April 6, 2021

Medacta International SA
% Mr. Christopher Lussier
Senior Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 83118

Re: K203673
Trade/Device Name: MySpine Pedicle Screw Placement Guides Extension (MySpine Low Profile Guides, MySpine MC and Drill Pilot Guides, and MySpine S2-Alar/Alar Iliac Guides)
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: PQC
Dated: March 12, 2021
Received: March 15, 2021

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203673

Device Name
MySpine Low Profile Guides

Indications for Use *(Describe)*
MySpine is intended as a thoracic and lumbar posterior pedicle targeting guide for patients requiring spinal fusion between the levels of T1 to L5. MySpine Screw Placement Guides are intended to be used as anatomical perforating guides specific for a single patient anatomy to assist intraoperatively in the positioning of pedicle screws in the vertebral body. 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 Low Profile screw placement guides are intended for the placement of K-wires to assist in the positioning of pedicle screws. Use of the guides involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of patient radiological images with identifiable placement anatomical landmarks and surgical equipment components. 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 Screw placement guides are intended for single use only.
Please see MySpine guides labeling 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)*
K203673

Device Name
MySpine MC and Drill Pilot Guides

Indications for Use *(Describe)*
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 guide 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:
o Drill based
o 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. Use of the guides involves a surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of patient radiological images with identifiable placement anatomical landmarks and surgical equipment components. 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 labeling 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)

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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)*
K203673

Device Name
MySpine S2-Alar/Alar Iliac Guides

Indications for Use *(Describe)*
MySpine S2-Alar/Alar-Iliac 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 S2-Alar/Alar-Iliac guides (referred to from this point on as, MySpine guides) are intended to be used as anatomical perforating guides, specific to a patient's anatomy, to assist intra-operatively 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 surgical equipment selected. MySpine guides are intended for single use only.
Please see MySpine S2-Alar/Alar-Iliac guides labeling 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)

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510(k) Summary

I. Submitter

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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: December 15, 2020
Date Revised: March 12, 2021

II. Device

Device Proprietary Name:	MySpine Pedicle Screw Placement Guides Extension (MySpine Low Profile Guides, MySpine MC and Drill Pilot Guides, and MySpine S2-Alar/Alar Iliac Guides)
Common or Usual Name:	Pedicle screw placement guide
Classification Name:	Thoracolumbosacral Pedicle Screw System
Primary Product Code:	PQC
Regulation Number:	21 CFR 888.3070
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:
Primary Predicate device

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

Additional Predicate devices

- Medacta International SA, MySpine Pedicle Screw Placement Guides - MC and Drill Pilot Instruments, K173472
- Medacta International SA, MySpine Pedicle Screw Placement Guides - LP, K153273
- Mighty Oak Medical Inc., FIREFLY® Midline Navigation Guide, K181883
- Mighty Oak Medical Inc., FIREFLY® Pedicle Screw Navigation Guide, K181399

IV. Device Description

The MySpine Pedicle Screw Placement Guides are the same of the predicate devices cleared within K200792, K173472 and K153273. Based on the predicate, different screw placement guide configurations are object of this submission, specifically:

510(k)	Product name and configurations description
K153273	MySpine Low Profile Guides: for K-wire guidance with conventional screw trajectory
K173472	MySpine Drill Pilot Guides: guidance for pedicle path preparation with conventional screw trajectory
	MySpine MC/S1 Guides: Drill Pilot and K-wire guidance with cortical bone path
K200792	MySpine S2-Alar/Alar Iliac Guides: Drill Pilot guidance with cortical bone path

The MySpine Pedicle Screw Placement Guides are for use in spinal levels T1-S2/S2AI and ilium.
The MySpine Pedicle Screw Placement Guides are a patient matched, pedicle targeted, technology involving the production of patient specific guides for placement of pedicle screws based on the patient's anatomy.

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 Pedicle Screw Placement Guides fitting the patient's vertebral anatomy.

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

The purpose of this submission is to obtain clearance of the MySpine Pedicle Screw Placement Guides for use with any compatible 510(k) cleared pedicle screw system.

V. Indications for Use

- MySpine Low Profile Guides

  MySpine is intended as a thoracic and lumbar posterior pedicle targeting guide for patients requiring spinal fusion between the levels of T1 to L5. MySpine Screw Placement Guides are intended to be used as anatomical perforating guides specific for a single patient anatomy to assist intraoperatively in the positioning of pedicle screws in the vertebral body. 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 Low Profile screw placement guides are intended for the placement of K-wires to assist in the positioning of pedicle screws. Use of the guides involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of patient radiological images with identifiable

placement anatomical landmarks and surgical equipment components. 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 Screw placement guides are intended for single use only.
Please see MySpine guides labeling for compatibility requirements between the MySpine guides and the 510(k) cleared pedicle screw system intended to be used.

- MySpine MC and Drill Pilot Guides
  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 guide 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. Use of the guides involves a surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of patient radiological images with identifiable placement anatomical landmarks and surgical equipment components. 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 labeling for compatibility requirements between the MySpine guides and the 510(k) cleared pedicle screw system intended to be used.

- MySpine S2-Alar/Alar Iliac Guides
  MySpine S2-Alar/Alar-Iliac 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 S2-Alar/Alar-Iliac guides (referred to from this point on as, MySpine guides) are intended to be used as anatomical perforating guides, specific to a patient's anatomy, to assist intra-operatively 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 surgical equipment selected. MySpine guides are intended for single use only.
  Please see MySpine S2-Alar/Alar-Iliac guides labeling 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 subject MySpine Pedicle Screw Placement Guides are the same devices of the predicate devices cleared within K200792, K173472 and K153273 with regards to the technological characteristics since they are exactly the same devices and the only difference is the indication for use.

The subject MySpine Pedicle Screw Placement Guides and the predicate devices (FIREFLY® Pedicle Screw Navigation Guide, K181399 and K181883) share the following characteristics:

- indication for use;
- pedicle screw placement and interaction;
- design;
- manufacturing process;
- biocompatibility;
- device usage; and
- packaging.

The subject MySpine Pedicle Screw Placement Guides differ from the predicate devices (FIREFLY® Pedicle Screw Navigation Guide, K181399 and K181883) with respect to:

- physical profile; and
- materials.

VII. Performance Data

The subject devices are the same of the predicate devices (K200792, K173472 and K153273); therefore:

- no additional testing was required to support this 510(k)
- justifications were provided to support the general usage of the subject devices with any compatible 510(k) cleared pedicle screw system.

No clinical studies were conducted for the predicate (K200792, K173472 and K153273) nor for the subject devices.

VIII. Conclusion

The subject devices are the same of the predicate devices (K200792, K173472 and K153273) with regards to technological characteristics. The only difference is the indication for use that is substantially equivalent to the one of the predicate FIREFLY® Pedicle Screw Navigation Guide (K181399 and K181883).
Based on the comparison of technological characteristics, provided within this submission, and the performance data of the predicate devices, submitted and cleared within K200792, K173472 and K153273, identical to the subject devices, the data supports the substantial equivalence of the subject MySpine Pedicle Screw Placement Guides with the predicate devices and thus the indication for use change object of this submission.