DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 2, 2017

Medacta International SA
% Elizabeth Rose, MST, RAC
Regulatory Affairs Manager
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

Re: K171595
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: July 21, 2017
Received: July 25, 2017

Dear Ms. Rose:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171595

Device Name
M.U.S.T. Sacral Iliac Screw 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.

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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 Affairs Manager
Date Prepared: May 30, 2017
Date Revised: August 1, 2017

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 Code:	HWC, HTN
Regulation Number:	21 CFR 888.3040, 21 CFR 888.3030
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate: Synthes 6.5 mm Cannulated Screw (Also referred to as Synthes Cannulated Screws), K021932, Synthes (USA)

Additional Predicates:
Pelvic Trauma and Washers

- Synthes 7.0/7.3 mm Cannulated Screws (Also referred to as Synthes Cannulated Screws), K962011, Synthes (USA)
- Asnis III Cannulated Screw System, K000080, Howmedica Osteonics Corp.
- Modification to Asnis III Cannulated Screw System, K024060, Howmedica Osteonics Corp.

Sacro-Iliac Joint Screws

- SI-LOK Sacroiliac Joint Fixation System, K112028, Globus Medical, Inc.
- SImmetry Sacroiliac Joint Fusion System, K130092, Zyga Technology, Inc.

Reference Devices

- Medacta Total Hip Prosthesis System – Quadra H and R Femoral Stems, K082792, Medacta International SA
- Medacta Bipolar Head, K091967, Medacta International SA

IV. Device Description

The purpose of this submission is to gain clearance for the new M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System. 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 screws are hollow-body threaded fusion devices with a self-tapping design to facilitate screw insertion, with a tapered tip to aid in guidance through pilot hole. The long pitch and dual thread aid in accelerated screw insertion and removal. A reverse cutting flute is incorporated in the design to facilitate screw removal. The cannulated shaft accepts a Ø 3.2 mm guide wire.

The sacroiliac joint screws are available in titanium and coated with rough Hydroxyapatite (HA) to accommodate sacroiliac joint degeneration. The HA coating allows for biological fixation and potentially leads to arthrodesis. The pelvic trauma screws are available in both full and partial thread designs to aid in fixation in trauma cases. Thread lengths, in combination with the washer application, fit into bone fragments to allow for compression. Radial windowed slots along the screw's body are intended to allow surrounding bone access to the bone substitute used during insertion. Washers are available in both standard and favored designs. The favored design provides angles to accommodate higher angulation.

The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System: Sacroiliac Screws are manufactured with Titanium-6Aluminum-4Vanadium Extra Low Interstitial (Ti-6Al-4V ELI) and the surface treatment consists of an HA coating. The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System: Pelvic Trauma Screws and Washers are manufactured from both Titanium-6Aluminum-4Vanadium Extra Low Interstitial (Ti-6Al-4V ELI) and Stainless Steel.

The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System is similar to predicate devices Synthes' Cannulated Screws (K962011 and K021932), Howmedica's Asnis III Cannulated Screw System (K000080 and K024060), Globus's SI-LOK Sacroiliac Joint Fixation System (K112028) and Zyga's SImmetry Sacroiliac Joint Fusion System (K130092).

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 and the predicate devices share the following characteristics:

- Indications for Use
- Materials of Construction
- Design
- Sterile
- Coating
- Threaded
- Thread Design
- Device Usage

The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System is technologically different from the predicate devices as follows:

- Diameters
- Lengths

The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System components are manufactured from Titanium-6Aluminum-4Vanadium Extra Low Interstitial Alloy (ISO 5832-3:1996 Implants For Surgery – Metallic Materials – Part 3: Wrought Titanium-6Aluminum-4Vanadium Alloy, ASTM F136-13 Standard Specification For Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy For Surgical Implant Applications) and/or Stainless Steel (ISO 5832-1 Fifth Edition 2016-07-15 Implants For Surgery-Metallic Materials-Part 1: Wrought Stainless Steel and ASTM F138-13 Standard Specification For Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire For Surgical Implants).

These materials have been reviewed in the predicate devices' 510(k) submissions Synthes' Cannulated Screws (K962011 and K021932), Howmedica's Asnis III Cannulated Screw System (K000080 and K024060), Globus's SI-LOK Sacroiliac Joint Fixation System (K112028) and Zyga's SImmetry Sacroiliac Joint Fusion System (K130092).

The Hydroxyapatite "Osprovit®" coating used on the M.U.S.T. Sacral Iliac Screws is provided by Eurocoating S.p.A. The Hydroxyapatite "Osprovit®" coating with a titanium alloy substrate was previously reviewed as part of Medacta's submission Total Hip Prosthesis System – Quadra H and R Femoral Stems (K082792).

Due to the extensive history of use in currently marketed medical devices made of the same material, following recognized standards, and following identical or similar manufacturing processes, additional biocompatibility testing was deemed unnecessary for the M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System or M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System Instruments.

A comparison of the subject and predicate device is provided in the tables below.

Technological comparison

M.U.S.T. Pelvic Trauma Screws and Washers

Parameters	M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System (Subject Device)	Synthes Cannulated Screws K962011 and K021932 (Predicate Devices)	Asnis III Cannulated Screw System K000080 and K024060 (Predicate Devices)
Screw Material	Titanium Alloy and Stainless Steel	Titanium Alloy and Stainless Steel	Titanium Alloy and Stainless Steel
Washer Material	Titanium Alloy Type II Anodized and Stainless Steel	Titanium Alloy Gold Anodized and Stainless Steel	Titanium Alloy and Stainless Steel
Washer Diameter	Standard: Ø 13 mm, Ø 15 mm, Ø 17 mm, Ø 20 mm Favored Angle: Ø 15 mm, Ø 17 mm, Ø 20 mm	Ø 13 mm	Unknown
Screw Diameter	Ø 7.3 mm, Ø 8 mm, Ø 9 mm and Ø 10 mm	Ø 6.5 mm and Ø 7.3 mm	Ø 6.5 mm and Ø 8.0 mm
Screw Length	70 mm to 200 mm	20 mm to 180 mm	30 mm to 180 mm
Screw Threaded	Partially and Fully Threaded	Partially and Fully Threaded	Partially and Fully Threaded
Screw Thread Design	Cannulated	Cannulated	Cannulated
Device Usage	Single Use	Single Use	Single Use
Biocompatibility	Implant with permanent >30 day (Equivalency determined)	Implant with permanent >30 day	Implant with permanent >30 day
Sterilization	Gamma	Gamma	Non-sterile and Gamma

M.U.S.T. Sacral Iliac Screws

Parameters	M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System (Subject Device)	SI-LOK Sacroiliac Joint Fixation System K112028 (Predicate Devices)	SImmetry Sacroiliac Joint Fusion System K130092 (Predicate Devices)
Material	Titanium Alloy	Titanium Alloy	Titanium Alloy
Coating	Hydroxyapatite (ASTM F1185)	w/Hydroxyapatite (ASTM F1185) or without	None
Diameter	8 mm, 9 mm, 10 mm	Unknown	6.5 mm to 12.5 mm
Length	25 mm to 80 mm	Unknown	30 mm to 70 mm
Threaded	Fully Threaded	Partially and Fully Threaded	Fully Threaded
Thread Design	Cannulated	Cannulated	Cannulated
Device Usage	Single Use	Single Use	Single Use
Biocompatibility	Implant with permanent >30 day (Equivalency determined)	Implant with permanent >30 day	Implant with permanent >30 day
Sterilization	Gamma	Gamma	Gamma

Discussion

The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness. As seen above, the M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System is the same or similar to the predicate devices in terms of intended use, materials of construction, design, threaded, thread design, coating, device usage, and sterility. Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System to the identified predicate devices.

VII. Performance Data

Based on the risk analysis, testing was conducted to written protocols with acceptance criteria that were based on standards. The following mechanical tests are being provided in support of a substantial equivalence determination:

Non-Clinical Studies

- Performance Tests
    - 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

- Coating Tests
  - 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
- Pyrogenicity
  - Medacta uses both the Bacterial Endotoxin Test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and the Pyrogen Test according to USP chapter <151> for pyrogenicity determination.
  - Medacta has no intentions of labeling the subject devices as non-pyrogenic or pyrogen free.

Clinical Studies

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System is as safe and effective as the predicate devices. Therefore, it is concluded that the M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System is substantially equivalent to the predicate devices.