Medacta International S.A.
% Christopher Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
6386 Global Drive, Suite 101
Memphis, Tennessee 38141

June 12, 2024

Re: K241034
Trade/Device Name: Meta+ Bone Cement & M.U.S.T. Fenestrated Pedicle Screw System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: PML, NKB, KWQ
Dated: April 16, 2024
Received: April 16, 2024

Dear Christopher Lussier:

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.

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
Date: 2024.06.12 10:34:59 -04'00'

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)*

K241034

Device Name

Meta+ Bone Cement & M.U.S.T. Fenestrated Pedicle Screw System

Indications for Use *(Describe)*

• M.U.S.T. Fenestrated Pedicle Screw
The M.U.S.T. Fenestrated Pedicle Screw System when used without cement is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) or anterolateral fixation (T8-L5). These devices are indicated as an adjunct to fusion for all of 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 (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used in conjunction with Meta+ Spine cement, the M.U.S.T. Fenestrated 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 allow for achievement of fusion. M.U.S.T. Fenestrated Pedicle Screw System augmented with Meta+ Spine cement is intended for use at spinal levels where the structural integrity of the spine is not severely compromised.

• Meta+ Spine Cement
Meta+ Spine cement, when used in conjunction with the M.U.S.T. Fenestrated 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 allow for achievement of fusion. The M.U.S.T. Fenestrated Pedicle Screw System, augmented with Meta+ Spine Cement, is 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.

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510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: April 16, 2024

II. Device

Device Proprietary Name:	Meta+ Bone Cement & M.U.S.T. Fenestrated Pedicle Screw System
Common or Usual Name:	Bone Cement, Posterior Screw Augmentation
Classification Name:	Polymethylmethacrylate (PMMA) bone cement
Primary Product Code	PML
Additional Product Codes	NKB, KWQ
Regulation Numbers:	21 CFR 888.3027, 21 CFR 888.3070 , 888.3060
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- CONFIDENCE™ High Viscosity Spinal Cement, VIPER® and EXPEDIUM® Fenestrated Screw Systems, K160879, DePuy Spine, Inc.

Additional Predicate devices

- M.U.S.T. Pedicle Screw Extension, K203482, Medacta International SA
- M.U.S.T. Pedicle Screw System, K171170, Medacta International SA
- M.U.S.T. Pedicle Screw System, K141988, Medacta International SA
- M.U.S.T. Pedicle Screw System, K132878, Medacta International SA
- M.U.S.T. Pedicle Screw System, K121115, Medacta International SA
- F20, K103433, Teknimed SAS

IV. Device Description

The purpose of this submission is to gain the clearance for the Meta+ Spine Cement to be used in conjunction with the M.U.S.T. Fenestrated Pedicle Screw System, a Medacta M.U.S.T. Pedicle Screws System line extension including the following screws:

A. Poly-Axial Screws with standard screw head design, Ø 5, 6 mm (Dual Diameter) and 7mm (Single Diameter)
B. Poly-Axial Screws with large screw head design, Ø 7, 8, 9, 10 mm (Dual Diameter)
C. Mono-Axial Screws, Ø 5, 6, 7 mm (Dual Diameter)
D. Long Tab (LT) Poly-axial screws Ø 4.5, 5, 6, 7, 8 mm (Single Diameter).

The Meta+ Spine Cement as well as the M.U.S.T. Fenestrated Pedicle Screws are provided individually packed, sterile and single-use.

V. Indications for Use

- *M.U.S.T. Fenestrated Pedicle Screw System*

The M.U.S.T. Fenestrated Pedicle Screw System when used without cement is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) or anterolateral fixation (T8-L5). These devices are indicated as an adjunct to fusion for all of 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 (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.
When used in conjunction with Meta+ Spine cement, the M.U.S.T. Fenestrated 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 allow for achievement of fusion. M.U.S.T. Fenestrated Pedicle Screw System augmented with Meta+ Spine cement is intended for use at spinal levels where the structural integrity of the spine is not severely compromised.

- *Meta+ Spine Cement*

Meta+ Spine cement, when used in conjunction with the M.U.S.T. Fenestrated 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 allow for achievement of fusion. The M.U.S.T. Fenestrated Pedicle Screw System, augmented with Meta+ Spine Cement, is for use at spinal levels where the structural integrity of the spine is not severely compromised.

VI. Comparison of Technological Characteristics

- *M.U.S.T. Fenestrated Pedicle Screws*

The subject M.U.S.T. Fenestrated Pedicle Screws are substantially equivalent to the primary predicate, VIPER® Fenestrated Screw Systems (K160879), with regards to the following characteristics:

- Diameters and lengths;
- Cannulation;
- Materials, except for the CoCrMo tulip and setscrew that are identical to Medacta predicate (K203482, K171170, K141988, K132878 and K121115);
- biocompatibility;
- device usage;
- sterilization; and
- packaging.

The subject M.U.S.T. Fenestrated Pedicle Screws differ from the primary predicate, VIPER® Fenestrated Screw Systems (K160879), with regards to the following characteristics:

- threading profile;
- shaft design;
- polyaxiality; and
- fenestration.

The partially different threading profile as well as the shaft design and polyaxiality have no impact on subject devices' safety and effectiveness since they do not affect the cement pathway and fenestration design. Additionally, both the threading profile and the polyaxiality of the subject screws are identical to the ones of Medacta predicate (K203482, K171170, K141988, K132878 and K121115).
The different fenestration design of the subject and predicate (K160879) screws does not raise new issues of safety and effectiveness as confirmed by bone cement injection test.

- *META+ Spine Cement*

The subject Meta+ is substantially equivalent to the primary predicate, CONFIDENCE™ High Viscosity Spinal Cement (K160879), with regards to the following characteristics:

- PMMA general material;
- cement handling flow characteristics profile based on a powder and a liquid to be mixed;
- biocompatibility;
- device usage; and
- packaging.

The different viscosity of the subject Meta+ with respect to the predicate cement (K160879) has no impact on device's safety and effectiveness as demonstrated by bone cement injection test.
The different working time as well as the sterilization methods are strictly related to the specific cements' composition but they do not raise any new issue with regards to safety and effectiveness since these Meta+ features are identical to the ones of F20 cleared within (K103433). Meta+ is identical to already cleared F20 (K103433): it is the identical device rebranded by the manufacturer Teknimed for Medacta.

- *Injection System*

The subject and primary predicate (K160879) cement injection systems are substantially equivalent with regards to the following features:

- same principle of use based on the presence of a mixing and an injection device;
- use of fluoroscopy to verify and monitor cement flow in order to prevent cement extravasation;
- removal procedure;
- device usage; and
- packaging.

The different cement delivery system (controlled and measured thanks to a pressure control gun for the subject MedV+ vs. automatic based on a hydraulic pump for the predicate) is strictly linked to the related cement viscosity, but the safety and effectiveness is not affected as demonstrated by bone cement injection test.

Discussion

The comparison of technological characteristics and performance data provided within the submission supports the substantial equivalence of the subject devices with respect to the predicate devices.

VII. Performance Data

Based on the risk analysis, testing activities were conducted to written protocols. The following validations and tests are provided in support of the substantial equivalence determination:

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - Mechanical properties rationale according to ASTM F1717-21;
  - M.U.S.T. Fenestrated screws pull-out test according to ASTM F543-17;
  - Geometrical analysis and comparison to prove fixation into the bone;
  - Implant-implant & Implant-instrument interface rationale; and
  - Bone cement injection test on cadaver specimen and PU foam.

- *PYROGENICITY*
  - Bacterial endotoxin test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>)
  - Pyrogen test according to USP chapter <151> for pyrogenicity determination
  - The subject devices are not labeled as non-pyrogenic or pyrogen free.

- *BIOCOMPATIBILITY* assessment

- *SHELF-LIFE* evaluation

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the subject devices are substantially equivalent to the predicate devices.