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

July 23, 2021

Re: K211386
Trade/Device Name: MySpine WebPlanner & MyBalance
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 26, 2021
Received: May 27, 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*

K211386

Device Name

MySpine WebPlanner & MyBalance

Indications for Use *(Describe)*

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 fusion surgeries). To properly use the MySpine WebPlanner, and the MyBalance module, 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.

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510(k) Summary – K211386

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: May 2, 2021
Date Revised: July 23, 2021

II. Device

Device Proprietary Name:	MySpine WebPlanner & MyBalance
Common or Usual Name:	Picture archiving and communications system (PACS)
Classification Name:	Medical image management and processing system
Primary Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- Surgimap Spine, K111019, Nemaris Inc.

Device Proprietary Name:	Surgimap Spine
Common or Usual Name:	Picture archiving and communications system (PACS)
Classification Name:	Medical image management and processing system
Primary Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Device Classification	II

Reference device:

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

Device Proprietary Name:	MySpine S2-Alar/Alar-Iliac Pedicle Screw Placement 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

IV. Device Description

The subject device MySpine WebPlanner & MyBalance is an interactive web application using the patient's radiological images and the related bone segmentations to allow the end-users performing a pre-operative surgical planning.
The data and the information displayed in the web interface named WebPlanner are computed and loaded by an internal software named MyPlanner.

The MyBalance is an optional module of the MyPlanner, thus available on the WebPlanner interface, and it allows the surgeon to verify the actual patient sagittal alignment and to simulate a sagittal correction in order to determine balance condition after the planned correction.

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

The purpose of the current 510(k) submission is to obtain the clearance for the MySpine WebPlanner & MyBalance as a planning software. The subject device software uses the computations made by the predicate MyPlanner software, already cleared within K200792, to manufacture MySpine guides thus the surgeons after the planning with the subject MySpine WebPlanner & MyBalance can request (if preferred by the surgeon) for the MySpine guides to be manufactured, per the clearance within K200792. Please review Figure 1 below for a breakdown of the MySpine software interactions.

The MySpine WebPlanner & MyBalance software are of a major level of concern according to FDA's Guidance for Industry and FDA Staff: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (issued May 11, 2005).

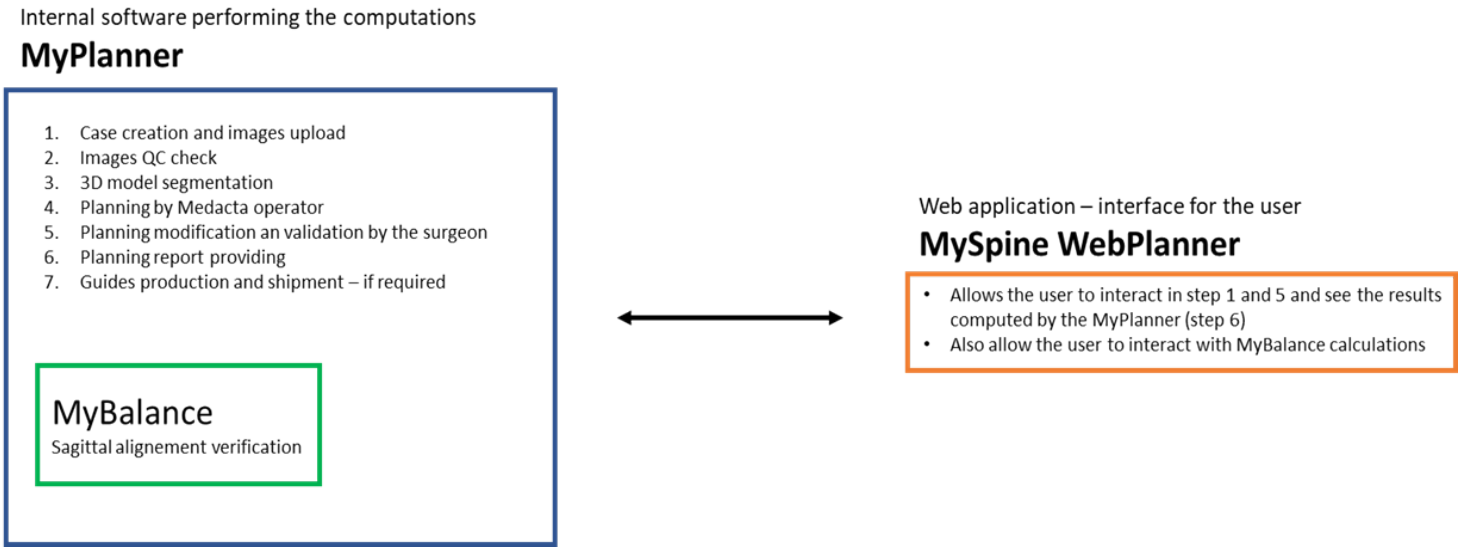

Figure 1. MySpine software interactions.

V. Indications for Use

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 fusion surgeries).
To properly use the MySpine WebPlanner, and the MyBalance module, clinical judgment and experience are required.

VI. Comparison of Technological Characteristics

The MySpine WebPlanner & MyBalance and the predicate devices, MySpine S2 (K200792) and Surgimap Spine (K111019), share the following characteristics:

- image input and storage;
- user interface;
- workflow;
- output and measurements; and
- patient contact.

The MySpine WebPlanner & MyBalance differs from the predicate devices, MyPlanner (K200792) and Surgimap Spine (K111019), with regards to the following characteristics:

- design;
- operative system; and
- user interactions.

The subject device's design is quite different from the predicate devices since it has been developed as a web application instead of a desktop application and this difference makes the subject device independent from the operative system and usable also on a tablet. It is a design choice not raising new questions of safety and effectiveness as demonstrated by software verification and validation activities.
The slightly different user interactions between the subject and predicate devices, especially with regards to the MyBalance and with respect to the predicate Surgimap Spine (K111019), does not introduce any further risk since the main workflow steps of the subject devices (e.g. images quality control check, initial planning, landmarks acquisition) are performed by Medacta operators specifically trained for this purpose and only the simulations and the final surgical planning steps are performed by the surgeons.

Discussion
The subject and predicate devices are substantially equivalent with reference to the intended use, user interfaces, input images and their storage, workflow, measurements output and patient contact. The slight differences between the subject and predicate devices with regards to design, operative system and user interactions do not raise new questions of safety and effectiveness as demonstrated by verification and validation activities. Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the MySpine WebPlanner & MyBalance to the identified predicate devices.

VII. Performance Data

Based on the risk analysis, testing activities were conducted to written protocols. The following validation and tests are being provided in support of the substantial equivalence determination:

Non-Clinical Studies

- software verification;
- software validation, including accuracy and repeatability test for MyBalance measurements.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the MySpine WebPlanner & MyBalance are substantially equivalent to the predicate devices.