March 19, 2021

OSARTIS GmbH
Volker Stirnal
Director, Quality Assurance and Regulatory Affairs
Auf der Beune 101
Münster, 64839
Germany

Re: K210125
Trade/Device Name: BonOs ® HV Genta, BonOs® MV Genta, BonOs® LV Genta
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD, MBB
Dated: January 15, 2021
Received: January 19, 2021

Dear Volker 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,

for

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

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)*

K210125

Device Name

BonOs® HV Genta, BonOs® MV Genta, BonOs® LV Genta

Indications for Use *(Describe)*

BonOs® HV Genta, BonOs® MV Genta and BonOs® LV Genta are intended for the fixation of prothesis to living bone 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.

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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OSARTIS GmbH Auf der Beune 101 64839 Münster Germany	**BonOs® HV Genta** **BonOs® MV Genta** **BonOs® LV Genta** 5. 510(k) Summary	Date of issue: Mar 10, 2021
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5. 510(k) Summary

1. General Information

1.1 Submitter and Owner of the 510(k)

OSARTIS GmbH
Auf der Beune 101
64839 Münster
Germany
Phone: +49 6071 / 929-0
Fax: +49 6071 / 929-100

1.2 Contact Person

Volker Stirnal

1.3 Devices Subject of this 510(k)

- BonOs® HV Genta
- BonOs® MV Genta
- BonOs® LV Genta

1.4 Date of Preparation

March 10, 2021

2. Name of the Device and Classification Information

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

- BonOs® HV Genta
- BonOs® MV Genta
- BonOs® LV Genta

2.1 Trade/Proprietary Name

- BonOs® HV Genta
- BonOs® MV Genta
- BonOs® LV Genta
-

2.2 Common/Usual Name

PMMA bone cement with antibiotic for orthopedics

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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

3. Predicate Device

The predicate devices are as follows:

- Rally™ HV AB Bone Cement (510(k) application K143100)
- Palacos® R+G (510(k) application K031673)

4. Device Description

BonOs® HV Genta, BonOs® MV Genta and BonOs® LV Genta are PMMA, radiopaque bone cements, containing gentamicin, designed for the fixation of prothesis to the living bone. BonOs® HV Genta, BonOs® MV Genta and BonOs® LV Genta are traditional bone cement products. 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 and transfer stresses evenly to the bone. 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:

BonOs® HV Genta, BonOs® MV Genta and BonOs® LV Genta are intended for the fixation of prothesis to living bone 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

BonOs® HV Genta, BonOs® MV Genta and BonOs® LV Genta share many of the same technological characteristics compared to the predicate Rally™ HV AB Bone Cement, including important considerations such as materials, mechanical performance and chemical-physical performances, for this reason, a second predicate (Palacos® R+G) was included.

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These comparisons are summarized in Table 2.

Table 2: Comparison of the Technological Characteristics with the Predicate Devices

Characteristics		**BonOs® HV Genta** **BonOs® MV Genta** **BonOs® LV Genta**	**Rally™ HV AB Bone Cement K143100**	**Palacos® R+G K031673**
Material powder	Polymer	Poly (methylacrylate/ methylmethacrylate) (PMA/PMMA)	Poly (methylacrylate/ methylmethacrylate) (PMA/PMMA)	Poly (methylacrylate/ methylmethacrylate) (PMA/PMMA)
	Initiator	Benzoyl peroxide	Benzoyl peroxide	Benzoyl peroxide
	Radio-pacifier	Zirconium dioxide	Barium sulfate	Zirconium dioxide
	Color Additives	None	Pigments (FD&C Blue No. 1 and FD&C Yellow No.5)	Chlorophyll VIII
	Antibiotic	Gentamicin sulfate	Gentamicin sulfate	Gentamicin sulfate
Material Liquid	Monomer	Methylmethacrylate (MMA) stabilized with Hydroquinone	Methylmethacrylate (MMA) stabilized with Hydroquinone	Methylmethacrylate (MMA) stabilized with Hydroquinone
	Activator	N,N-Dimethyl-p-toluidine	N,N-Dimethyl-p-toluidine	N,N-Dimethyl-p-toluidine
	Color Additives	None	None	Chlorophyll VIII in oil solution
Powder Sterilization Method		Ethylene oxide	Gamma-ray irradiation	Ethylene oxide
Liquid Sterilization Method		Aseptic processing	Aseptic processing	Aseptic processing
Terminal Liquid Sterilization Method		Ethylene oxide	Ethylene oxide	Ethylene oxide

7. Performance Data

This 510(k) notification 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: Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA" dated July 17, 2002. The following is a summary of the performance data.

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Sterilization and Shelf Life: The sterilization process, including the ethylene oxide method and the membrane filter sterilization has been validated and the sterility of the subject devices has been verified according to ISO 11135 and ISO 13408-1/2.

Biocompatibility: The biological evaluation of BonOs® HV Genta, BonOs® MV Genta and BonOs® LV Genta was performed in accordance with ISO 10993-1. BonOs® HV Genta, BonOs® MV Genta and BonOs® LV Genta contain identical materials as other well-known bone cements on the market and shows no additional risks. Evaluation for BonOs® HV Genta, BonOs® MV Genta and BonOs® LV Genta additionally conformed to ISO 10993-1.

Performance Testing (Chemical, Material and Mechanical): 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)

Results show comparable performances to the predicate device and are in compliance with ASTM F451-16, ISO 5833:2002, ISO 527:1/2, ASTM F2118-14, ASTM D2990-17, ASTM D732-17 and ASTM E399-20.

The performance data demonstrate that the new devices **BonOs® HV Genta, BonOs® MV Genta and BonOs® LV Genta** are substantially equivalent to the predicate device **Rally™ HV AB Bone Cement 510(k) application K143100** and meet the requirements of the Special Controls Guidance document.

Bacterial endotoxins of BonOs® HV Genta, BonOs® MV Genta and BonOs® LV Genta have been evaluated using Recombinant Factor C Assay (EndoZyme) following Ph. Eur. 5.01.10, based on USP <161>Test results meet the endotoxin limits of 20 endotoxin units (EU)/device as defined in USP and as recommended by the FDA guidance "Submission and Review of Sterlity Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile (2016). This Test for bacterial endotoxins is performed for all produced batches. The device meets the pyrogen limit specifications as described by the FDA guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile" (2016).

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8. Conclusion

BonOs® HV Genta, BonOs® MV Genta and BonOs® LV Genta have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance and intended use. The information provided within this premarket notification supports substantial equivalence of the subject to the predicate devices.