PALACOS® R+G pro

No clinical testing of the PALACOS® R+G pro has been conducted.

PALACOS® MV+G

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

X. CONCLUSIONS

PALACOS® R

The PALACOS® R is substantially equivalent to the predicate device (PALACOS® R, K030902) identified in this premarket notification.

PALACOS® R pro

The PALACOS® R pro is substantially equivalent to the predicate device (PALACOS® R pro, K150119) identified in this premarket notification.

PALACOS® R+G

The PALACOS® R+G is substantially equivalent to the predicate device (PALACOS® G, K031673) identified in this premarket notification.

PALACOS® R+G pro

The PALACOS® R+G pro is substantially equivalent to the predicate device (PALACOS® R+G pro, K142157) identified in this premarket notification.

PALACOS® MV+G

The PALACOS® MV+G is substantially equivalent to the predicate device (PALAMED® G, K050855) identified in this premarket notification.