May 18, 2021

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

Re: K202458/S001
Trade/Device Name: BonOs® Inject, Neo Pedicle Screw System™
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: PML, NDN, NKB
Dated: April 16, 2021
Received: April 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,

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)*
K202458

Device Name
BonOs® Inject

Indications for Use *(Describe)*
BonOs® Inject bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using vertebroplasty or balloon kyphoplasty procedure.

When used in conjunction with NEO Pedicle Screw System™ BonOs® Inject is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. NEO Pedicle Screws augmented with BonOs® Inject Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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.

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)*
K202458

Device Name
NEO Pedicle Screw System™

Indications for Use *(Describe)*
The NEO Pedicle Screw System™, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. The system is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, tumor, pseudarthrosis, and/or failed previous fusion.

When used in conjunction with BonOs® Inject Cement, the NEO Pedicle Screw System™ is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. NEO Pedicle Screws augmented with BonOs® Inject Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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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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 Device Subject of this 510(k)

BonOs® Inject Bone Cement, Neo Pedicle Screw System™

1.4 Date of Preparation

20.08.2020

2. Name of the Device and Classification Information

This traditional 510(k) has been submitted for the following device.
BonOs® Inject Bone Cement, Neo Pedicle Screw System™

2.1 Trade/Proprietary Name

BonOs® Inject Bone Cement, Neo Pedicle Screw System™

2.2 Common/Usual Name

PMMA bone cement for vertebroplasty, Bone Screw, Pedicle Screw

2.3 Classification Information

Classification Name:	Polymethylmethacrylate (PMMA) Bone Cement, Vertebroplasty, Bone Cement Posterior Screw Augmentation
Classification Regulation:	21 CFR § 888.3027
Regulatory Class:	Class II
Product Code:	PML, NDN
Panel:	Orthopedic

Subsequent Product Codes (if any): NKB
Neo Pedicle Screw System™
21 CFR § 888.3070
Class II

3. Predicate Device

Subject devices

- BonOs® Inject
- Neo Pedicle Screw System™

Predicate Device

- Medtronic HV-R™ Bone Cement, Kyphon™ Xpede™ Bone Cement, CD Horizon™ Fenestrated Screw Set (510(k) applications K152604, S.E., 01/06/2016; K170347, S.E. 04/04/2017 and K191148, S.E. 09/12/2019)

Additional Predicate Device

- BonOs® Inject (510(k) application (K090460, S.E.04/14/2009)

Reference Device

- Neo Pedicle Screw System™ (510(k) application K171582, S.E. 09/12/2017)

4. Device Description

BonOs® Inject:
BonOs® Inject is a radiopaque, injectable bone cement for use in spine surgery like percutaneous vertebral augmentation during vertebroplasty or kyphoplasty. It is a two–component system consisting of a powder and a liquid. Methylmethacrylate polymer is the primary constituent of the powder component. Zirconium dioxide is added as radiopacifier. Methylmethacrylate monomer is the primary constituent of the liquid component. Mixing the two separate sterile components, initially an injectable paste is produced which can be transferred into a syringe and which then can be injected under slight pressure into the vertebral body. After curing of the bone cement by exothermic polymerization it stabilizes the vertebral lesions and vertebral compression fractures.

Neo Pedicle Screw System™:
The Neo Pedicle Screw System™ consists of pedicle screws and connecting rods which differ in length and diameter. The system includes the relevant instruments which are single use, disposable and delivered sterile. All components and instruments are sterilized by gamma irradiation.
The screws are offered in diameters of 5.0 - 7.0 mm and lengths of 35 - 55mm. Three different types of rods are available: pre-bent, straight or special bent rod for S1/L5.

All rods have a diameter of 5.5 mm. Pre-bent rods are offered in lengths of 40 – 100mm, straight rods in lengths from 30 - 300 mm and the special-bent rod in either 30 or 40mm length. All spinal implant components are made of titanium alloy (Ti6Al4V Eli) in accordance with ASTM F136. The screws are color coded for better identification of the different diameters. The screws are double threaded, cannulated, fenestrated and selftapping.

5. Indication for Use

BonOs® Inject:
BonOs® Inject bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using vertebroplasty or balloon kyphoplasty procedure.

When used in conjunction with NEO Pedicle Screw System™ BonOs® Inject is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. NEO Pedicle Screws augmented with BonOs® Inject Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

Neo Pedicle Screw System™:
The NEO Pedicle Screw System™, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. The system is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, tumor, pseudarthrosis, and/or failed previous fusion.

When used in conjunction with BonOs® Inject Cement, the NEO Pedicle Screw System™ is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. NEO Pedicle Screws augmented with BonOs® Inject Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

6. Comparison of the technological Characteristics with the Predicate Device

The subject devices BonOs® Inject and Neo Pedicle Screw System™ are the same as the currently cleared BonOs® Inject (K090460, S.E.04/14/2009) and Neo Pedicle Screw System™ (K171582, S.E. 09/12/2017). There are no technology changes to the existing cleared devices. The subject devices have the same overall design, packaging, sterilization and materials as the currently cleared devices.

The additional predicate device for the subject device BonOs® Inject is BonOs® Inject (K090460, S.E.04/14/2009). The subject BonOs® Inject has the same or similar intended use, same or similar overall design, packaging, sterilization and materials as

the following FDA additional predicate cleared in K090460 (S.E.04/14/2009). The predicate and subject have the identical function and scientific fundamental technology. There are no technology changes to the existing predicate device BonOs® Inject.
However, when used in combination, BonOs® Inject and the Neo Pedicle Screw System™ labeling has been updated to reflect the same indications for use as the predicate device Kyphon™ Xpede™ Bone Cement Medtronic HV-R™ Fenestrated Screw Cement CD Horizon™ Fenestrated Screw Set (K191148, S.E. 09/12/2019).

The expanded indications enable the BonOs® Inject cement to be delivered through the cannulated fenestrated screws of the Neo Pedicle Screw System™ for a controlled flow of cement into the pedicle. After a screw is placed posteriorly, the cement is delivered through the cannulated screw and distal fenestrations. The cement hardens over time.

The Neo Pedicle Screw System™ is similar to the Medtronic CD Horizon™ Fenestrated Screw Set. The screw design of the subject device is similar to the predicate with cannulations and side fenestrations at the distal tip to allow cement delivery.

The subject devices are already used together for cement augmentation outside the United States.

7. Performance Data

No changes were made to the existing devices BonOs® Inject (K090460) and Neo Pedicle Screw System™ (K171582). Therefore, no additional testing was required or performed.

To demostrate substantial equivalence to the additional predicate device Kyphon™ Xpede™ Bone Cement Medtronic HV-R™ Fenestrated Screw Cement CD Horizon™ Fenestrated Screw Set (K191148, S.E. 09/12/2019), axial pullout strength according to ASTM F2193 / ASTM F543, cement flow and bolus formation were tested.

Additionally, Bacterial endotoxins of BonOs® Inject have been evaluated using Recombinant Factor C Assay (EndoZyme) following Ph. Eur. 5.1.10 and 2.6.32 (draft), 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 Sterility 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).

8. Conclusion

BonOs® Inject and Neo Pedicle Screw System™ 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 and predicate devices.