DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 29, 2016

Medacta International SA
% Roshana Ahmed, MA, RAC
Senior Manager, Regulatory Affairs – Medical Devices
Mapi USA, Incorporated
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

Re: K153273
Trade/Device Name: MySpine Pedicle Screw Placement Guides - LP
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI
Dated: June 1, 2016
Received: June 1, 2016

Dear Ms. Ahmed:

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 Parts 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)*
K153273

Device Name
MySpine Pedicle Screw Placement Guides - LP

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

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.

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

Applicant/Sponsor:	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 Phone: +41 91 696 60 60 Fax: +41 91 696 60 66 Email: baj@medacta.ch

Date Prepared: June 27, 2016

DEVICE INFORMATION

Trade/Proprietary Name:	MySpine Pedicle Screw Placement Guides - LP
Common or Usual Name:	Pedicle Screw Placement Guide
Classification Name:	Pedicle Screw Spinal System
Product Code:	MNI
Regulation Number:	21 CFR 888.3070
Device Class:	II

PREDICATE DEVICE INFORMATION

MySpine Pedicle Screw Placement Guides, K132788, Medacta International SA

DEVICE DESCRIPTION

MySpine Pedicle Screw Placement Guides - LP are a design modification to MySpine Pedicle Screw Placement Guides (K132788). MySpine Pedicle Screw Placement Guides are patient specific surgical instruments that allow for guided K-wire placement. The MySpine software platform allows the surgeon to complete the preoperative planning in 3D based on the patient's spinal CT scans. Then, the K-wire is guided through the patient's anatomically matched MySpine LP Guides in order to provide positioning according to the surgeon's preoperative planning.

For the standard guides introduced and cleared by FDA in K132788, the holes guide the instruments used to open and prepare the pedicle to the planned entry point. After pedicle preparation, the pedicle screws will be inserted through the guiding hole into the pedicle and the vertebrae respectively. For the LP guides introduced with this 510(k), the guiding holes allow placement of the K-wire. Then, the MySpine guide is removed and the wires are used to insert cannulated implants. As an intermediate step, the surgeon can also use the cannulated awl and/or tap to better prepare the entry point in order to simplify the screw tightening.

The components of the MySpine Pedicle Screw Placement Guides - LP include a Drill Guide (PA12 Medical Grade) and Vertebral Bone Models (PA12 Medical Grade). The MySpine Pedicle Screw Placement Guides – LP are single use, external communicating devices with limited (<24 hours) contact duration and are provided in sterile and nonsterile versions.

INDICATIONS FOR USE

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

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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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The materials of the MySpine Pedicle Screw Placement Guides - LP are identical to the previously cleared predicate device. The design features, geometries, and sizes of the subject devices are substantially equivalent to those of the predicate device. The fundamental scientific technology of the modified devices has not changed relative to the predicate device. The safety and effectiveness of the MySpine Screw Placement Guides - LP are adequately

supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

PERFORMANCE TESTING

The following testing was leveraged or conducted to support substantial equivalence:

- Sterilization validation in accordance with ANSI/AAMI/ISO 11137-1 and -2
- Packaging validation in accordance with ANSI/AAMI/ISO 11607
- Biocompatibility in accordance with ISO 10993-1
- Mechanical testing
- Cadaver testing

CONCLUSION:

Based on the above information, the MySpine Pedicle Screw Placement Guides – LP are substantially equivalent to the predicate devices.