Medacta International SA
% Mr. Christopher Lussier
Senior Director, Quality & Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

April 20, 2021

Re: K210427
Trade/Device Name: M.U.S.T. Midline Cortical (MC) Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP
Dated: February 9, 2021
Received: February 11, 2021

Dear Mr. 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 (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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210427

Device Name
M.U.S.T. Midline Cortical (MC) Screw System

Indications for Use *(Describe)*

The M.U.S.T. Pedicle screws 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, Senior Director of Quality and Regulatory, Medacta USA
Date Prepared: February 9, 2021
Date Revised: April 12, 2021

II. Device

Device Proprietary Name:	M.U.S.T. Midline Cortical (MC) Screw System
Common or Usual Name:	Pedicle screw spinal system
Classification Name:	Thoracolumbosacral pedicle screw system
Primary Product Code:	NKB
Secondary Product Code	KWQ, KWP
Regulation Number:	21 CFR 888.3070, 21 CFR 888.3060, 21 CFR 888.3050
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- M.U.S.T. Pedicle Screw System, K171170, Medacta International SA

Additional predicate devices:

- M.U.S.T. Pedicle Screw System, K121115, Medacta International SA
- M.U.S.T. Pedicle Screw System, K153664, Medacta International SA
- M.U.S.T. Combined Set Screws, K171758, Medacta International SA
- Valeo Pedicle Screw System, K072022, Amedica Corp.

IV. Device Description

The M.U.S.T. Midline Cortical (MC) Screw System is intended to be used as part of the M.U.S.T. Pedicle Screw system (K121115, K132878, K141988, K153664, K162061, K171170, K171758, K193365) for the stabilization and the fusion of the lumbar and thoracic spine. The M.U.S.T. pedicle screw system includes cannulated or non-cannulated poly-axial pedicle screws (K121115, K132878, K153664), cannulated or non-cannulated mono-axial pedicle screws (K132878), set screws (K121115, K171758), straight and pre-bent rods (K121115, K141988, K162061), lateral connectors (K162061) and cross connectors (K132878, K193365). The M.U.S.T. pedicle screw system also includes the enhanced screws and rods designed for percutaneous surgery (K141988).

The M.U.S.T. Midline Cortical (MC) Screw System introduce new polyaxial screws and reduction screws (solid and cannulated), developed with a focus on Midline Cortical Trajectory approach.
The devices subject of this submission are:

- M.U.S.T. MC polyaxial screws Solid
- M.U.S.T. MC polyaxial screws Cannulated
- M.U.S.T. MC polyaxial reduction screws Solid
- M.U.S.T. MC polyaxial reduction screws Cannulated

Intended purpose and the performance specification of the devices are equivalent to the ones of the current US cleared portfolio: polyaxial screws are already used in the MUST implant construct.

The M.U.S.T. Midline Cortical (MC) Screws and the Inlay are manufactured from Ti-6Al-4V ELI (ISO 5832-3 Implants for surgery -Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy + ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401); the Tulip and the Setscrew are made of Co-Cr-Mo alloy according to ISO 5832-12:2019, Implants for Surgery – Metallic materials – Part 3: Wrought cobalt-chromium-molybdenum alloy, the same material of the previous cleared M.U.S.T. Pedicle Screw (K153664, K121115, K171170).

V. Indications for Use

The M.U.S.T. Pedicle screws 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 new M.U.S.T. Midline Cortical (MC) Screws and the predicate devices (K153664, K121115, K171170) share the following characteristics:

- indication for use;
- screw shaft dimensions;
- screw and inlay material (Ti6Al4V ELI);
- tulip and setscrew material (CoCrMo)
- setscrew (cleared through K171758)
- through hole diameter (applicable to cannulated versions);
- biocompatibility;
- device usage;
- sterility;
- shelf life;
- packaging.

The difference between the M.U.S.T. Midline Cortical (MC) Screws and the predicate devices are:

- Tulip dimensions;
- Screw thread, Spherical Head dimensions and recess.

VII. Performance Data

The introduction of the M.U.S.T. Midline Cortical (MC) Screw components into M.U.S.T. - Pedicle Screw System portfolio was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system.

The following validation and tests are being provided in support of the substantial equivalence determination:

<u>Non-Clinical Studies</u>

- *DESIGN VALIDATION*
    - A wetlab has been performed to validate the MUST MC implants and related instruments. The cadaver labs were performed by 3 experienced surgeons according to MUST MC surgical technique

- Geometrical Analysis – MUST MC implants: To ensure that the implant has sufficient fixation in the bone, a geometrical analysis was performed in comparison to approved and marketed implants, related to the most important dimensions of the threads.

- *PERFORMANCE TESTING*

  - *Worst Case definition for ASTM F1717 testing:* discussion of implant types and sizes, chosen as the worst case for mechanical testing of the spinal construct in a vertebrectomy model.

  - Mechanical evaluation under static compression bending according to *ASTM F1717-18 Standard test methods for Spinal Implants Construct in a Vertebrectomy model*

  - Mechanical evaluation under dynamic compression bending according to *ASTM F1717-18 Standard test methods for Spinal Implants Construct in a Vertebrectomy model*

  - Mechanical evaluation under static torsion according to *ASTM F1717-18 Standard test methods for Spinal Implants Construct in a Vertebrectomy model*

- *PYROGENICITY*

  - ENDOTOXINS-MEDIATED PYROGENICITY ASSESSMENT REPORT FOR: "MUST PEDICLE SCREWS IMPLANTS SURGICAL KITS" TF VI-PS-01, RAS-01.008.141 Rev. 5, Dated: October 17 2020
  - ENDOTOXINS-MEDIATED PYROGENICITY ASSESSMENT FOR: "MUST MC MODULAR TAP" TF VS-PS-01, RAS-01.008.260 Rev. 0, Dated: February 18 2020.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

Based on the above information, the M.U.S.T. Midline Cortical (MC) Screws are substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance evaluations.