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Medacta International  
Michael G. Loiterman, MPD, RAC, CCEP  
Director – Quality, Regulatory and Compliance  
Medacta USA  
1556 West Carroll Avenue  
Chicago, Illinois 60607

Re: K153664  
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: December 18, 2015  
Received: December 21, 2015

Dear Mr. Loiterman:

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" (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 yours,

Lori A. Wiggins -S

for

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)

**K153664**

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) 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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### 510(k) Summary

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Date Prepared: December 18, 2015

#### DEVICE INFORMATION

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

Predicate Device(s):  
Primary Predicate

510(k)	Product	510(k) Holder	Clearance Date
K121115	M.U.S.T. Pedicle Screw System	Medacta International	7/18/2012

Additional Predicate

510(k)	Product	510(k) Holder	Clearance Date
K141988	M.U.S.T. Pedicle Screw System	Medacta International	8/1914

Product Description

The M.U.S.T. Extension is intended to be used as part of the M.U.S.T. pedicle screw system (K121115, K132878, K141988) 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 M.U.S.T. pedicle screw system also includes the enhanced screws and rods designed for percutaneous surgery (K141988).

This Special 510(k) introduces a new design of the pedicle screw head (Tulip). The new design features two additional tabs in order to perform the rod reduction with the setscrew. The tulip has also changed materials from to CoCrMo to Ti6Al4V ELI.

The size range of the modified Pedicle Screws introduced with this 510(k) is the same as the predicate devices.

The M.U.S.T. Extension consists of the following components, which are all provided in both sterile and unsterile packaging:

<b>Component</b>	<b>Diameter</b>	<b>Length</b>	<b>Material</b>
Solid Poly-Axial Pedicle Screws	4.5, 5, 6, 7mm	20-90mm	Ti6Al4V ELI (ISO 5832-3 ASTM F 136)
Cannulated Poly-Axial Pedicle Screws	5, 6, 7mm	25-90mm	Ti6Al4V ELI (ISO 5832-3 ASTM F 136)

### Indications for Use

The M.U.S.T. Pedicle Screw System is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) 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.

### Comparison to Predicate Devices

The indications for use, design features and materials of the M.U.S.T. Extension are substantially equivalent to those of the predicate devices. The substantial equivalence of the M.U.S.T. Extension implants is supported by the performance testing, materials information, and data analysis provided within this Premarket Notification.

### Performance Testing

The modification to the device system to include the addition of the M.U.S.T. Extension was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system.

The following mechanical tests, per ASTM F 1717, were performed on the device:

1. Static compression/bending strength ASTM F 1717
2. Dynamic compression/bending strength ASTM F 1717
3. Static torsion strength ASTM F 1717

The device's behavior and performance can be considered equivalent to its predicate.

### Conclusion:

Based on the above information, the M.U.S.T. Extension can be considered as substantially equivalent to its predicate devices.