



Food and Drug Administration
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October 21, 2016

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

Re: K162061
Trade/Device Name: M.U.S.T. Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWQ, KWP
Dated: July 26, 2016
Received: July 28, 2016

Dear Ms. Wheeler:

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 Parts 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" (21CFR 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

Indications for Use

510(k) Number (if known)

K162061

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 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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3 510(k) Summary

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Date Prepared: July 25, 2016
Date Revised: September 30, 2016

DEVICE INFORMATION

Trade/Proprietary Name: M.U.S.T. Pedicle Screw System
Common or Usual Name: Pedicle screw spinal system
Classification Name: Pedicle screw spinal system
Primary Product Code: NKB
Secondary Product Code: MNI, MNH, KWQ, KWP
Regulation Number: 21 CFR 888.3070, 21 CFR 888.3060, 21 CFR 888.3050
Device Class: III

PREDICATE DEVICE INFORMATION

Primary Predicate:
M.U.S.T. Pedicle Screw System, K121115, Medacta International SA

Additional Predicates
M.U.S.T. Pedicle Screw System, K141988, Medacta International SA
M.U.S.T. Extension, K141044, Medacta International SA
M.U.S.T. Extension, K132878, Medacta International SA
Expendium Spine System, K041119, DePuy Spine, Inc.

Synergy D2 Spinal Implants, K984578, Interpore Cross International
MOSS Miami Spinal System, K983583, DePuy Inc.

DEVICE DESCRIPTION

The M.U.S.T. Pedicle Screw System devices are fixation devices intended 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), cannulated or non-cannulated mono-axial pedicle screws (K132878), set screws (K121115), straight and pre-bent rods (K121115), and cross connectors (K132878).

The new lateral connectors can be used when a certain off-set screw has to be implanted with the rod. The lateral connectors offer the same interface to the rod as the monoaxial screw (K132878). The lateral connectors are offered in three sizes (20, 40 and 60 mm sizes) to accept a 5.5mm rod and manufactured of Ti-6Al-4V ELI (ISO 5832-3, ASTM F136).

The new anodized rods and anodized enhanced rods act as a connector between the different screws to create a stable construct. The screws are used in combination with 5.5mm titanium alloy rods. This allows the surgeon to choose the construct stiffness based on the indication by maintaining the screw sizes. They are offered as a 5.5mm diameter in various lengths (100, 200, 300 and 480 mm sizes) and manufactured of Ti-6Al-4V ELI (ISO 5832-3, ASTM F136).

The new rod-to-rod connectors can be used to connect two rods to increase the construct stability. The cross connectors have a medial/lateral length adjustable element in order to address different distances. Rod distances from 35mm to 98 mm can be addressed with the different connector sizes. The rod to rod connectors are manufactured of Ti-6Al-4V ELI (ISO 5832-3, ASTM F136) and the set-screws are made of Co-Cr-Mo (ISO 5832-12, ASTM F1537).

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.

Discussion:

The Indications for Use Statement is identical to the predicate device.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The indications for use, design features, and materials of the subject devices are substantially equivalent to those of the predicate devices.

Feature	Lateral Connectors	M.U.S.T. Pedicle Screw System K121115, K132878	DePuy Expedium K041119
Material of Construction	Connector: Ti-6Al-4V ELI (ISO 5832-3, ASTM F136) Set Screw: Co-Cr-Mo (ISO 5832-12, ASTM F1537)	SAME	SAME
Sterilization Method	Sterile: Gamma Non-sterile	SAME	SAME
Device Usage	Single Use	SAME	SAME
Sizes	3 Sizes (20mm, 40mm, 60mm)	40mm	3 sizes (20mm, 50mm, 150mm)
Rod Compatibility	5.5mm	SAME	SAME
Shelf Life	5 years	5 years	SAME

Features	Anodized Rods and Anodized Enhanced Rods	M.U.S.T. Pedicle Screw System K121115, K132878, K141044, K141988
Material of Construction	Ti-6Al-4V ELI (ISO 5832-3, ASTM F136)	SAME
Adonization	Gold	SAME (Screws, Hooks, Cross Connectors)
Sterilization Method	Sterile: Gamma Non-sterile	SAME
Device Usage	Single Use	SAME
Diameter	5.5mm	SAME
Lengths	4 sizes (100mm, 200mm, 300mm, 480mm)	SAME
Shelf Life	5 years	SAME

Features	Rod to Rod Connectors	M.U.S.T. Pedicle Screw System K121115	Synergy Spinal System K984578	DePuy Moss Miami K983583	DePuy Expedium K041119
Material of Construction	Connector: Ti-6Al-4V ELI (ISO 5832-3, ASTM F136) Set Screw: Co-Cr-Mo (ISO 5832-12, ASTM F1537)	SAME	Titanium and Stainless Steel	Connector: Ti-6Al-4V ELI (ISO 5832-3, ASTM F136) Stainless Steel (ASTM F138)	Connector: Ti-6Al-4V ELI (ISO 5832-3, ASTM F136)
Sterilization Method	Sterile: Gamma Non-sterile	SAME	UNKNOWN	SAME	SAME
Device Usage	Single Use	SAME	SAME	SAME	SAME
Lengths	4 sizes (10.5mm, 16mm, 29mm, 31mm)	N/A	UNKNOWN	UNKNOWN	4 Sizes (5mm, 10mm, 15mm, 20mm)
Rod Diameter	5.5mm up to 6.35mm	5.5mm	4.75mm, 6.35mm	5.0mm, 6.35mm	5.5mm
Shelf Life	5 years	SAME	UNKNOWN	SAME	SAME
Additional Features	In Line, In Line Open, Domino Narrow, Domino Wide, Domino Open, Tulip Based Narrow, Tulip Base Wide	NA	UNKNOWN	UNKNOWN	In Line, Domino

The fundamental scientific technology of the devices has not changed relative to the predicate devices. The safety and effectiveness of the subject devices is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

PERFORMANCE TESTING

The addition of the subject devices was evaluated by risk analysis to identify any new risks associated with the screw modification and inclusion of the rod to rod connectors, lateral connectors and anodized rods. 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 following mechanical tests were performed or leveraged to support the substantial equivalence on the subject devices:

Rod to Rod Connectors, Lateral Connectors, Anodized Rods

1. Static Compression Bending Strength ASTM F1717
2. Static Torsion Strength ASTM F1717
3. Dynamic Compression Bending Strength ASTM F1717
4. Static Transverse Moment ASTM F1798
5. Four-Point Dynamic Bending Strength ASTM F2193

Conclusion:

Based on the above information, the M.U.S.T. Pedicle Screw System can be considered substantially equivalent to the identified predicate devices.