January 26, 2021

Medacta International SA
% Chris Lussier
Senior Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K203482
Trade/Device Name: M.U.S.T. Pedicle Screw Extension and Long Tab Implants
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP
Dated: November 24, 2020
Received: November 27, 2020

Dear Chris 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,

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)*

K203482

Device Name

M.U.S.T. Pedicle Screw Extension and Long Tab implants

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: November 24, 2020

II. Device

Device Proprietary Name:	M.U.S.T. Pedicle Screw Extension and Long Tab Implants
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, K153664, Medacta International SA

Reference predicate devices:

- M.U.S.T. Pedicle Screw System, K121115, Medacta International SA
- M.U.S.T. Pedicle Screw System, K132878, Medacta International SA
- M.U.S.T. Pedicle Screw System, K141988, Medacta International SA
- M.U.S.T. Pedicle Screw System, K162061, Medacta International SA
- M.U.S.T. Pedicle Screw System, K171170, Medacta International SA
- M.U.S.T. Combined Set Screws, K171758, Medacta International SA
- M.U.S.T. Pedicle Screw System, K193365, Medacta International SA

IV. Device Description

The M.U.S.T. Extension and M.U.S.T. Long Tab 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. Extension and M.U.S.T. Long Tab introduce new sizes of sterile implantable devices intended to be used for posterior non-cervical pedicle fixation (T1-S2/ilium) or anterolateral fixation (T8-L5). The devices subject of this submission are:

- New size of Straight Rods (both Titanium and CoCr version): length 600mm – Hex interface at the end
- New size of Straight Rods (Anodized Titanium version): length 600mm
- Pre-contoured Rods (both Titanium and CoCr version)
- New sizes of Lateral Connectors: length 80; 100; 125 & 150mm
- New sizes of Enhanced Cannulated Pedicle Screws: Ø8; Ø9; Ø10 length from 30 to 100mm
- New cannulated pedicle screws with thread 4 leads (15 and 25 mm)
- Setscrews in Titanium

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

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

- *M.U.S.T. Extension*

The new sizes of Straight Rods (Titanium and CoCr version) included in the M.U.S.T. Extension and the predicate devices (K121115) share the following characteristics:

- indication for use;
- design;
- diameters;
- materials;

- biocompatibility;
- device usage;
- sterility;
- shelf life;
- packaging.

The only difference between the Straight Rods included in the M.U.S.T. Extension and the predicate devices (K121115) is the rods length.

- *M.U.S.T. Extension*

The new size of Straight Rod and Enhanced Straight Rod (Anodized Titanium version) included in the M.U.S.T. Extension and the predicate devices (K162061) share the following characteristics:

- indication for use;
- geometry;
- diameters;
- materials;
- biocompatibility;
- device usage;
- sterility;
- shelf life;
- packaging.

The only difference between the Straight Rods included in the M.U.S.T. Extension and the predicate devices (K162061) is the rods length.

- *M.U.S.T. Extension*

The subject Pre-contoured Rods and Straight Enhanced Rods (both Titanium and CoCr version) included in the M.U.S.T. Extension and the predicate devices (K141988) share the following characteristics:

- indication for use;
- design;
- diameters;
- materials;
- biocompatibility;
- device usage;
- sterility;
- shelf life;
- packaging.

The only difference between the Pre-contoured Rods and Straight Enhanced Rods included in the M.U.S.T. Extension and the predicate devices (K141988) is the rods length.

- *M.U.S.T. Extension*

The new sizes of Lateral connectors included in the M.U.S.T. Extension and the predicate devices (K162061) share the following characteristics:

- indication for use;
- geometry;
- diameters;
- materials;
- interconnection mechanism;
- biocompatibility;
- device usage;
- sterility;
- shelf life;
- packaging.

The only difference between the Lateral connectors included in the M.U.S.T. Extension and the predicate devices (K162061) is the connector length.

- *M.U.S.T. Extension*

The new sizes of Enhanced Cannulated Pedicle Screws included in the M.U.S.T. Extension and the predicate devices (K171170 and K141988) share the following characteristics:

- indication for use;
- design;
- materials;
- biocompatibility;
- device usage;
- sterility;
- shelf life;
- packaging.

The only difference between the Enhanced Cannulated Pedicle Screws included in the M.U.S.T. Extension and the predicate devices (K141988) is the screws diameters and lengths; the thread of the new sizes is substantially equivalent to the thread shape of the predicate device.

- *M.U.S.T. Long Tab (LT)*

The new M.U.S.T. LT Cannulated pedicle screws included in the M.U.S.T. LT and the predicate devices (K153664 and K171170) share the following characteristics:

- indication for use;
- design;
- materials;

- diameters;
- screw lengths;
- biocompatibility;
- device usage;
- sterility;
- shelf life;
- packaging.

The only difference between the M.U.S.T. LT Cannulated pedicle screws included in the M.U.S.T. LT and the predicate devices (K153664 and K171170) is the pedicle screw head that has two long tabs, that can easily allow reduction operation during the surgery (two different lengths of reduction; 15mm and 25mm). The MUST LT tulip is equivalent to the predicate device in terms of material and geometry. In fact, the two tabs are intended to the broken, during surgery and after rod reduction. The resulting tulip has a similar profile and dimensions reduced as the predicate device.

The new M.U.S.T. LT Combined setscrew in the M.U.S.T. LT and the predicate devices (K171758) share the following characteristics:

- indication for use;
- diameters;
- biocompatibility;
- device usage;
- sterility;
- shelf life;
- packaging.

The differences between the M.U.S.T. LT Combined setscrews in the M.U.S.T. LT and the predicate devices (K171758) are material and dimensions.

VII. Performance Data

The addition of the M.U.S.T. Extension and M.U.S.T. LT components to 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:

Non-Clinical Studies

- *DESIGN VALIDATION*

- Geometrical Analysis – MUST LT Thread Geometry: 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.

- Cadaver surgery performed according to the well-known MIS percutaneous (Minimally invasive system) technique (99.PERC46.12 rev.04) by experienced surgeons and according to the M07.138.001 prepared for the Chicago Wetlab.

- Tab welding MUST LT - Flexion strength test according to IL07.09.598 to characterize the specific design of the tulip in the dedicated breaking area

- *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 and dynamic axial compression according to *ASTM F1717-18 Standard test methods for Spinal Implants Construct in a Vertebrectomy model*: *Endolab 970_200220_30_1413 part 1 rev.0 and 970_200220_30_1414 part 1 rev.0*

  - Mechanical evaluation under static torsion according to *ASTM F1717-18 Standard test methods for Spinal Implants Construct in a Vertebrectomy model*: *Endolab 970_200220_30_1413 part 2 rev.0* and *970_200220_30_1414 part 2 rev.0*

  - Mechanical evaluation of axial tensile force resistance according to *ASTM F543-17 Standard specification and test methods for metallic medical bone screws and ASTM F2193-18a Standard Specification and test methods for components used in the surgical fixation of the spinal skeletal system-A1: Endolab 970.200227.120.867-part1 rev. 0 and 970.200227.120.868-part1 rev. 0*

  - Mechanical evaluation of torsion force resistance according to *ASTM F543-17 Standard specification and test methods for metallic medical bone screws and ASTM F2193-18a Standard Specification and test methods for components used in the surgical fixation of the spinal skeletal system: Endolab 970.200227.120.867-part2 rev. 0 and 970.200227.120.868-part2 rev. 0*

  - Mechanical evaluation of torsional yield strength, maximum torque and braking angle according to *ASTM F543-17 Standard specification and test methods for metallic medical bone screws - A1: Endolab 970.200227.120.867-part3 rev. 0 and 970.200227.120.868-part3 rev. 0*

  - Characterization and evaluation of risk of breakage during the insertion in the bone of MUST screws according to *ASTM F543-17 Standard specification and test methods for metallic medical bone screw: Medacta test report ASTM F543 Summary Report*

- *PYROGENICITY*

  - Pyrogenicity Assessment, ENDOTOXINS-MEDIATED PYROGENICITY ASSESSMENT REPORT FOR: "MUST PEDICLE SCREWS IMPLANTS SURGICAL KITS" TF VI-PS-01, RAS-01.008.141 Rev. 5, Dated: 17 October 2020

  - Pyrogenicity Assessment, ENDOTOXINS-MEDIATED PYROGENICITY ASSESSMENT REPORT FOR: "MUST LT IMPLANTS (VI-PS-01)", RAS-01.008.277, Rev. 0, Dated: 16 September 2020

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

Based on the above information, the M.U.S.T. Extension and M.U.S.T. LT components 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.