November 16, 2020

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

Re: K203149
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: October 21, 2020
Received: October 22, 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,

Colin O'Neill, M.B.E.
Assistant Director
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)*

K203149

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: Christopher Lussier, Senior Director, Quality and Regulatory, Medacta USA
Date Prepared: October 21, 2020
Date Revised: November 4, 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:	Posterior Cervical Screw System
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:

- M.U.S.T. MINI Posterior Cervical Screws System Extension, K182837, Medacta International SA
- M.U.S.T. MINI Posterior Cervical Screws System Extension, K190631, Medacta International SA
- M.U.S.T. MINI Posterior Cervical Screws System Extension, K200130, Medacta International SA
- 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.

Reference Predicate:

- MUST Pedicle Screw System, K1121115, Medacta International SA
- MUST Pedicle Screw System, K141988, Medacta International SA
- MUST Pedicle Screw System, K162061, Medacta International SA

IV. Device Description

The M.U.S.T. MINI Anodized Rods and the Rod to Rod Connectors (parallel and in-line) are a line extension to the previously cleared Medacta M.U.S.T. MINI Posterior Cervical Screws System (K171369), M.U.S.T. MINI Posterior Cervical Screws System extension (K182837) and M.U.S.T. MINI Posterior Cervical Screws System extension (K200130).

Rod to rod connectors are extended to additional design: the parallel and the In-line design, available in both open/closed design. Connectors are designed to accommodate both the rods in Ø3.5mm and Ø5.5mm. This solution allows to connect the cervical and upper thoracic spine with axial or parallel rods from equal diameter or different: 3.5mm versus 3.5mm and 3.5mm versus 5.5mm.

Anodized rods (straight and pre-curved) are provided in straight and pre-curved designs and the diameters and lengths are within the range of existing M.U.S.T. MINI Posterior Cervical Screws System rods product range, with equivalent overall characteristics: same intended use, diameter 3.5mm, in the range 30-420mm, material, machining, washing, packaging and final storing condition.

The subject devices 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 Posterior Cervical Screws System (K171369) and M.U.S.T. MINI Posterior Cervical Screws System Extension (K182837 and K200130).

Surface finishing of both subjects devices is further characterized by color anodization like for existing Polyaxial screws, hooks, lateral connector, rod to rod connector, cross connector clamp and spinous reconstruction cross connectors (all cleared under K171369), Occipital Plates (K182837) and are Type III color anodized.

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 Posterior Cervical Screws Rods subject of this submission and the predicate devices share the following characteristics:

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

The rods are substantially equivalent to the primary predicate device M.U.S.T. MINI Posterior Cervical Screws System (K171369), Synapse Occipital-Cervical-Thoracic (OCT) System, (K142838 and K070573) and Synthes Cervifix/Axon System (K991089 and K023675)

In particular the Straight Anodized Rods subject of this submission have the same diameter of the predicates devices M.U.S.T. MINI Posterior Cervical Screws System (K171369), Synapse Occipital-Cervical-Thoracic (OCT) System, (K142838 and K070573) and Synthes Cervifix/Axon System (K991089 and K023675).

The length range included in the Predicates devices, except the longest sizes that don't introduce any worst case than the shorter one, have no impact on safety and performance of the overall construct. A long rod can be cut to adapt the length to patient anatomy.

Pre-curved anodized Rods subject of this submission have the same diameter as the predicate devices M.U.S.T. MINI Posterior Cervical Screws System (K171369), Synapse Occipital-Cervical-Thoracic (OCT) System, (K142838 and K070573) and Synthes Cervifix/Axon System (K991089 and K023675). The length range of Pre-curved anodized Rods is identical to the straight rods included in the predicates devices except the smaller and longest size. The pre-curved rod design reduces intraoperative steps and stress for contouring the rod. Shorter and longer sizes offer improved versatility in the system to accommodate individual patient's anatomy.

The M.U.S.T. MINI Posterior Cervical Screws System Rod to Rod connectors subject of this submission and the predicate devices share the following characteristics:

- smaller rod diameter interface Ø3.5mm
- materials of construction;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The Extension M.U.S.T. MINI Posterior Cervical Screws System rod connectors are substantially equivalent to the predicate devices in terms of smaller rod diameter interface, materials, biocompatibility, device usage, sterility, shelf life and packaging.

In details, the parallel Rod to Rod Connectors have no difference with the predicates devices. The In-line connectors have no impact on the overall construct performance since the fixation interface at the connector-rod is equivalent to the parallel ones.

The new devices 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 this line-extension created a new worst-case product size. It was determined that the subject devices 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.

VIII. Conclusion

The information provided within this submission supports that the subject devices are as safe and effective as the predicate devices.

Although minor differences 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 subject devices are substantially equivalent to the identified predicate devices.