Medacta International S.A.
% Chris Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
3973 Delp Street
MEMPHIS, TENNESSEE 38118

January 20, 2023

Re: K221725
Trade/Device Name: Advanced MyHip Planner
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 22, 2022
Received: December 23, 2022

Dear Chris 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,

Jessica Lamb

Jessica Lamb,
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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)*

K221725

Device Name
Advanced MyHip Planner

Indications for Use *(Describe)*

The MyHip Planner software is intended for image processing and preoperative planning of acetabular cup and femoral stem positioning for Total Hip Arthroplasty (THA). The user is assisted in producing a preoperative plan, making decisions based on the leg offsets, the patient's potential impingement and, optionally, the spino-pelvic interaction. Through the software, the user can request 3D Printed Patient Specific Bone Models not intended for diagnostic use, but only intended for a physical representation of the 3D anatomical models visualized in the software. The 3D Printed Patient Specific Bone Models are provided non-sterile.

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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K221725
510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Sr. Director of Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: June 13, 2022
Date Revised: January 19, 2023

II. Device

Device Proprietary Name:	Advanced MyHip Planner
Common or Usual Name:	Advanced MyHip Planner
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 primary predicate device:

- MyHip Planner, K200350, Medacta Interational SA

In addition, the following reference device is cited within the submission:

- My Knee Cutting Blocks, K093806, Medacta International SA

IV. Device Description

The MyHip Planner is a software whose output is a patient-specific preoperative plan based on CT scans and aimed at evaluating the effects of different device choices and positioning options on the patient's hip joint biomechanics in terms of leg length and offset.
It is intended to be used in Primary Hip Arthroplasty and it is compatible with Windows and Mac OS operating system.
The subject Advanced version of the MyHip Planner additionally allows to evaluate patient`s spino-pelvic deformities and pelvic tilt starting from preoperative X-ray images, to help the surgeon to

understand the implications of spinopelvic mobility on THA stability and optimize implant components orientation.

Through the software, the user can request non-sterile 3D Printed Patient Specific Bone Models intended to be used as an additional visual reference of the patients' specific anatomy.

V. Indications for Use

The MyHip Planner software is intended for image processing and preoperative planning of acetabular cup and femoral stem positioning for Total Hip Arthroplasty (THA). The user is assisted in producing a preoperative plan, making decisions based on the leg offsets, the patient's potential impingement and, optionally, the spino-pelvic interaction.

Through the software, the user can request 3D Printed Patient Specific Bone Models not intended for diagnostic use, but only intended for a physical representation of the 3D anatomical models visualized in the software. The 3D Printed Patient Specific Bone Models are provided non-sterile.

VI. Comparison of Technological Characteristics

Parameters	Advanced MyHip Planner (Subject device)	MyHip Planner (Predicate device K200350)
Indication for use	The MyHip Planner software is intended for image processing and preoperative planning of acetabular cup and femoral stem positioning for Total Hip Arthroplasty (THA). The user is assisted in producing a preoperative plan, making decisions based on the leg offsets, the patient's potential impingement and, optionally, the spino-pelvic interaction. Through the software, the user can request 3D Printed Patient Specific Bone Models not intended for diagnostic use, but only intended for a physical representation of the 3D anatomical models visualized in the software. The 3D Printed Patient Specific Bone Models are provided non-sterile.	The MyHip Planner software is intended for image processing and pre-operative planning of acetabular cup and femoral stem positioning for Total Hip Arthroplasty (THA). The device assists the user in assessing potential leg length and offset differences as well as potential range of motion impingement.
Operative system	Windows or Mac OS	Same
Hardware	Laptop and/or PC	Same
Input images	• CT scan images	CT scan images

Parameters	Advanced MyHip Planner (Subject device)	MyHip Planner (Predicate device K200350)
	• X-rays	
Input images acquisition method	Through hard disk (CD/USB) or wireless through MySolution website	Same
User interface	GUI	Same
Workflow	1. CT images upload 2. Segmentation 3. Planning including spino-pelvic evaluation 4. Bone models production and shipping (optional)	1. CT images upload 2. Segmentation 3. Planning
Segmentation	Automatic but the user has to check, eventually modify, and confirm it	Same
Available implants	Medacta hip implants cleared to FDA by Medacta	Same
Measurements output	• Cup positioning • Stem positioning • ROM evaluation • Spino-pelvic evaluation	• Cup positioning • Stem positioning • ROM evaluation

The subject Advanced MyHip Planner and the predicate device are substantially equivalent with regards to the following characteristics:

- operative system compatibility;
- design concept/principle of operation;
- user interface;
- images importation method;
- segmentation and landmark acquisition method; and
- available implants.

The subject Advanced MyHip Planner differs from the predicate device with respect to:

- input images;
- workflow; and
- measurements output.

Discussion

The slightly different input images and workflow of the subject device with respect to the predicate does not affect the safety and effectiveness of the Advanced MyHip Planner since it is only related to the addition of new input images (x-rays) and workflow steps strictly related to the newly developed feature allowing spino-pelvic evaluation and the manufacturing of bone models, both optional steps. Identically to the bone models included in the reference device clearance (K093806), the subject bone models are manufactured through the software starting from the patient's CT as an additional visual reference of the patients' specific anatomy, thus no new issue of safety and effectiveness arise.

Also measurements output differences are strictly related to the new spino-pelvic evaluation feature and does not raise any new issue of safety and effectiveness since the other output measurements are identical to the ones of the predicate device (K200350).
The comparison of technological characteristics and verification and validation provided within this submission, supports the substantial equivalence of the subject devices respect to the predicate devices.

VII. Performance Data

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

Non-Clinical Studies

- Software verification and validation including segmentation validation.
  No statistical divergence between the algorithm and the manual segmentation has been revealed by an analysis of the automatic segmentation and landmark picking performance on a two-sided students t-distribution.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the Advanced MyHip Planner is substantially equivalent to the predicate devices.