April 19, 2018

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

Re: K173472
Trade/Device Name: MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PQC
Dated: March 19, 2018
Received: March 19, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K173472

Device Name
MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments

Indications for Use *(Describe)*

MySpine is intended for use with M.U.S.T Pedicle Screw System and its cleared indications for use.
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.

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."*

# 3.0 510(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
Consultant: Elizabeth Rose, Regulatory Affairs Manager, Medical Devices, Mapi USA, Inc.
Date Prepared: November 8, 2017
Date Revised: April 19, 2018

## II. Device

| | |
|---|---|
| Device Proprietary Name: | MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments |
| 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

- MySpine Pedicle Screw Placement Guides – LP, K153273, Medacta International SA

Additional Predicate:

- MySpine Pedicle Screw Placement Guides, K132788, Medacta International SA

## IV. Device Description

The MySpine Pedicle Screw Placement Guides – MC (Midline Cortical) and Drill Pilot Instruments are a line extension to Medacta's MySpine Pedicle Screw Placement Guides. The MySpine Pedicle Screw Placement Guides – MC and S1 Guide Instruments are for use in spinal levels L5 to S1. The MySpine Pedicle Screw Placement Guides – Drill Pilot Guide Instruments are for use in spinal levels T1 to S1.

The MySpine product line is a patient matched, pedicle targeted, technology involving the production of patient specific guides for placement of the M.U.S.T. Pedicle Screw System based on the patient's anatomy. The MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments are intended to be used with Medacta's M.U.S.T. Pedicle Screw System (K121115, K132878, K141988, K153664, K162061, and K171170) for the following indications: degenerative disc disease (DDD), spondylolisthesis, trauma, spinal stenosis, curvatures, tumor, pseudo-arthrosis, and failed previous fusion.

The MySpine platform allows the surgeon to complete pre-operative planning in 3D, based on the patient's spinal CT scans. Medacta International SA uses these images in combination with SW Mimics® (Materialize®) and W Solidworks® (Dassault Systèmes®) to import DICOM images from a patient's CT scans and then process the scans into accurate 3D models. CT imaging is used to create a 3D model of the vertebrae according to the patient's anatomy. The subsequent vertebral model represents the template used to generate the corresponding MySpine Screw Placement Guides to fit the patient's vertebral anatomy.

## V. Indications for Use

MySpine is intended for use with M.U.S.T Pedicle Screw System and its cleared indications for use.

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.

## VI. Comparison of Technological Characteristics

The MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments and the predicate devices share the following characteristics:

- design;
- software;
- material of construction;
- biocompatibility;
- manufacturing process;
- device usage;
- sterility;
- shelf life; and
- packaging.

The MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments have a different physical profile from the predicate devices.

The MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments are manufactured from medical grade nylon (Polyamide PA12) which is identical to predicate devices, Medacta's MySpine Pedicle Screw Placement Guides (K132788) and MySpine Pedicle Screw Placement Guides – LP (K153273).

Due to the extensive history of use in currently marketed medical devices, as well as similarities in the manufacturing processes between the subject and reference devices, additional biocompatibility testing was deemed unnecessary for the MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments.

A comparison of the subject and predicate devices is provided in the table below.

Technological comparison

| Parameters | MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments | MySpine Pedicle Screw Placement Guides – LP (K153273) | MySpine Pedicle Screw Placement Guides (K132788) |
|---|---|---|---|
| **Design** | Patient specific surgical instruments generated from patient's CT scan | Identical | Identical |
| **Software** | SW Mimics® (Materialize®) and W Solidworks® (Dassault Systèmes®) | Identical | Identical |
| **Physical Profile** | Drill Pilot Guides: guide drill to prepare hole for positioning of the pedicle screws<br>MC and S1 Guides:<br>• drill based - guide drill to prepare hole for positioning of the pedicle screws<br>• K-wire based – low profile guides | Low Profile | Standard Size |
| **Manufacturing Process** | Additive manufacturing using a sintering process of medical grade nylon on a laser sintering system. | Identical | Identical |
| **Material** | Medical Grade Nylon for sintering (PA12 Medical Grade) | Identical | Identical |
| **Biocompatibility** | External communicating devices with limited (<24 hours) contact duration | Identical | Identical |
| **Device Usage** | Single Use | Identical | Identical |
| **Sterility** | Gamma Radiation and Non-Sterile | Identical | Identical |
| **Shelf Life** | 6 months after CT scan | Identical | Identical |
| **Packaging** | Individual packaging | Identical | Identical |

*Discussion*

There are differences between the subject and predicate devices with respect to the indications for use statement. The subject devices indications for use are being expanded to include lumbar and sacral posterior pedicle targeting guide for patients requiring spinal fusion between the levels of L1 to S1 with option of drill based or K-wire based positioning.

The differences in the indications for use and physical profile 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 intended use, materials of construction, design, manufacturing process, software, device usage, or of the subject devices. Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments to the identified predicate devices.

## VII. Performance Data

Risks were identified based on the proposed design and testing was conducted to mitigate those risks. Based on the risk analysis, testing was conducted according to written protocols with acceptance criteria. The following performance data was provided in support of the substantial equivalence determination:

Non-Clinical Studies

- Performance Tests
    - design validation: validated the design, intended use and procedure;
    - stability assessment: verified the stability of contact points related to the degrees of freedom;
    - post-operative evaluation: validated the guide accuracy; and
    - wear test: quantified the debris generated by an instrument during pedicle preparation and screws insertion, because of moving parts wear.

Clinical Studies

- no clinical studies were conducted.

## VIII. Conclusion

Based on the above information, the MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments can be considered substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics, as well as performance evaluations. The MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments are as safe and effective as the

predicate devices, Medacta's MySpine Pedicle Screw Placement Guides (K132788) and MySpine Pedicle Screw Placement Guides – LP (K153273).