DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 25, 2017

Medacta International SA
% Elizabeth Rose
Manager, Regulatory Affairs
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

Re: K171170
Trade/Device Name: M.U.S.T. Pedicle Screw System Extension - Straight Connectors and Additional Screws
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class III
Product Code: NKB, KWQ, KWP
Dated: April 20, 2017
Received: April 21, 2017

Dear Ms. Rose:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171170

Device Name
M.U.S.T. Pedicle Screw System Extension - Straight Connectors and Additional Screws

Indications for Use *(Describe)*
The M.U.S.T. Pedicle Screw System is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) and nonpedicle 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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Consultant: Elizabeth Rose, Regulatory Affairs Manager at Mapi USA, Inc.
Date Prepared: April 20, 2017
Date Revised: May 23, 2017

II. Device

Device Proprietary Name:	M.U.S.T. Pedicle Screw System Extension - Straight Connectors and Additional Screws
Common or Usual Name:	Pedicle Screw Spinal System
Classification Name:	Thoracolumbosacral Pedicle Screw Spinal 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	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate:

- M.U.S.T. Pedicle Screws System, K121115, Medacta International SA

Additional Predicates:

- M.U.S.T. Extension, K132878, Medacta International SA (also known as M.U.S.T. Pedicle Screws System)
- M.U.S.T. Pedicle Screws System, K141988, Medacta International SA
- M.U.S.T. Pedicle Screws System, K153664, Medacta International SA

IV. Device Description

The M.U.S.T. Extension - Straight Connectors and Additional Screws are intended to be used as part of the M.U.S.T. Pedicle Screws System (K121118, K132878, K141988, K153664) for the stabilization and the fusion of the lumbar and thoracic spine. The M.U.S.T. Pedicle Screws System includes: cannulated or non-cannulated poly-axial pedicle screws (K121115and K132878), cannulated or non-cannulated mono-axial pedicle screws (K132878), set screws (K121115), straight and pre-bent rods (K121115), cross connectors (K132878), enhanced screws and rods designed for percutaneous surgery (K141988), and cannulated or non-cannulated reduction screws (K153664).

The M.U.S.T. Additional Pedicle Screws (standard and enhanced pedicle) are made of Ti6Al4V ELI (ISO 5832-3, ASTM F136-13) and CoCrMo (ISO 5832-12, ASTM F1537-11), while the M.U.S.T. Additional Reduction Screws are made of Ti6Al4V ELI (ISO 5832-3, ASTM F136-13). The screw shaft is color anodized to simplify the identification of the screw diameter. The pedicle screw has a dual lead thread to simplify the screw insertion and reduce the number of turns. The threads are designed with a cylindrical diameter.

The M.U.S.T. Straight Connectors and Additional Screws introduces the following additional components:

Component	Diameter	Length	Material
Pedicle screw (Sterile and non-sterile)	4 mm	20 - 50 mm	Ti6Al4V ELI and CoCrMo
Enhanced Solid Pedicle screw (Sterile and non-sterile)	4 mm	20 - 50 mm	Ti6Al4V ELI and CoCrMo
Enhanced Cannulated Pedicle screw (Sterile and non-sterile)	4.5 mm	20 - 50 mm	Ti6Al4V ELI and CoCrMo
Reduction Pedicle screw (Sterile and non-sterile)	4 mm	20 - 50 mm	Ti6Al4V ELI
Reduction Cannulated Pedicle screw (Sterile and non-sterile)	4.5 mm	20 - 50 mm	Ti6Al4V ELI
Straight Cross Connector	N/A	20–100 mm	Ti6Al4V ELI and CoCrMo

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 M.U.S.T. Extension - Straight Connectors and Additional Screws and the predicate devices share the following characteristics:

- indications for use;
- design – screws only;
- materials – screws only;
- packaging;
- sterile.

The M.U.S.T. Extension - Straight Connectors and Additional Screws are technologically different from the predicate devices as follows:

- new diameters added;
- addition of a straight connector;
- materials - straight connector.

The M.U.S.T. Extension - Straight Connectors and Additional Screws components are manufactured from Titanium-6Aluminum-4Vanadium Extra Low Interstitial Alloy (ISO 5832-3:1996 Implants For Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy and ASTM F136-13 Standard Specification For Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy For Surgical Implant Applications) and Cobalt-Chromium-Molybdenum alloy (Co-Cr-Mo) (ISO 5832-12 Second Edition 2007-05-01: Implants For Surgery -- Metallic Materials -- Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy [Including: Technical Corrigedum 1 (2008)] and ASTM F1537-11 Standard Specification for Wrought Cobalt-28Chromium-6-Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539).

Biocompatibility testing was conducted on the predicate devices for the same material and testing supports the biological safety of the M.U.S.T. Extension - Straight Connectors and Additional Screws. Additional biocompatibility testing was deemed unnecessary because the materials and manufacturing process are identical to the predicate devices described below.

A comparison of the subject and predicate devices are provided in the tables below:

Technological comparison

Parameters	M.U.S.T. Extension - Pedicle Screw (Subject Device)	M.U.S.T. Pedicle Screw K121115 and K124034 (Predicate Device)
Design/Types	Posterior fixation devices to be used with rods and set screws	Identical
Material	Ti6Al4V ELI CoCrMo	Identical
Diameter	4.0 mm	4.5 – 10 mm
Length	20 – 50 mm	20 – 100 mm
Device usage	Single Use	Identical
Shelf Life	5 years	Identical
Biocompatibility	Implant with permanent >30 day	Identical
Sterilization	Sterile: Gamma Non-sterile	Identical
Packaging	Individual packaging	Identical

Parameters	M.U.S.T. Extension - Solid Enhanced Pedicle Screw (Subject Device)	M.U.S.T. Solid Enhanced Pedicle Screw K141988 (Predicate Device)
Design/Types	Posterior fixation devices to be used with rods and set screws	Identical
Material	Ti6Al4V ELI CoCrMo	Identical
Diameter	4.0 mm	4.5 – 7 mm
Length	20 – 50 mm	20 – 90 mm
Device usage	Single Use	Identical
Shelf Life	5 years	Identical
Biocompatibility	Implant with permanent >30 day	Identical
Sterilization	Sterile: Gamma Non-sterile	Identical
Packaging	Individual packaging	Identical

Parameters	M.U.S.T. Extension - Cannulated Enhanced Pedicle Screw (Subject Device)	M.U.S.T. Cannulated Enhanced Pedicle Screw K141988 (Predicate Device)
Design/Types	Posterior fixation devices to be used with rods and set screws	Identical
Material	Ti6Al4V ELI CoCrMo	Identical

Parameters	M.U.S.T. Extension - Cannulated Enhanced Pedicle Screw (Subject Device)	M.U.S.T. Cannulated Enhanced Pedicle Screw K141988 (Predicate Device)
Diameter	4.5 mm	5 – 7 mm
Length	20 – 50 mm	20 – 90 mm
Device usage	Single Use	Identical
Shelf Life	5 years	Identical
Biocompatibility	Implant with permanent >30 day	Identical
Sterilization	Sterile: Gamma Non-sterile	Identical
Packaging	Individual packaging	Identical

Parameters	M.U.S.T. Extension - Solid Reduction Pedicle Screw (Subject Device)	M.U.S.T. Solid Reduction Pedicle Screw K153664 (Predicate Device)
Design/Types	Posterior fixation devices to be used with rods and set screws	Identical
Material	Ti6Al4V ELI	Identical
Diameter	4.0 mm	4.5 – 7 mm
Length	20 – 50 mm	20 – 90 mm
Device usage	Single Use	Identical
Shelf Life	5 years	Identical
Biocompatibility	Implant with permanent >30 day	Identical
Sterilization	Sterile: Gamma Non-sterile	Identical
Packaging	Individual packaging	Identical

Parameters	M.U.S.T. Extension - Cannulated Reduction Pedicle Screw (Subject Device)	M.U.S.T. Cannulated Reduction Pedicle Screw K153664 (Predicate Device)
Design/Types	Posterior fixation devices to be used with rods and set screws	Identical
Material	Ti6Al4V ELI	Identical
Diameter	4.5 mm	5 – 7 mm
Length	20 – 50 mm	25 – 90 mm
Device usage	Single Use	Identical
Shelf Life	5 years	Identical
Biocompatibility	Implant with permanent >30 day	Identical

Parameters	M.U.S.T. Extension - Cannulated Reduction Pedicle Screw (Subject Device)	M.U.S.T. Cannulated Reduction Pedicle Screw K153664 (Predicate Device)
Sterilization	Sterile: Gamma Non-sterile	Identical
Packaging	Individual packaging	Identical

Parameters	M.U.S.T. Extension – Straight Connectors (Subject Device)	M.U.S.T. Cross Connectors K132878 (Predicate Device)
Design/Types	Posterior fixation devices to be used with rods and set screws	Identical
Material	Ti6Al4V ELI CoCrMo	Ti6Al4V ELI
Length	20 – 50 mm	20 – 90 mm
Device usage	Single Use	Identical
Shelf Life	5 years	Identical
Biocompatibility	Implant with permanent >30 day	Identical
Sterilization	Sterile: Gamma Non-sterile	Identical
Packaging	Individual packaging	Identical
Additional technical features	Length is not adjustable	Length is adjustable from 35 – 98 mm

Discussion
As seen above, the differences between the subject and predicate devices are the addition of new screw diameters (4.0 mm for solid screws and 4.5 mm for cannulated screws) to the range of sizes and the addition of a straight connector. These technological differences do not raise new questions of safety or effectiveness. A comparison evaluation shows there are no new risks associated with the subject device design.

VII. Performance Data

The addition of the subject devices was evaluated by risk analysis to identify any new risks associated with the extension of the pedicle screw sizes and the inclusion of the straight connectors. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and predefined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system.

The M.U.S.T. Extension - Straight Connectors and Additional Screws was tested per ASTM F1717-12 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model using the worst-case device for each of the following tests:

1. Dynamic Compression - Bending
2. Static Compression – Bending
3. Static Torsion

The testing met all acceptance criteria and verifies that the performance of the M.U.S.T. Extension - Straight Connectors and Additional Screws is substantially equivalent to the predicate devices.

VIII. Conclusion

The information provided above supports that the M.U.S.T. Extension - Straight Connectors and Additional Screws are as safe and effective as the predicate devices. Therefore, it is concluded that the M.U.S.T. Extension - Straight Connectors and Additional Screws is substantially equivalent to the predicate devices.