January 22, 2019

Medacta International SA
% Mr. Christopher Lussier
Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K182837
Trade/Device Name: M.U.S.T. Mini Extension
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: December 17, 2018
Received: December 18, 2018

Dear Mr. Lussier:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182837

Device Name
M.U.S.T. MINI Extension

Indications for Use *(Describe)*
The M.U.S.T. MINI Posterior Cervical Screw System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion, in skeletally mature patient, for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The M.U.S.T. MINI Posterior Cervical Screw System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the M.U.S.T. MINI Posterior Cervical Screw System may be connected to the M.U.S.T. System rods with the M.U.S.T. MINI rod connectors. Transition rods with differing diameters may also be used to connect the M.U.S.T. MINI Posterior Cervical Screw System to the M.U.S.T. System. Refer to the M.U.S.T. System package insert for a list of the M.U.S.T. Indications of Use.

When used with the Occipital Plate, the M.U.S.T MINI Posterior Cervical Screw System is also intended to provide immobilization and stabilization for the occipito-cervico-thoracic junction (occiput – T3) in treatment of the instabilities mentioned above, including occipitocervical dislocation.

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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2.0 510(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, Medacta International SA
Date Prepared: October 5, 2018
Date Revised: December 14, 2018

II. Device

Device Proprietary Name:	M.U.S.T. MINI Extension
Common or Usual Name:	Spinal Interlaminal Fixation Orthosis
Classification Name:	Appliance, Fixation, Spinal Interlaminal
Primary Product Code:	NKG, KWP
Regulation Number:	Unclassified, 21 CFR 888.3050
Device Classification	Unclassified, II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- Mountaineer OCT Spinal System - K110353, DePuy;

Additional predicate devices:

- M.U.S.T. MINI Posterior Cervical Screws System - K171369, Medacta International SA;
- Synapse Occipital-Cervical-Thoracic (OCT) System - K070573 and K142838, Synthes;
- Mountaineer OCT Spinal System - K042508, DePuy; and
- Solanas Avalon Posterior Fixation System - K111076, Alphatec.

IV. Device Description

The subject M.U.S.T. MINI Extension implants are line extension to the previously cleared Medacta M.U.S.T. MINI Posterior Cervical Screws System (K171369).

The new subject Posterior Occipital-Cervical Screw System is a multi-component device, manufactured from Titanium-based and CoCr materials, consisting of occipital plates, occipital screws and straight and pre-bent rods that longitudinally connect the occiput with the posterior cervical spine. The system is intended to stabilize and fuse the spine in degenerative disc disease, spinal fusion, cervical fractures and in surgically repaired spinal pseudoarthrosis. In addition, it is used in deformity correction e.g. scoliosis to correct and stabilize the spine.

The M.U.S.T. MINI Extension implants have been designed with the same or similar shape, dimensions and materials as the previously cleared Medacta M.U.S.T. MINI Posterior Cervical Screws System (K171369), Synthes Synapse OCT System (K070573 and K142838), DePuy Mountaineer OCT Spinal System (K042508 and K110353) and Alphatec Solanas Avalon Posterior Fixation System (K111076).

The M.U.S.T. MINI Extension implants are manufactured with the same materials of the Medacta predicate device M.U.S.T. MINI Posterior Cervical Screws System (K171369): Ti-6Al-4V ELI (*ISO 5832-3 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy + ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*) and CoCrMo (*ISO 5832-12 Implants for surgery -- Metallic materials -- Part 12: Wrought cobalt-chromium-molybdenum alloy + ASTM F1537 Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)*).

Additionally, the new 4x and 6x package for the already cleared (K171369) M.U.S.T. MINI set screw implant have been introduced.

V. Indications for Use

The M.U.S.T. MINI Posterior Cervical Screw System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion, in skeletally mature patient, for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The M.U.S.T. MINI Posterior Cervical Screw System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the M.U.S.T. MINI Posterior Cervical Screw System may be connected to the M.U.S.T. System rods with the M.U.S.T. MINI rod connectors. Transition rods with differing diameters may also be used to connect the M.U.S.T. MINI Posterior Cervical Screw System to the M.U.S.T. System. Refer to the M.U.S.T. System package insert for a list of the M.U.S.T. Indications of Use.

When used with the Occipital Plate, the M.U.S.T MINI Posterior Cervical Screw System is also intended to provide immobilization and stabilization for the occipito-cervico-thoracic junction (occiput – T3) in treatment of the instabilities mentioned above, including occipitocervical dislocation.

VI. Comparison of Technological Characteristics

The M.U.S.T. MINI Extension implants and the predicate devices share the following characteristics:

- design;
- range of products;
- materials of construction;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The subject devices are substantially identical to the predicate devices M.U.S.T. MINI Posterior Cervical Screws System (K171369), Synthes Synapse OCT System (K070573 and K142838), DePuy Mountaineer OCT Spinal System (K042508 and K110353) and Alphatec Solanas Avalon Posterior Fixation System (K111076).

Due to the extensive history of use in currently marketed medical devices, biocompatibility testing conducted on the predicate device M.U.S.T. MINI Posterior Cervical Screws System (K171369) for the same materials supports the biological safety of the M.U.S.T. MINI Extension implants.

VII. Performance Data

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following mechanical studies were performed in support of a substantial equivalence determination:

Non-Clinical Studies:

- Characterization Test
    - Design Validation Workshop
- Performance Tests
    - static compression bending test: *ASTM F2706-08 (Reapproved 2014) Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model*
    - static torsion test: *ASTM F2706-08 (Reapproved 2014) Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model*

- dynamic axial compression test: *ASTM F2706-08 (Reapproved 2014) Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model*
- dynamic torsion test: *ASTM F2706-08 (Reapproved 2014) Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model*
- axial gripping test: *ASTM F1798-13 Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants*
- plate torque to failure test
- screw torque to failure test

- Pyrogenicity
  - Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and pyrogen test according to USP chapter <151> for pyrogenicity determination
  - the subject devices are not labeled as non-pyrogenic or pyrogen free

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

Based on the above information, the M.U.S.T. MINI Extension implants are substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance evaluations. The M.U.S.T. MINI Extension implants are as safe and effective as the predicate devices M.U.S.T. MINI Posterior Cervical Screws System (K171369), Synapse OCT System (K070573 and K142838), Mountaineer OCT Spinal System (K042508 and K110353) and Solanas Avalon Posterior Fixation System (K111076).