



December 2, 2019

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

Re: K192394  
Trade/Device Name: Hi-Fatigue Bone Cement  
Regulation Number: 21 CFR 888.3027  
Regulation Name: Polymethylmethacrylate (PMMA) bone cement  
Regulatory Class: Class II  
Product Code: LOD  
Dated: August 30, 2019  
Received: September 3, 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](mailto: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)  
K192394

Device Name  
Hi-Fatigue Bone Cement

*Indications for Use (Describe)*

Hi-Fatigue 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.

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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# **Hi-Fatigue Bone Cement**

## **510(k) Summary**

### **K192394**

#### **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 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 Bone Cement

##### **2.1 Trade/Proprietary Name**

Hi-Fatigue Bone Cement

##### **2.2 Common/Usual Name**

PMMA bone cement for orthopedics

##### **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

Panel: Orthopedic

## Hi-Fatigue Bone Cement

### 510(k) Summary

### 3. Predicate Device

The predicate devices are as follows:

- Palacos® R (510(k) application K030902)
- Cobalt™ MV Bone Cement (510(k) application K091608)

### 4. Device Description

Hi-Fatigue Bone Cement is a PMMA, radiopaque bone cement, designed for the fixation of prosthesis to the living bone. Hi-Fatigue 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 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.*

### 6. Comparison of the technological Characteristics with the Predicate Device

Hi-Fatigue Bone Cement shares many of the same technological characteristics compared to the predicates Palacos® R and Cobalt™ MV 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 K030902                                    | Cobalt™ MV Bone Cement K091608                            |
|-----------------|------------------|-----------------------------------------------------------------------------------------|-------------------------------------------------------|-----------------------------------------------------------|
| Material powder | Polymer          | Poly (methyl acrylate/methyl methacrylate) (PMMA)<br>Poly (methyl methacrylate/styrene) | Poly (methyl acrylate/methyl methacrylate) (PMMA)     | Poly (methyl methacrylate)<br>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<br>Aluminium Lake                         |
| Material Liquid | Monomer          | Methylmethacrylate (MMA) stabilized with Hydroquinone                                   | Methylmethacrylate (MMA) stabilized with Hydroquinone | Methylmethacrylate stabilized with Hydroquinone           |

## Hi-Fatigue Bone Cement

510(k) Summary

| Characteristics |                  | Hi-Fatigue G Bone Cement | Palacos® R K030902                | Cobalt™ MV Bone Cement K091608 |
|-----------------|------------------|--------------------------|-----------------------------------|--------------------------------|
|                 | 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 demonstrate that the new devices **Hi-Fatigue Bone Cement** is substantially equivalent to the predicate device **Palacos® R 510(k) application K030902** and meet the requirements of the Special Controls Guidance document.

Bacterial endotoxins of Hi-Fatigue 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).