February 10, 2020

Medacta International SA
℅ Mr. Chris Lussier
Senior Director of Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K200130
Trade/Device Name: M.U.S.T. MINI Posterior Cervical Screws System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior cervical screw system
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: January 17, 2020
Received: January 21, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K200130

Device Name
M.U.S.T. MINI Posterior Cervical Screws System

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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510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Sr. Director of Quality and Regulatory, Medacta USA
Date Prepared: January 17, 2019
Date Revised: February 10, 2020

II. Device

Device Proprietary Name:	M.U.S.T. MINI Posterior Cervical Screws System
Common or Usual Name:	Spinal Interlaminal Fixation Orthosis
Classification Name:	Appliance, Fixation, Spinal Interlaminal
Primary Product Code:	NKG, KWP
Regulation Number:	21 CFR, 888.3075, 21 CFR 888.3050
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- M.U.S.T. MINI Posterior Cervical Screws System, K171369, Medacta International SA

Additional predicate devices:

- Synapse Occipital-Cervical-Thoracic (OCT) System, K142838, Synthes USA Products, LLC (also referred to as Synthes' Synapse System)
- Synapse System, K070573, Synthes Spine Co. LP, (also referred to as Synthes' Synapse System)
- Synthes Cervifix/Axon, K023675, Synthes (USA), (also referred to as Synthes' Axon System)
- Synthes Cervifix System, K991089, Synthes Spine, (also referred to as Synthes' Axon System)
- Depuy Mountaneer OCT spinal system, K042508, DEPUY SPINE (USA), INC.

IV. Device Description

The M.U.S.T. MINI poly-axial screws and lateral connectors are a line extension to the previously cleared Medacta M.U.S.T. MINI Posterior Cervical Screws System (K171369).

The poly-axial screws included in the line-extension are equivalent to the ones legally marketed, with the exception of individual length. For the Ø4.5mm poly screws, the length is extended from "26 to 50mm" to "14 to 50mm" (adding the 14 to 24 mm sizes).

The range of Ø4mm and Ø4.5mm partial thread screws design is extended from "26 to 42mm" to "26 to 50mm" (adding the 44 to 50mm sizes) with 2 mm of increments. For the Ø3.5mm partial thread screws, the lengths of 26 to 40mm are added, 2 mm increments.

The range of full thread screw design Ø4.5mm is extended from 26-50mm to 14-50mm with 2 mm increments.

All the poly-axial screws features are the same: intended use, diameters, pitch, threading pitch, length increment, range of motion, driving interface, material, surface finishing, manufacturing process, washing, packaging and final storing condition.

The lateral connectors introduced as line-extension are equivalent to the ones legally marketed, with the exception of the length: same intended use, diameter of the shaft, fixing interfaces, material, surface finishing, machining, washing, packaging and final storing condition.
The Lateral connector included in this line extension are aimed to extended the product range from 10-15mm to 10-30mm, in steps of 5mm.

The M.U.S.T. MINI poly-axial screws and lateral connectors are manufactured from 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)*), *the same material of the previous cleared* M.U.S.T. MINI M.U.S.T. MINI Posterior Cervical Screws System (K171369).

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.

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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.

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VI. Comparison of Technological Characteristics

The M.U.S.T. MINI Posterior Cervical Screws System poly-axials screws and the predicate devices share the following characteristics:

- diameter and length;
- materials of construction;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.
- lengths

The poly-axials screws are substantially equivalent to the primary predicate device M.U.S.T. MINI Posterior Cervical Screws System (K171369).

The M.U.S.T. MINI Posterior Cervical Screws System lateral connectors and the predicate devices share the following characteristics:

- diameter
- materials of construction;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The Extension M.U.S.T. MINI Posterior Cervical Screws System lateral connectors are technologically different from the predicate devices as follows:

- lengths

As seen above, the M.U.S.T. MINI Posterior Cervical Screws System lateral connectors are substantially equivalent to the predicate devices in terms of diameter; materials, biocompatibility, device usage, sterility, shelf life and packaging.

Regarding the M.U.S.T. MINI Posterior lateral connectors, the only difference between the subject and predicate devices is the lengths: extended from “10m and 15mm” to 10mm, 15mm, 20mm, 25mm, and 30mm (an addition of the 20m, 25mm, and 30mm lengths). This addition of connector

lengths does not introduce any new worst case as compared to the shorter lengths and thus there is no impact on safety and performance of the overall construct.

The new feature has been designed in order to increase the product range. This technological difference does not raise new questions of safety or effectiveness and a comparison evaluation shows there are no new risks associated with the subject device design.

VII. Performance Data

- Engineering Rationale
  A comparative analysis of the subject devices to the identified predicate and reference devices was performed to determine if the line-extension created a new worst-case product size. It was determined that the subject poly-axial screws and lateral connectors are substantially equivalent to the previously cleared predicate device and that the line-extension can be considered within the scope of the design verification and validation testing previously completed for the initial MUST MINI implants product range.

The predicate M.U.S.T. MINI Posterior Cervical Screws System (cleared under K171369) was tested using the worst-case device for each of the following tests:

Non-Clinical Studies

- Performance Tests
  - o Static and Fatigue Testing: ASTM F1717-15 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
    - o Static and Fatigue Testing: ASTM F1798-13 Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
- Cadaver Testing
- Design Comparisons
- Bacterial Endotoxin Testing (LAL Method)

Clinical Studies

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the M.U.S.T. MINI Posterior Cervical Screws System poly-axial screws and lateral connectors are as safe and effective as the predicate devices.

Although minor differences in length exist between the subject and primary predicate device, testing supports that these differences do not raise any new questions of safety or effectiveness. Therefore, it is concluded that the M.U.S.T. MINI Posterior Cervical Screws System poly-axial screws and lateral connectors are substantially equivalent to the identified predicate devices.