Medacta International SA
℅ Mr. Chris Lussier
Director, Quality and Regulatory
Medacta USA
3973 Delp Street
MEMPHIS TN 38118

February 19, 2021

Re: K200589
Trade/Device Name: MyPAO Planning Report
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 11, 2021
Received: January 12, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200589

Device Name
MyPAO Planning Report

Indications for Use *(Describe)*

Medacta MyPAO surgical planning report is intended to provide users with patient's pre-operative information and an estimation of the post-operative parameters after the realignment of the acetabulum following the osteotomy.
It is intended to be used for the pre-operative planning phase of Peri-Acetabular Osteotomy surgeries and it consists of a report in .pdf format elaborated on the basis of Patient's Anatomical Data derived from the CT scan of the patient. The planning report is generated through a validated internal Medacta Manufacturing software and with a highly specialized engineering manual landmark selection.
The Medical Device, in accordance with a written prescription of the Surgeon, is intended for the sole use of the specific patient for which the case is created. Medacta MyPAO surgical planning is intended to be used on a skeletally mature population for which a PAO surgery is 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.

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

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2.0 510(k) Summary

K200589

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager, Medacta International SA
Applicant Correspondent: Christopher Lussier, Director of Quality and Regulatory, Medacta USA
Date Prepared: March 4, 2020
Date Revised: January 11, 2021

II. Device

Device Proprietary Name:	MyPAO Planning Report
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

Substantial equivalence is claimed to the following device:

- Move Forward 3D Motion Simulation Service, K162559, Biomet Inc.

IV. Device Description

MyPAO uses the patients' CT scan to segment the patient's bones in order to provide the surgeons with a report (MyPAO Surgical Planning Report) with some parameters of interest that can be used to properly plan the peri-acetabular osteotomy (PAO) and the manual repositioning of the acetabulum during standard PAO procedures. Specifically, the MyPAO Planning Report includes all the relevant preoperative anatomic data of the patient's hip, a proposal of the repositioning of the acetabulum, following the manual osteotomy, and a calculation of the expected postoperative results in relation to the anatomical reference data.

V. Indications for Use

Medacta MyPAO surgical planning report is intended to provide users with patient's pre-operative information and an estimation of the post-operative parameters after the realignment of the acetabulum following the osteotomy.
It is intended to be used for the pre-operative planning phase of Peri-Acetabular Osteotomy surgeries and it consists of a report in .pdf format elaborated on the basis of Patient's Anatomical Data derived from the CT scan of the patient. The planning report is generated through a validated internal Medacta Manufacturing software and with a highly specialized engineering manual landmark selection.
The Medical Device, in accordance with a written prescription of the Surgeon, is intended for the sole use of the specific patient for which the case is created. Medacta MyPAO surgical planning is intended to be used on a skeletally mature population for which a PAO surgery is required.

VI. Comparison of Technological Characteristics

The MyPAO Planning Report and the predicate device, Move Forward 3D Motion Simulation Service (K162559), share the following characteristics:

- design concept/principle of operation;
- workflow;
- image processing method;
- user interactions.

The subject MyPAO Planning Report and the predicate device, Move Forward 3D Motion Simulation Service (K162559), are technologically different with respect to the specific contents of the report and the provided parameters.

A comparison of key technological features between the subject and predicate device is provided in the table below.

Parameters	**MyPAO Planning Report [Subject device]**	**Move Forward 3D Motion Simulation Service (K162559) [Predicate device]**
Input images	CT images	CT or MRI images
Design	Image processing software providing a report with parameters of interest calculated on the pre-operative images of the patient	Same
Report generation workflow	1) Surgeon uploading of the patient's CT images 2) Images quality control check	Same

Parameters	MyPAO Planning Report [Subject device]	Move Forward 3D Motion Simulation Service (K162559) [Predicate device]
	3) Segmentation and 3D bone model reconstruction 4) Anatomic landmark selection 5) Surgery plan upload 6) Surgery plan validation by the surgeon 7) Report provision	
Image quality control, segmentation and landmark acquisition	Performed manually by Medacta operators who have been specifically trained for this purpose	Performed by Zimmer Biomet operators who have been specifically trained for this purpose
User interactions	Clinicians do not interact with the image analysis software directly. The image analysis software is only operated by Medacta operators who have been specifically trained for this purpose. The user is only required to upload the patients' images and validate the plan	Same
Report content	• Parameters of interest calculated on the pre-operative anatomical situation of the patient's pelvis • Proposed correction of the pathological situation (Hip dysplasia). • Calculation of the same parameters referred to the proposed post-op position.	• Parameters of interest calculated on the pre-operative anatomical situation of the patient's pelvis • Proposed correction of the pathological FAI situation.
Parameters and evaluation provided in the report	• Center Edges Angle (LCE-MCE) • Tonnis angle • Femoral Head coverage • Range of Motion analysis • Femoral neck anteversion • PAO correction proposal	• Femoral Head and neck diameters • Alpha angles • Center Edge Angle (LCE) • Femoral Head coverage • Acetabular orientation analysis (inclination and version) • Range of Motion analysis along defined path • FAI treatment proposal

Discussion

The subject and predicate devices are substantially equivalent with reference to the intended use, design concept, workflow, image processing method and user interactions. The differences in the report contents and provided parameters do not raise new questions of safety or effectiveness as

demonstrated by design validation testing. The comparison of technological characteristics and performance data provided within this submission, shows that there are no new risks associated with the subject device design, and supports the substantial equivalence of the MyPAO Planning Report to the identified predicate device.

VII. Performance Data

Based on the risk analysis, verification and validation activities were conducted according to written protocols with defined acceptance criteria. The following tests are being provided in support of a substantial equivalence determination:

Non-Clinical Studies

- software verification and validation;
- measurements repeatability test based on an analysis intra and inter-observer of two different parameters, chosen for their relevance to detect Hip Dysplasia, on different PAO cases planned with MyPAO software. Intraclass correlation coefficients (ICC) analysis revealed excellent intra-observer and intra-observer agreement for both the relevant parameters measurements, with the whole 95% confidence interval lying above 0.9. All differences between paired measurements were less than ±5°. Therefore, test results have been met the established acceptance criteria.

Clinical Studies

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the MyPAO Planning Report is as safe and effective as the identified predicate devices.
Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance evaluations provided within this submission. Therefore, it is concluded that the MyPAO Planning Report can be considered substantially equivalent to the identified predicate device.