April 26, 2022

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

Re: K220570
Trade/Device Name: M.U.S.T. MINI Posterior Cervical Screws System Extension
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: February 25, 2022
Received: February 28, 2022

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220570

Device Name
M.U.S.T. MINI Posterior Cervical Screws System 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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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 and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director of Quality and Regulatory, Medacta USA
Date Prepared: February 25, 2022
Date revised: April 20, 2022

II. Device

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

III. Predicate Device

Substantial equivalence is claimed to the following predicate 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, K200130, Medacta International SA
- BRIDALVEIL Occipital Cervical Thoracic System, K171250, Astura Medical

Reference devices:

- M.U.S.T. Pedicle Screw System, Medacta International, K121115, Medacta International SA
- M.U.S.T. Pedicle Screw System Extension - Straight Connectors and Additional Screws, Medacta International, K171170, Medacta International SA

IV. Device Description

The subject M.U.S.T. MINI Posterior Cervical Screws System Extension is a Medacta M.U.S.T. MINI Posterior Cervical Screws System line extension. Specifically, the current submission includes the following implants:

- M.U.S.T. MINI Polyaxial screw dual lead solid and cannulated with diameters ranging from 4 to 6mm and lengths from 20 to 50mm;
- M.U.S.T. MINI cross connector top load, four sizes.

The subject devices are made of Ti6Al4V ELI according to ISO 5832-3 *Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy* and ASTM F136-13 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*.

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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VI. Comparison of Technological Characteristics

The subject devices are substantially equivalent to the predicate (K171369 and for the screws also K200130 and K171250) with regards to the following characteristics:

- connectors fixation method;

- lengths;
- materials;
- biocompatibility;
- device usage;
- sterility;
- shelf-life; and
- packaging.

The subject implants differ from the predicate devices (K171369 and for the screws also K200130 and K171250) as follows:

- design; and
- diameters.

Discussion

Medacta International SA has not made any change to the indications for use, general design and shape, fixation, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the predicate devices.

Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the M.U.S.T. MINI Posterior Cervical Screws System Extension implants to the identified predicate devices.

VII. Performance Data

Based on the risk analysis, performance testing was conducted to written protocols. The following tests and rationales are provided in support of the substantial equivalence determination:

Non-Clinical Studies

- *DESIGN VALIDATION*
  - MUST MINI Cross connectors top loading line extension - Design Validation Report

- *PERFORMANCE TESTING*
  - MUST MINI Poly-axial screws line extension – Geometrical comparison rationale
  - Dynamic axial compression bending on Occipital-Cervical bilateral construct according to ASTM F2706
  - Dynamic compression bending on cervical bilateral construct according to ASTM F1717

- *PYROGENICITY*
  - Bacterial endotoxin test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>)
  - Pyrogen test according to USP chapter <151> for pyrogenicity determination
  - The subject devices are not labeled as non-pyrogenic or pyrogen free.

- *BIOCOMPATIBILITY evaluation*

- *SHELF-LIFE evaluation*

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 Extension implants are substantially equivalent to the predicate devices.