July 21, 2023

Medacta International SA
% Mr. Christopher Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
6386 Global Drive, Suite 101
Memphis, Tennessee 38141

Re: K231483
Trade/Device Name: MySpine Unilateral Guides
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: PQC, QSR
Dated: May 23, 2023
Received: May 23, 2023

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 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231483

Device Name
MySpine Unilateral Guides

Indications for Use *(Describe)*
MySpine MC and Drill Pilot

MySpine is intended to be used with any 510(k) cleared, legally marketed, pedicle screw spinal system (for its approved indications for use) and its respective compatible components for non-cervical open, posterior spinal fixation procedures intended for fusion. MySpine Drill Pilot is intended as a thoracic and lumbar posterior pedicle targeting guides for patients requiring spinal fusion between the levels of T1 to L5. The device is intended for perforating a guiding hole to assist in the positioning of pedicle screws in the vertebral body.
MySpine MC is intended as a lumbar and sacral posterior pedicle targeting guide for patients requiring spinal fusion between the levels of L1 to S1.
The device is provided with two options:
• Drill based
• K-wire based
MySpine MC drill based are intended for perforating a guiding hole to assist in the positioning of pedicle screws in the vertebral body. MySpine MC K-wire based are intended for the placement of K-wires to assist in the positioning of pedicle screws in the vertebral body.
The use of the guides involves a surgical planning software, with which the surgeon preoperatively plans the surgical placement of the implants based upon the radiological images of the patients' anatomical landmarks and the selected surgical equipment. These components include patient-specific guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. MySpine MC and Drill Pilot 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.

MySpine S2-Alar/Alar-Iliac and MySpine Anchor guides
MySpine S2-Alar/Alar-Iliac and MySpine Anchor 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 Anchor guide is only intended to be used with M.U.S.T. SI Headless Screw System and its cleared indications for use.
MySpine S2-Alar/Alar-Iliac and MySpine Anchor 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 use of the guides involves a surgical planning software, with which the surgeon preoperatively plans the surgical placement of the implants based upon the 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 posterior fixation 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
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, Sr. Director, Quality, Regulatory, and Clinical, Medacta USA
Date Prepared: May 23, 2023
Date Revised: July 19, 2023

II. Device

Device Proprietary Name:	MySpine Unilateral Guides
Common or Usual Name:	Pedicle screw placement guide
Classification Name:	Thoracolumbosacral Pedicle Screw System
Primary Product Code	PQC
Secondary Product code	QSR
Regulation Number:	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

Additionally, the following predicate devices are used within the submission:

- MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides, K220888, Medacta International SA
- MySpine S2-Alar/Alar-Iliac Pedicle Screw Placement Guides, K200792, Medacta International SA
- MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments, K173472, Medacta Interational SA

IV. Device Description

MySpine Unilateral Guides are a line extension to Medacta's MySpine pedicle and sacro-iliac screw placement guides. Identically to the other Medacta MySpine products, the subject guides are single use, 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 Unilateral Guides have been designed starting from the correspondent bilateral guides which have been modified to allow the drilling of only the left or the right side of vertebra/sacrum through the left or right tube.

Identically to the predicate devices, MySpine Unilateral Guides are manufactured from medical grade nylon for sintering and they can be provided in both non-sterile and sterile version.

V. Indications for Use

- *MySpine MC and Drill Pilot*

MySpine is intended to be used with any 510(k) cleared, legally marketed, pedicle screw spinal system (for its approved indications for use) and its respective compatible components for non-cervical open, posterior spinal fixation procedures intended for fusion. MySpine Drill Pilot is intended as a thoracic and lumbar posterior pedicle targeting guides for patients requiring spinal fusion between the levels of T1 to L5. The device is intended for perforating a guiding hole to assist in the positioning of pedicle screws in the vertebral body.

MySpine MC is intended as a lumbar and sacral posterior pedicle targeting guide for patients requiring spinal fusion between the levels of L1 to S1.

The device is provided with two options:

- Drill based
- K-wire based

MySpine MC drill based are intended for perforating a guiding hole to assist in the positioning of pedicle screws in the vertebral body. MySpine MC K-wire based are intended for the placement of K-wires to assist in the positioning of pedicle screws in the vertebral body.

The use of the guides involves a surgical planning software, with which the surgeon preoperatively plans the surgical placement of the implants based upon the radiological images of the patients' anatomical landmarks and the selected surgical equipment. These components include patient-specific guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. MySpine MC and Drill Pilot 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.

- *MySpine S2-Alar/Alar-Iliac and MySpine Anchor guides*

MySpine S2-Alar/Alar-Iliac and MySpine Anchor 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 Anchor guide is only intended to be used with M.U.S.T. SI Headless Screw System and its cleared indications for use.

MySpine S2-Alar/Alar-Iliac and MySpine Anchor 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 use of the guides involves a surgical planning software, with which the surgeon preoperatively plans the surgical

placement of the implants based upon the 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 posterior fixation screw system intended to be used.

VI. Comparison of Technological Characteristics

The subject MySpine Unilateral Guides are substantially equivalent to the predicate MySpine (K203673, K220888, K200792 and K173472) with regards to the following characteristics:

- Body region
- Spinous process contact;
- Anchoring points;
- Instruments compatibility;
- Design workflow and related software;
- Manufacturing process;
- Material;
- Biocompatibility;
- Device usage;
- Sterility;
- Shelf-life; and
- Packaging.

The subject MySpine Unilateral Guides differs respect to the predicate MySpine (K203673, K220888, K200792 and K173472) with respect to the unilateral guide design, not raising any new issue of safety and effectiveness thanks to the ensured contact on both sides.

Discussion
The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness.
Medacta International SA has not made any change to the manufacturing process, material, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices with respect to the predicate devices.
The comparison of technological characteristics and performance data provided within the submission supports the substantial equivalence of the subject devices respect to the predicate devices.

VII. Performance Data

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

<u>Non-Clinical Studies</u>

- Design validation workshop to validate the design and the overall functionality of the subject device as well as to evaluate their accuracy;

- MySpine Unilateral Guides optional design features rationale to demonstrate that these features do not alter docking stability nor instruments guidance parameters, thus they are not considered a worst case;
- Biocompatibility data, shelf-life 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 subject devices are substantially equivalent to the predicate devices.