May 24, 2022

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

Re: K220888
Trade/Device Name: MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: QSR, PQC
Dated: March 25, 2022
Received: March 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)*

K220888

Device Name
MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides

Indications for Use *(Describe)*

MySpine S2-Alar/Alar-Iliac and MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides are intended to be used with any 510(k) cleared, legally marketed, pedicle screw system (for its approved indications for use) and its respective compatible components for non-cervical open, posterior spinal fixation procedures intended for fusion. The SI trajectory of the MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guide is only intended to be used with M.U.S.T. SI Headless Screw System and its cleared indications for use. The MySpine S2-Alar/Alar-Iliac and MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides (hereinafter referred to as "MySpine guides") are intended to be used as anatomical perforating guides, specific to a patient's anatomy, to assist intraoperatively in the preparation of the screw trajectory in S1, S2 and in the Ilium. The guides are created using a surgical planning software which pre-operatively plans the positions of the components based upon radiological images of the patients' anatomical landmarks and the selected surgical equipment. The MySpine guides are intended for single use only.

Please see MySpine guides labelling for compatibility requirements between the MySpine guides and the 510(k) cleared pedicle screw system intended to be used.

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

c/o Chris Lussier, Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118
(312) 244-0232

Additional Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Date Prepared: March 25, 2022
Date Revised: May 19, 2022

II. Device

Device Proprietary Name:	MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides
Common or Usual Name:	Screw Placement Guide
Product Code, Name, Regulation	1) QSR, Sacroiliac Screw Placement Guide, 21 CFR 888.3040 2) PQC, Pedicle Screw Placement Guide, 21 CFR 888.3070
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- MySpine Pedicle Screw Placement Guides Extension, K203673, Medacta International SA

In addition the following predicate device is referenced within the submission :

- MySpine S2-Alar/Alar-Iliac Pedicle Screw Placement Guides, K200792, Medacta International SA

IV. Device Description

The MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides are a line extension to Medacta's MySpine Pedicle Screw Placement Guides. Identically to the other Medacta MySpine products, the MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides are a patient matched, pedicle targeted, technology involving the production of patient specific guides for placement of pedicle and sacro-iliac screws based on patient's anatomy. Specifically, the subject MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides are intended to be used as anatomical perforating guides to assist intra-operatively in the preparation of the screw trajectory in S1, S2 and in the Ilium.
The MySpine software platform allows the surgeon to complete 3D pre-operative planning based on the patient's spinal CT scans. CT images are used to create a 3D model of the vertebrae that will

represent the template used to generate the corresponding MySpine Screw Placement Guides fitting the patient's vertebral anatomy.

The MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides as well as their bone models are single-use and they can be provided in sterile or non-sterile version.

V. Indications for Use

MySpine S2-Alar/Alar-Iliac and MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides are intended to be used with any 510(k) cleared, legally marketed, pedicle screw system (for its approved indications for use) and its respective compatible components for non-cervical open, posterior spinal fixation procedures intended for fusion. The SI trajectory of the MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guide is only intended to be used with M.U.S.T. SI Headless Screw System and its cleared indications for use. The MySpine S2-Alar/Alar-Iliac and MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides (hereinafter referred to as "MySpine guides") are intended to be used as anatomical perforating guides, specific to a patient's anatomy, to assist intraoperatively in the preparation of the screw trajectory in S1, S2 and in the Ilium. The guides are created using a surgical planning software which pre-operatively plans the positions of the components based upon radiological images of the patients' anatomical landmarks and the selected surgical equipment. The MySpine guides are intended for single use only.
Please see MySpine guides labelling for compatibility requirements between the MySpine guides and the 510(k) cleared pedicle screw system intended to be used.

VI. Comparison of Technological Characteristics

The MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides and the predicate MySpine S2-Alar/Alar-Iliac Pedicle Screw Placement Guides share the following characteristics:

- body region of use;
- manufacturing process;
- material;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides differs from the predicate device, MySpine S2-Alar/Alar-Iliac Pedicle Screw Placement Guides, with regards to the following characteristics:

- design; and
- instruments compatibility.

Discussion
The differences between the subject and predicate devices do not raise new questions of safety and effectiveness. Medacta International SA has not made any changes to the manufacturing process, material, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the predicate devices.
The comparison of technological characteristics and performance data provided within this submission, shows that there are no new risks associated with the subject devices design, and supports the substantial equivalence of the MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides to the identified predicate devices.

VII. Performance Data

Based on the risk analysis, testing activities were conducted to written protocols. The following validation and tests are being provided in support of the substantial equivalence determination:

Non-Clinical Studies

- Software validation
- Cadaver testing;
- Guide accuracy.

Biocompatibility data and sterilization validation studies submitted in support of the predicate devices were leveraged.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides are substantially equivalent to the identified predicate devices.