DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 18, 2014

Medacta International SA
% Mr. Adam Gross
Medacta USA
1556 West Carroll Avenue
Chicago, Illinois 60607

Re: K141044
Trade/Device Name: M.U.S.T. Extension
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWQ, KWP
Dated: July 17, 2014
Received: July 18, 2014

Dear Mr. Gross:

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 yours,

Ronald P. Jean -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)*
K141044

Device Name
M.U.S.T. Extension

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)

**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)*

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**510(k) Summary**

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Date Prepared: July 16, 2014

DEVICE INFORMATION

Trade/Proprietary Name: M.U.S.T. Extension
Common Name: Pedicle screw spinal system
Classification Name: orthosis, Spinal pedicle fixation, for degenerative disc disease
21 CFR 888.3070, 21 CFR 888.3060, 21 CFR 888.3050
Class III
Device Product Codes: MNI, MNH, NKB, KWQ, KWP
Predicate Device(s):

| 510(k) | Product | 510(k) Holder | Clearance Date |
|---|---|---|---|
| K121115 | M.U.S.T Pedicle Screw System | Medacta International | 7/18/2012 |
| K132878 | M.U.S.T Extension | Medacta International | 12/18/2013 |
| K083393 | XIA3 | Stryker | 4/23/2009 |
| K042962, K091445 | CD Horizon | Medtronic | 12/14/2004, 9/27/2010 |
| K052151 | Pangea | Synthes | 12/7/2005 |
| K041119 | Expedium | Depuy | 7/19/2004 |
| K072022 | Valeo Pedicle Screw System | Amedica | 11/19/2007 |
| K022949 | USS | Synthes Spine | 3/24/2003 |
| K100952 | Matrix | Synthes Spine | 8/6/2010 |
| K024096 | Optima | U&I | 3/12/2003 |

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) 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. Extension consists of the following components, which are all provided in both sterile and unsterile packaging

| Component | Sizes | Material |
|---|---|---|
| Wide blade hook | Small, Medium, Large | Ti6Al4V ELI (ISO 5832-3/ASTM F 136) |
| Pedicle hook | Xsmall, Small, Medium, Large | Ti6Al4V ELI (ISO 5832-3/ASTM F 136) |
| Pedicle hook screw | Diameter 3.5mm; Length 15 & 20mm | Ti6Al4V ELI (ISO 5832-3/ASTM F 136) |
| Angled hook | Right and Left | Ti6Al4V ELI (ISO 5832-3/ASTM F 136) |
| Offset hook | Right and Left | Ti6Al4V ELI (ISO 5832-3/ASTM F 136) |
| Narrow blade hook | Small, Medium, Large | 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) 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.

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 geometrical comparisons were performed in order to substantiate the applicability of the tests already performed on the predicate devices and to demonstrate that the M.U.S.T. Extension is not worst case compared to the predicate devices:

- Implant/Rod/Set Screw interface (Hooks)
- Implant/Bone interface (Hooks)

There were not any additional tests performed on the hooks as the interface to the rod, the tulip and thread geometry, the set screw and the final tightening torque are exactly the same as for the M.U.S.T. monoaxial screws (K132878). Therefore, the biomechanical implant performance regarding yield strength, fatigue strength and construct stiffness can be considered at least equal to the predicate devices.

Conclusion:

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