DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 1, 2017

Medacta International SA
% Roshana Ahmed, M.A., RAC
Associate Director, Regulatory Affairs
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

Re: K171758
Trade/Device Name: M.U.S.T. Combined Set Screws
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: July 27, 2017
Received: July 27, 2017

Dear Ms. Ahmed:

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,

Mark N. Melkerson -S

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)*
K171758

Device Name
M.U.S.T. Combined Set 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 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

Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: June 12, 2017

II. Device

Device Proprietary Name:	M.U.S.T. Combined Set Screws
Common or Usual Name:	Pedicle Screw Spinal System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Regulation Number:	21 CFR 888.3070, 21 CFR 888.3060, 21 CFR 888.3050
Product Code:	NKB, KWP, KWQ
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

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

IV. Device Description

The M.U.S.T. Combined Set Screws are intended to be used as part of the M.U.S.T. Pedicle Screw System (cleared under K121115, K132878, K141044, K141988, K153664, K162061, and K171170) 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 and K132878), cannulated or non-cannulated mono-axial pedicle screws (K132878), set screws (K121115), straight and pre-bent rods (K121115 and K162061), cross connectors (K132878), hooks (K141044), enhanced screws and rods designed for percutaneous surgery (K141988 and K162061), cannulated or non-cannulated reduction

screws (K153664), connectors (K162061 and K171170), and standard, enhanced, and reduction pedicle screws (K171170).

The M.U.S.T. Combined Set Screws are manufactured from CoCrMo alloy (ISO 5832-12 and ASTM F1537-11) and are provided sterile and non-sterile. The sterile screw is packaged individually as well as in packages of 2, 4, 6, and 8 screws. The non-sterile screw is packaged individually.

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 M.U.S.T. Combined Set Screws and the predicate device's set screws share the following characteristics:

- materials of construction;
- packaging; and
- sterilization method.

The M.U.S.T. Combined Set Screws are technologically different from the predicate device's set screws with respect to the design of the screw interface.

A comparison of the subject and the predicate devices is provided in the table below.

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Technological comparison

Parameter	M.U.S.T. Combined Set Screws	M.U.S.T. Pedicle Screw System (Set Screws Only) (K121115)
Material	CoCrMo	CoCrMo
Diameter	Ø 9	Ø 9
Interface Design	Torx (Hexalobe T27)	Hexagon
Device Use	Single Use	Single Use
Shelf Life	5 years	5 years
Sterilization	Sterile: Gamma	Sterile: Gamma

Discussion

As seen above, the only difference between the subject and predicate device's set screws is the interface design. This technological difference does not raise different questions of safety or effectiveness and the difference is addressed by the performance data identified below.

VII. Performance Data

The following performance studies were conducted in support of the substantial equivalence determination:

- Dynamic Compression Bending in accordance with ASTM F1717-15 *Standard Test Methods For Spinal Implant Constructs In A Vertebrectomy Model*;
- Interconnection Mechanism Testing in accordance with ASTM F1798-13 *Standard Guide For Evaluating The Static And Fatigue Properties Of Interconnection Mechanisms And Subassemblies Used In Spinal Arthrodesis Implants*;
- Sawbones Testing
- Pyrogenicity Testing (LAL Endotoxin Test)

VIII. Conclusion

The information provided above supports that the M.U.S.T. Combined Set Screws are as safe and effective as the predicate devices. Although there is a minor difference in design between the subject and predicate devices, the testing supports that this difference does not raise any new questions of safety and effectiveness. Therefore, it is concluded that the M.U.S.T. Combined Set Screws are substantially equivalent to the predicate devices.