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

February 13, 2024

Re: K234048
Trade/Device Name: M.U.S.T. Pedicle Screw System - Extension
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: December 21, 2023
Received: December 21, 2023

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: 2024.02.13 10:13:36 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K234048

Device Name
M.U.S.T. Pedicle Screw System - Extension

Indications for Use *(Describe)*
The M.U.S.T. Pedicle screw system is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) and non-pedicle fixation, 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.

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, Sr. Director, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: December 21, 2023
Date Revised: February 02, 2024

II. Device

Device Proprietary Name:	M.U.S.T. Pedicle Screw System - Extension
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Primary Product Code	NKB
Secondary Product Code	KWP, KWQ
Regulation Number:	21 CFR 888.3070, 21 CFR 888.3050, 21 CFR 888.3060
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- M.U.S.T. Pedicle Screw Extension, K203482, Medacta International SA

Additional Predicate devices

- Apex-DL Spine System, K143683, SpineCraft LLC
- Whistler Modular Pedicle Screw System, K182478, Evolution Spine LLC
- M.U.S.T. Pedicle Screw System, K171170, Medacta International SA
- M.U.S.T. Pedicle Screw System, K162061, 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
- M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System, K171595, Medacta International SA

IV. Device Description

The subject M.U.S.T. Pedicle Screw System - Extension is a Medacta M.U.S.T. Pedicle Screws System line extension aiming to include the following new implants:

- M.U.S.T. Uniplanar screws (solid and cannulated);
- M.U.S.T. Uniplanar reduction screws (solid and cannulated);
- M.U.S.T. polyaxial pedicle screws (solid and cannulated);
- M.U.S.T. polyaxial reduction pedicle screws (solid and cannulated);
- M.U.S.T. S2AI polyaxial cannulated screws (with or without HA plasma spray coating, fully and partially threaded);
- M.U.S.T. S2AI polyaxial reduction cannulated screws (with or without HA plasma spray coating, fully and partially threaded);
- M.U.S.T. rod straight, transition and pre-contoured (double curvature, J-rod and Z-rod) of different lengths and Ø5.5 or Ø6.0 mm diameters made of Ti6Al4V or CoCrMo alloys;
- M.U.S.T. Link cross connectors for Ø5.5 or Ø6.0 mm rods.

The M.U.S.T. Pedicle Screw System - Extension implants are provided individually packed, sterile and single-use.

V. Indications for Use

The M.U.S.T. Pedicle screw system is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) and non-pedicle fixation, 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.

VI. Comparison of Technological Characteristics

The subject M.U.S.T. Pedicle Screw System - Extension and the predicate devices (Medacta devices - K121115, K132878, K141988, K162061, K171170, K203482, in addition to Apex-DL Spine System - K143683 for M.U.S.T. uniplanar and polyaxial screws and Whistler Modular Pedicle Screw System - K182478 for M.U.S.T. S2AI screws) are substantially equivalent with respect to the following characteristics:

- Design, except for S2AI partial thread and J-rod/Z-rod;
- Rods compatibility;
- Materials;
- Coating, if available;
- Biocompatibility;
- Device usage;
- Packaging;
- Shelf-life; and
- Sterilization.

The subject M.U.S.T. Pedicle Screw System - Extension differ from the predicate devices (Medacta devices - K121115, K132878, K141988, K162061, K171170, K203482, in addition to Apex-DL Spine System - K143683 for M.U.S.T. uniplanar and polyaxial screws and Whistler Modular Pedicle Screw System - K182478 for M.U.S.T. S2AI screws) with respect to:

- Range of products;

- Thread of S2AI screws; and
- J-rod and Z-rod design.

Discussion
The partially different range of products between the subject and predicate devices has no impact on safety and effectiveness:

- M.U.S.T. uniplanar, polyaxial and S2AI screws range of sizes is included within the one of the predicate devices.
- The new Ø6mm rods do not introduce any new worst case with respect to the predicate devices (rods Ø5.5mm cleared within K121115, K162061, K203482) due to the larger diameter.
- The subject M.U.S.T. Link cross connector for Ø6mm rods also, do not introduce any new worst case with respect to the predicate devices (K132878) as demonstrated by comparative testing.

The availability of the partial thread for the subject M.U.S.T. S2AI screws does not raise any new issue related to safety and effectiveness since the core diameter of the subject screw is larger respect to the one of the predicate devices (K141988, K203482 and K182478) with a full thread version.

The subject J-rod and Z-rod do not introduce any new issue with regards to safety and effectiveness since they can be considered as pre-contoured rods with slightly modified curvature.

The comparison of technological characteristics and performance data provided within the submission supports the substantial equivalence of the subject devices 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

- *DESIGN VALIDATION*
  - M.U.S.T. Uniplanar & Polyaxial Screws for Ø5.5 and 6.0 rods, Ø5.5 and 6.0 rods and cross connectors - Pedicle Screw System Design validation to validate the subject devices features ensuring compatibility with existing and new implants and instruments
  - M.U.S.T. S2AI - Pedicle Screw System design validation to validate the new features

- *PERFORMANCE TESTING*
  - Worst-case determination between M.U.S.T. Link cross connector for Ø5.5 and Ø6 rods according to ASTM F1798-21
  - Worst-case determination mechanical test of interconnection mechanism according to ASTM F1798-21
  - Static and dynamic compression bending test on pedicle screw constructs according to ASTM F1717-21
  - Static torsion test on pedicle screw constructs according to ASTM F1717-21
  - Evaluation of the forces causing tulip opening during the final tightening process

- Justification to use M.U.S.T. SI Screw coating validation activity to characterize M.U.S.T. S2AI screw

- *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.