April 28, 2026

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

Re: K253940
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 9, 2025
Received: December 9, 2025

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

COLIN O'NEILL -S

Colin O'Neill, M.B.E.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253940

Please provide the device trade name(s).

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

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Group VP Regulatory, Legal, and Compliance, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality and Regulatory, Medacta USA
Date Prepared: December 09, 2025
Date Revised: April 28, 2026

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 Devices

Primary Predicate:

- M.U.S.T. Pedicle Screw System – Extension, K234048

Additional Predicates:

- M.U.S.T. Extension, K141044
- M.U.S.T. Pedicle Screw System, K162061
- M.U.S.T. Pedicle Screw System, K193365

IV. Device Description

The M.U.S.T. Pedicle Screw System - Extension includes the following implants:

- M.U.S.T. Lateral, Coaxial Lateral and Rod to Rod Connectors for Ø5.5 or Ø6.0 mm rods;
- M.U.S.T. Connector Ti Setscrew;
- M.U.S.T. Hooks for Ø5.5 or Ø6.0 mm rods;
- M.U.S.T. MC – Cross-Connectors intermediate size for both ‘’straight’’ and ‘’adjustable’’ configurations;

- M.U.S.T. S2AI Ø7 screws with length from 20mm to 60mm and with length 120mm, for both HA and non-HA coating variants;
- M.U.S.T. S2AI Ø8, 9, 10 HA coated screws available for all the screws lengths of the non-HA range (addition of Ø8 screws lengths from 20 to 60 mm, Ø9 screws lengths from 30 to 60 mm, Ø10 screws lengths from 30 to 65 mm);
- M.U.S.T. Pre-Contoured rods of different lengths, curvature and diameters (Ø5.5 or Ø6.0 mm) made of Ti6Al4V or CoCrMo.

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 (K141044, K162061, K193365, K234048) are substantially equivalent with respect to the following characteristics:

- Indications for use;
- Design of MC Cross-connectors, S2AI Pedicle Screws and Pre-contoured rods;
- Materials, except for the addition of compatibility with titanium setscrews for connectors and hooks;
- 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 with respect to:

- Range of products;
- Design of Rod-to-rod connectors, Lateral connectors and Hooks;
- Rod compatibility for rod-to-rod connectors, lateral connectors and hooks;

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

- *DESIGN VALIDATION*
  - Design Validation for Rod-to-Rod Connectors;
  - Design Validation for Hooks and Lateral connectors;
  - Design Comparison Analysis for Lateral connector (Ø5.5-6), Coaxial Lateral connectors (Ø5.5-6), Hooks (Ø5.5-6);
  - Design Comparison Analysis for MUST MC Cross Connectors 23-35mm;
  - Design Comparison Analysis for MUST S2AI screws and Pre-Contoured Rods.

- *PERFORMANCE TESTING*
  - Static compression strength test of the M.U.S.T. construct with Rod-to-Rod Connectors in accordance with ASTM F1717;
  - Static torsion strength test of the M.U.S.T. construct with Rod-to-Rod Connectors in accordance with ASTM F1717;
  - Dynamic compression strength test of the M.U.S.T. construct with Rod-to-Rod Connectors in accordance with ASTM F1717;
  - Axial Gripping test for M.U.S.T. Hooks and M.U.S.T. Uniplanar Screws both for Ø5.5 and Ø6 Rods in accordance with ASTM F1798;
  - Dynamic four-point bending test for spinal rods in accordance with ASTM F2193;
  - Justification to use M.U.S.T. SI Screw 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> and USP <161>)
  - 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.