October 28, 2021

% Sandra Soniec
Managing Director
meditec Consulting GmbH
Obermoosstrasse 23
Boll, Berne 3067
Switzerland

Re: K212489
Trade/Device Name: BonOs Inject Bone Cement; 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: October 16, 2021
Received: October 22, 2021

Dear Sandra Soniec:

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 and Part 809); 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,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*
K212489

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, curvatures (scoliosis, kyphosis, and/or lordosis), 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 with 5 mm to 8 mm screw diameters 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K212489

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)

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510(k) Summary

In accordance with 21 CFR 807.92 the following information is provided for the BonOs® Inject Bone Cement, NEO Pedicle Screw System™.

ADMINISTRATIVE INFORMATION

Date prepared	October 11, 2021
Submission type	Traditional 510(k)
Purpose of 510(k)	Line extension, modification to currently marketed NEO Pedicle Screw System™
Submitter	Neo Medical S.A. Route de Lausanne 157 A 1096 Villette (Lavaux), Switzerland
Official Correspondent	Sandra Soniec Senior consultant, meditec Consulting GmbH Phone +41 31 535 3193 Email soniec@meditec-consulting.ch
US agent	Vicky Verna, confinis corporation Phone +1 240 252 0891 Email vicky.verna@confinis.com

DEVICE NAME AND CLASSIFICATION

Trade name	1) BonOs® Inject Bone Cement, 2) NEO Pedicle Screw System™
Common name	1) PMMA bone cement for vertebroplasty 2) Pedicle Screw System
Regulation number, Regulation name, Regulatory class, Product Codes	1) BonOs® Inject Bone Cement 21 CFR 888.3027 Polymethylmethacrylate (PMMA) bone cement Class II PML, NDN 2) NEO Pedicle Screw System™ 21 CFR 888.3070 Thoracolumbosacral pedicle screw system Class II NKB

PREDICATE DEVICES

Primary	BonOs® Inject Bone Cement, NEO Pedicle Screw System™ (K202458)
Additional	DePuy Synthes EXPEDIUM and VIPER/VIPER2 System (K111136, K131802, K160879)
	Medtronic CD Horizon™ Fenestrated Screw Set (K152604, K170347, K191148)

INDICATIONS FOR USE

1) 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.

2) 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, curvatures (scoliosis, kyphosis, and/or lordosis), 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 of the spine is not severely compromised. for use with 5 mm to 8 mm screw diameters at spinal levels where the structural integrity

DEVICE DESCRITION

1) 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.

2) NEO Pedicle Screw System™

The NEO Pedicle Screw System™ consists of screws, rods and connectors which are available in different sizes. The system includes the relevant instruments which are mainly single use, disposable and delivered sterile, just few optional instruments are reusable and delivered non-sterile.

All the system components are made of materials compliant with ASTM and/or ISO standards. The screws are made out of a titanium alloy and delivered pre-mounted to a screw extender including a tissue dilator and sterile. The rods are made out of a titanium alloy or cobalt chrome alloy and delivered sterile. Connectors are made out of titanium alloy and delivered sterile.

The pedicle screws are offered in diameters of 4.5 – 8.0 mm and lengths of 25 - 55 mm. Iliac screws are offered in diameters of 8.0 mm and lengths of 70 – 100 mm. 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 – 100 mm, straight rods in lengths from 30 - 500 mm and the special-bent rod in either 30 or 40 mm length.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE

The NEO Pedicle Screw System™ is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function.
Non-clinical performance testing demonstrate that the NEO Pedicle Screw System™ meets the requirements for Pedicle screw spinal systems according to Spinal System 510(k)s Guidance for Industry and FDA Staff Document issued on: May 3, 2004 and is as safe, as effective, as its predicate devices.

SUMMARY OF PERFORMANCE DATA

To demonstrate that the modified NEO Pedicle Screw System™ is safe and effective biocompatibility testing, MRI safety and compatibility evaluation and the following mechanical tests have been performed with the new worst case constructs: static compression bending, dynamic compression bending, and static torsion as per ASTM F1717 and axial gripping capacity as per ASTM 1798. The alternative X-ray sterilization cycle has been successfully validated in accordance with ISO 11137-2. Bacterial endotoxin testing is performed per ANSI/ AAMI ST72:2011 using the limulus amebocyte lysate (LAL) pyrogen testing. Usability testing confirmed suitability of the modified device including updated labeling. No clinical studies were conducted.

CONCLUSION

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject modified BonOs® Inject Bone Cement, NEO Pedicle Screw System™ has been shown to be substantially equivalent to legally marketed predicate devices.