Neo Medical SA
℅ Dawn Balazs-Metz
Senior Consultant
meditec Consulting GmbH
Obermoosstrasse 23
Berne, BE 3067
Switzerland

December 23, 2024

Re: K243693
Trade/Device Name: NEO Pedicle Screw System™
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, PML, NDN
Dated: November 25, 2024
Received: November 29, 2024

Dear Dawn Balazs-Metz:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

EILEEN CADEL -S Digitally signed by EILEEN CADEL -S for

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243693

Device Name

NEO Pedicle Screw System™

Indications for Use *(Describe)*

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 for use with 5 mm to 8 mm screw diameters at spinal levels (thoracic and lumbar T1 to L5) where the structural integrity of the spine is not severely compromised.

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.

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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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	November 25, 2024
Submission type	Special 510(k)
Purpose of 510(k)	Modification to currently marketed NEO Pedicle Screw System™, New system component – axial connectors, Line Extension – 10.0 mm diameter iliac screws and 150 mm connectors, announcement of minor modifications to the device since the last clearance (K222256)
Submitter	Neo Medical S.A. Route de Lausanne 157 A 1096 Villette (Lavaux), Switzerland
Official Correspondent	Dawn Balazs-Metz Senior consultant, meditec Consulting GmbH Phone +41 79 772 5540 Email balazs-metz@meditec-consulting.ch
US agent	Richie Robel, confinis corporation Phone +1 716 867-2417 Email Richie.Robel@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

PRIMARY PREDICATE DEVICE

BonOs® Inject Bone Cement, NEO Pedicle Screw System™ (K222256)

INDICATIONS FOR USE

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 for use with 5 mm to 8 mm screw diameters at spinal levels (thoracic and lumbar T1 to L5) where the structural integrity of the spine is not severely compromised.

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.

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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™ has been optimized and consists of 27 pedicle and 8 iliac screws, rods and connectors which are available in different sizes. The system includes a reduced optimized tray of instruments providing options for open and MIS surgical techniques. The implants are all delivered sterile and ready to use. The relevant instruments are mainly delivered as single use, disposable and delivered sterile, just a few optional instruments are reusable and delivered non-sterile.

All the system components are made of materials compliant with ASTM and/or ISO standards. Screws and rods are made of titanium-alloy (Ti-6AI-4VELI) and comply with ISO 5832-3 or ASTM-F136. 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 CoCrMo (ISO 5832-12, ASTM F1537) 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 10.0 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 35 – 100 mm, straight rods in lengths from 30 - 500 mm and the special-bent rod in either 30 or 40 mm length.

The NEO Pedicle Screw System™ provides immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The system can be used via an open or minimally invasive posterior approach. Iliac screws shall be placed via Sacral Alar Iliac (SAI) and/or Posterior Superior Iliac Spine (PSIS) approach. The size and form of the device is adjusted to the morphology of the body and the surgical technique.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE

The modified NEO Pedicle Screw System™ is substantially equivalent to it's the currently cleared device 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 substantially equivalent to its predicate devices.

SUMMARY OF PERFORMANCE DATA

Finite element analysis and engineering rationales were performed to justify that the subject components do not represent a new worst case for mechanical performance. Additionally, the new axial connector was included in a construct tested according to ASTM F1717 for dynamic compression bending. Mechanical testing also confirmed that the conical press-fit connection between the ball attachment and the 10.0 mm diameter iliac screw thread is sufficiently strong through measurement of the torque resistance of the assembled screw. Results of these evaluations demonstrate substantially equivalent mechanical performance.

Biological evaluation has been performed for the new 10.0 mm diameter iliac screws of the modified NEO Pedicle Screw System™ in accordance with the ISO 10993-1 series. A new cleaning and sterilization validation has been performed for the new 10.0 mm diameter iliac screws.

The new system components have been evaluated in regards to Magnetic field interactions ASTM F2052-15, MRI-related heating ASTM F2182-11a and Artifacts ASTM F2119-07 (R2013). Non-clinical testing demonstrated that the entire family of the NEO Pedicle Screw System™ is MRI conditional. The previous conclusions and MR conditional K222256 remain valid.

An internal validation of the new axial connectors of the modified NEO Pedicle Screw System™ was performed and confirmed they function as intended.

No clinical studies were conducted.

CONCLUSION

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