November 27, 2019

OSARTIS GmbH
Volker Stirnal
Director, Quality Assurance and Regulatory Affairs
Lagerstrasse 11-15
Dieburg, 64807
Germany

Re: K192379
Trade/Device Name: Hi-Fatigue G Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: LOD, MBB
Dated: August 28, 2019
Received: August 30, 2019

Dear Mr. Stirnal:

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,

Laurence D. Coyne, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192379

Device Name

Hi-Fatigue G Bone Cement

Indications for Use *(Describe)*

Hi-Fatigue G Bone Cement 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 when reconstruction is necessary. The cement is intended 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Hi-Fatigue G Bone Cement

510(k) Summary
K192379

1. General Information

1.1 Submitter and Owner of the 510(k)

OSARTIS GmbH
Lagerstraße 11-15
64807 Dieburg
Germany
Phone: +49 6071 / 929-0
Fax: +49 6071 / 929-100

1.2 Contact Person

Volker Stirnal

1.3 Device Subject of this 510(k)

Hi-Fatigue G Bone Cement

1.4 Date of Preparation

28.10.2019

2. Name of the Device and Classification Information

This traditional 510(k) has been submitted for the following device.

Hi-Fatigue G Bone Cement

2.1 Trade/Proprietary Name

Hi-Fatigue G Bone Cement

2.2 Common/Usual Name

PMMA bone cement with antibiotic for orthopaedics

2.3 Classification Information

Classification Name:	Polymethylmethacrylate (PMMA) Bone Cement
Classification Regulation:	21 CFR § 888.3027
Regulatory Class:	Class II
Product Code:	LOD – Bone Cement MBB – Bone Cement, Antibiotics
Panel:	Orthopedic

Hi-Fatigue G Bone Cement

510(k) Summary

3. Predicate Device

The predicate devices are as follows:

- Palacos® R+G (510(k) application K031673)
- Cobalt™ MV with Gentamicin Bone Cement (510(k) application K092150)

4. Device Description

Hi-Fatigue G Bone Cement is a PMMA, radiopaque bone cement, containing gentamicin, designed for the fixation of prothesis to the living bone. Hi-Fatigue G Bone Cement is a traditional bone cement product. The bone cement is made of two separate sterile components. When both components are mixed together, they become a self-hardening, radiopaque bone cement which fixes the implant. The liquid is contained in a vial and the powder in a pouch; these components are packed in blister with Tyvek lid or an aluminium pouch. The devices are sold disposable, single-use and sterile.

5. Indication for Use

Below is the indication for use:

Hi-Fatigue G Bone Cement 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 when reconstruction is necessary. The cement is intended for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

6. Comparison of the technological Characteristics with the Predicate Device

Hi-Fatigue G Bone Cement shares many of the same technological characteristics compared to the predicates Palacos® R+G and Cobalt™ MV with Gentamicin Bone Cement, including important considerations such as most materials.

Table 1: Comparison of the Technological Characteristics with the Predicate Devices

Characteristics		**Hi-Fatigue G Bone Cement**	**Palacos® R+G K031673**	**Cobalt™ MV with Gentamicin Bone Cement K092150**
Material powder	Polymer	Poly (methyl acrylate/methyl methacrylate) (PMMA) Poly (methyl methacrylate/styrene)	Poly (methyl acrylate/methyl methacrylate) (PMMA)	Poly (methyl methacrylate) Methyl methacrylate-Styrene
	Initiator	Benzoyl peroxide	Benzoyl peroxide	Benzoyl peroxide
	Radio-pacifier	Zirconium dioxide	Zirconium dioxide	Zirconium dioxide
	Colour Additives	None	Chlorophyll VIII	FD&C Blue No. 2 Aluminium Lake
	Antibiotic	Gentamicin sulfate	Gentamicin sulfate	Gentamicin sulfate

Hi-Fatigue G Bone Cement

510(k) Summary

Characteristics		Hi-Fatigue G Bone Cement	Palacos® R+G K031673	Cobalt™ MV with Gentamicin Bone Cement K092150
Material Liquid	Monomer	Methylmethacrylate (MMA) stabilized with Hydroquinone	Methylmethacrylate (MMA) stabilized with Hydroquinone	Methylmethacrylate stabilized with Hydroquinone
	Activator	N,N-dimethyl-p-toluidine	N,N-dimethyl-p-toluidine	N,N-dimethyl-p-toluidine
	Colour Additives	None	Chlorophyll VIII in oily solution	None

7. Performance Data

This 510(k) submission provided performance data to establish the substantial equivalence of the new bone cements to the predicate bone cement. Performance testing was conducted in accordance with the "FDA Class II Special Controls Guidance Document: Polymethylacrylate (PMMA) Bone Cement; Guidance for Industry and FDA" dated July 17, 2002.

Non-clinical performance testing was performed to characterize the bone cements in accordance with special controls guidance document. This testing included the following:

- Mixing and Application characteristics (e.g. dough time, setting time, viscosity, intrusion)
- Chemical Composition (e.g. trace elements, residual low MW molecules, leachables)
- Molecular weight and Polymer structure (e.g. molecular weight, glass transition temperature)
- Physical Properties (e.g. porosity, shrinkage)
- Stability of Components (e.g. change in monomer viscosity due to artificial aging)
- Thermal Properties (e.g. maximum polymerization temperature)
- Mechanical properties (e.g. cyclic fatigue properties, bending properties, compressive properties, tensile properties, fracture toughness)

The performance data fulfill the pre-defined acceptance criteria and demonstrate that the new devices **Hi-Fatigue G Bone Cement** is substantially equivalent to the predicate device **Palacos® R+G 510(k) application K031673** and meet the requirements of the Special Controls Guidance document.

Bacterial endotoxins of Hi-Fatigue G Bone Cement have been evaluated using Recombinant Factor C Assay (EndoZyme) following Ph. Eur. 5.01.10 and 2.06.14, based on USP <161> and USP<85>. Test results meet the endotoxin limits of 20 endotoxin units (EU)/device as defined in USP and as recommended by the FDA guidance "Pyrogen and Endotoxins Testing: Question and Answers" (2012).