May 4, 2021

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

Re: K203671
Trade/Device Name: M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, HWC, HTN

Dear Chris Lussier:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 13, 2021. Specifically, FDA is updating this SE Letter as an administrative correction for an incorrect Indications for Use Statement.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Colin O'Neill, M.B.E., OHT6: Office of Orthopedic Devices, (301) 796-6428, colin.oneill@fda.hhs.gov.

Sincerely,

Colin O'neill -S

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

January 13, 2021

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

Re: K203671
Trade/Device Name: M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, HWC, HTN
Dated: December 15, 2020
Received: December 16, 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 and Part 809; 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 -S

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)*

K203671

Device Name
M.U.S.T. Sacro-Iliac Screws and Pelvic Trauma System

Indications for Use *(Describe)*
The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System is intended for use in skeletally mature patients for fracture fixation of small and long bones of the pelvis, and for sacroiliac joint fusion for patients suffering from sacroiliac joint disruptions and degenerative sacroiliitis.

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
Applicant Correspondent: Chris Lussier, Senior Director Quality / Regulatory, Medacta USA
Date Prepared: December 15, 2020

II. Device

Device Proprietary Name:	M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System
Common or Usual Name:	Pelvic Joint Fixation
Classification Name:	Smooth or threaded metallic bone fixation fastener
Primary Product Code:	OUR
Secondary Product Codes:	HWC, HTN
Regulation Number:	21 CFR 888.3040, 21 CFR 888.3030
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

Primary Predicate Device:

- M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System, K193083, Medacta International SA

Reference Predicate Device

- M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System, K171595, Medacta International SA

IV. Device Description

The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System is designed for sacroiliac joint fusion in degenerative sacroiliitis, as well as for the fixation of small and long bone fractures in trauma cases.

The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System consists of various sized screws, manufactured from Ti6Al4V ELI and coated with rough Hydroxyapatite (HA). The HA coating allows for biological fixation and potentially leads to arthrodesis.

The sacroiliac (SI) joint screws are hollow-body threaded fusion devices with a multiple-fenestrated pattern shaft to promote arthrodesis, a self-tapping design to facilitate screw insertion, and a tapered tip to aid in guidance through pilot hole. Radial windowed slots along the shaft facilitate bone ingrowth after implantation and "bone filling" after insertion.

The SI joint screws are provided in standard and headless designs. The standard screw can be coupled to modular washers of different diameters to optimize and stabilize the contact between the screw head and the cortical bone and to improve the compression activity of the screw. The standard screws are provided sterile in three diameters (8, 9, and 10 mm) and multiple lengths (25 – 80 mm).

The headless screw has an anatomical shape which allows for full insertion into the bone. The headless screws are provided sterile in three diameters (7.5, 9, and 11 mm) and multiple lengths (30 – 75 mm). The M.U.S.T. Sacral Iliac Screws Extension introduces new sizes of these screws keeping the same diameters (7.5, 9, and 11 mm) with new lengths from 80 mm to 100 mm (5 mm increment).

V. Indications for Use

The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System is intended for use in skeletally mature patients for fracture fixation of small and long bones of the pelvis, and for sacroiliac joint fusion for patients suffering from sacroiliac joint disruptions and degenerative sacroiliitis.

VI. Comparison of Technological Characteristics

The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System SI joint screws and the predicate devices share the following characteristics:

- material of construction;
- diameters;
- coating and coating composition;
- biocompatibility;

- sterility;
- shelf life; and
- packaging.

The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System SI joint screws are technologically different from the predicate device with respect to length of the screw and number of the radial windowed slots on the screw shaft.
These differences do not raise different questions of safety or effectiveness and design verification testing supports there are no new risks associated with the subject devices.

VII. Performance Data

The introduction of new sizes of M.U.S.T. SI-Joint Headless screws does not create a new worst case; therefore, the following performance testing from the predicate device was leveraged to support this submission:

- ASTM F543-13 Standard Specification and Test Methods for Metallic Medical Bone Screws;
- ASTM F2193-14 Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System;
- ISO 13779-3: 2008 Implants for Surgery - Hydroxyapatite - Part 3: Chemical Analysis and Characterization of Crystallinity and Phase Purity;
- ASTM F1185-03 (Reapproved 2014) Standard Specification for Composition of Hydroxyapatite for Surgical Implants;
- sterilization validation; and
- shelf-life testing
- Cadaver/Sawbones Workshop

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 M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System product range.

VIII. Conclusion

The information provided within this submission supports that the M.U.S.T. SI-Joint Headless screws are are substantially equivalent to the predicate device**.**