Medacta International S.A.
% Christoper Lussier
Senior Director, Quality, Regulatory, and Clinical Research
Medacta USA
6386 Global Drive, Suite 101
Memphis, TN 38141

April 23, 2025

Re: K243697
Trade/Device Name: MySpine WebPlanner
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 29, 2024
Received: March 25, 2025

Dear Christoper 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

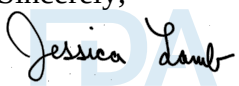
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



Jessica Lamb, PhD
Assistant Director
Imaging Software Team
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243697

Device Name

MySpine WebPlanner

Indications for Use *(Describe)*

The MySpine WebPlanner software is designed to be used by a competent person who will generate a preoperative plan that may give relevant information to an authorized orthopedic or neurosurgeon before spinal posterior fixation surgery. The MySpine WebPlanner is a surgical preoperative planning software intended to provide assistance to surgeons in viewing, storing, and measuring radiological images, as well as planning the surgical placement of Medacta's spinal fixation and fusion devices in skeletally mature and immature individuals. The MySpine WebPlanner software is designed to support the surgeon in producing a preoperative plan and making preliminary decisions on implant size and positioning. To properly use the MySpine WebPlanner, clinical judgment, and experience are required.

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.

510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Director of Quality and Regulatory, Medacta USA

Date Prepared: November 29, 2024
Date Revised: April 22, 2025

II. Device

Device Proprietary Name:	MySpine WebPlanner
Common or Usual Name:	Picture archiving and communications system (PACS)
Classification Name:	System, Image Processing, Radiological
Primary Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Device Classification:	II

III. Predicate Device

MySpine WebPlanner & MyBalance, K211386, Medacta International SA

IV. Device Description

The MySpine WebPlanner is an interactive web application using the patient's radiological images and the related bone segmentations to allow the end-users to perform preoperative surgical planning. The data and the information displayed in WebPlanner web interface are computed and loaded by Medacta International's internal software named MyPlanner. The image

format supported is DICOM. The end-user can access the MySpine WebPlanner at https://myspine.medacta.com/.

The purpose of the current submission is to obtain clearance to expand the indications for use of MySpine WebPlanner include surgical planning of fusion devices (i.e., cages).

V. Indications for Use

The MySpine WebPlanner software is designed to be used by a competent person who will generate a preoperative plan that may give relevant information to an authorized orthopedic or neurosurgeon before spinal posterior fixation surgery. The MySpine WebPlanner is a surgical preoperative planning software intended to provide assistance to surgeons in viewing, storing, and measuring radiological images, as well as planning the surgical placement of Medacta's spinal fixation and fusion devices in skeletally mature and immature individuals. The MySpine WebPlanner software is designed to support the surgeon in producing a preoperative plan and making preliminary decisions on implant size and positioning. To properly use the MySpine WebPlanner, clinical judgment, and experience are required.

VI. Comparison of Technological Characteristics

	MySpine WebPlanner (Subject device)	**MySpine WebPlanner [K211386] (Predicate device)**
Manufacturer	Medacta International SA	Medacta International SA
Indications for Use	The MySpine WebPlanner software is designed to be used by a competent person who will generate a preoperative plan that may give relevant information to an authorized orthopedic or neurosurgeon before spinal posterior fixation surgery. The MySpine WebPlanner is a surgical preoperative planning software intended to provide assistance to surgeons in viewing, storing, and measuring radiological images, as well as planning the surgical placement of Medacta's spinal fixation and fusion devices in skeletally mature and immature individuals. The MySpine WebPlanner software is designed to support the surgeon in producing a preoperative plan and making preliminary decisions on implant size and positioning. To properly use the MySpine WebPlanner,	The MySpine WebPlanner is a surgical pre-operative planning software intended to provide assistance to surgeons in viewing, storing, and measuring radiological images, as well as planning the surgical placement of the spinal fixation devices. The MyBalance, a module of the MySpine WebPlanner, allows to perform generic as well as specific measurements of patient's sagittal alignment and to plan spinal surgical procedures (osteotomies or Lordosis/ Kyphosis correction in spinal

	MySpine WebPlanner (Subject device)	**MySpine WebPlanner [K211386] (Predicate device)**
	clinical judgment, and experience are required. The MySpine WebPlanner software leads to the generation of a planning report.	fusion surgeries). To properly use the MySpine WebPlanner, and the MyBalance module, clinical judgment and experience are required.
Hardware	Laptop and/or PC and/or tablet	Identical
Operative system	Independent from the operative system since it is a web application	Identical
Image input	DICOM images	Identical
Design	Web application accessible through Chrome or Firefox browsers	Identical
Database	Images are stored on the Medacta server	Identical
User interface	GUI	Identical
Workflow	1. Surgeon uploading of the patient's radiological images 2. Images quality control check 3. Segmentation of the 3D bone model 4. Surgery plan 5. Surgery plan validation by the surgeon 6. Report provision 7. Patient-matched guides	Identical
User interactions	Steps 2-3-4 as well as steps 6-7 of the workflow are performed by Medacta operators who have been specifically trained for this purpose. The surgeon is required to upload the patients' images (Step 1 of the workflow) and to check and eventually modify the implant position and size on each vertebra (step 5 of the workflow)	Identical
Output Measurements	• Planning report showing the surgical parameters (including screws and cages planning) • Patient-matched guides creation according to the planning (optional) • MyBalance module only: Analysis of the spinopelvic anatomy (e.g. SS, PT, LL, PI-LL) including variations resulting from natural and modified lordosis	• Planning report showing the surgical parameters (including screws planning) • Patient-matched guides creation according to the planning (optional) • MyBalance module only: Analysis of the spinopelvic anatomy (e.g. SS, PT, LL, PI-LL) including variations resulting from natural and modified lordosis

	MySpine WebPlanner (Subject device)	**MySpine WebPlanner [K211386] (Predicate device)**
Patient contact	None	Identical

There are slight differences between the subject and predicate device indications for use statements; however, the differences do not alter the intended use of the subject device when compared to the predicate device. Both devices are software only devices intended for use in pre-operative surgical planning in spine cases.

Apart from the addition of cage planning capability, the subject and predicate devices are identical.

The addition of cage planning to the MySpine WebPlanner interface does not introduce different questions of safety and effectiveness when compared to the predicate device. Software verification and validation was performed to address the introduction of the new module.

VII. Performance Data

Software verification and validation studies are provided in support of a substantial equivalence determination.

VIII. Conclusion

The information provided above supports that the MySpine WebPlanner is substantially equivalent to the predicate device.