January 27, 2020

Medacta International SA
Mr. Stefano Baj
Regulatory and Compliance Director
Strada Regina
Castel San Pietro, Switzerland CH-6874

Re: K193365
Trade/Device Name: M.U.S.T. Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: December 3, 2019
Received: December 4, 2019

Dear Mr. Baj:

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

(Ronald Jean) Vacant
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)*
K193365

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

Indications for Use *(Describe)*
The M.U.S.T. Pedicle Screw System is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) and 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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2.0 510(k) Summary

I. Submitter

Medacta International SA
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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Date Prepared: December 3, 2019
Date Revised: January 24, 2020

II. Device

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

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- M.U.S.T. Extension, K132878, Medacta International

Additional predicate devices:

- M.U.S.T. Extension Straight Connector and Additional Screws, K171170, Medacta International SA
- 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. Pedicle Screw System, K141988, Medacta International SA

IV. Device Description

The purpose of this submission is to add the M.U.S.T. MC Cross Connectors to the M.U.S.T. Pedicle Screw System (K132878, K171170, K121115, K153664, K141988) for the stabilization and fusion of

the non-cervical spine. The M.U.S.T. Pedicle System includes a wide range of implants: Rods, Poly-axial and Mono-axial Pedicle Screws, Hooks, Connectors of various design and size, that are used in combination to compose a spinal construct.

V. Indications for Use

The M.U.S.T. Pedicle Screw System is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) and 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 M.U.S.T. MC Cross Connector implants and the predicate devices share the following characteristics:

- Rod compatibility (Ø5.5mm);
- materials of construction;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging

The M.U.S.T. MC Cross Connector implants and the predicate devices are technologically different with respect to:

- connector length;
- connector configuration

Discussion

Medacta International SA has not made any changes to the intended use, materials of construction, biocompatibility, device usage, sterility, shelf life, and packaging of the subject devices. Based on the comparison of technological characteristics and performance data provided within this submission, the M.U.S.T. MC Cross Connector implants are substantially equivalent to the identified predicate devices.

VII. Performance Data

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following mechanical studies were performed on worst-case implants in support of a substantial equivalence determination:

Non-Clinical Studies:

- Performance Tests
  - Static compression / bending per ASTM F1717
  - Dynamic compression bending per ASTM F1717
  - Cadaver studies

- Pyrogenicity
  - Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and pyrogen test according to USP chapter <151> for pyrogenicity determination
  - the subject devices are not labeled as non-pyrogenic or pyrogen free

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the M.U.S.T. MC Cross Connector implants 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.