November 4, 2020

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

Re: K200350
Trade/Device Name: MyHip Planner & Verifier
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 24, 2020
Received: September 25, 2020

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 and Part 809); 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,

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)*

K200350

Device Name
MyHip Planner & Verifier

Indications for Use *(Describe)*

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.

The MyHip Verifier software is intended to assist in the intra-operative evaluation of leg length and offset differences as well as acetabular cup positioning for anterior approach Total Hip Arthroplasty when the patient is positioned supine.

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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1.0 510(k) Summary

I. Submitter

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, Medacta International SA
Applicant Correspondent: Christopher Lussier, Director of Quality and Regulatory, Medacta USA
Date Prepared: January 20, 2020
Date Revised: November 2, 2020

II. Device

Device Proprietary Name:	MyHip Planner & Verifier
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 devices:

Primary predicate device for MyHip Planner:

- MediCAD 4.0, K170702, MediCAD Hectec Gmbh

Primary predicate device for MyHip Verifier:

- JointPoint, K160284, JointPoint Inc.

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.
The MyHip Verifier is a software whose output is an intra-surgical numerical evaluation of the implant positioning based on fluoroscopy and aimed at evaluating the effects in terms of leg length and offset of cup and stem positioning.

Both software are intended to be used in Primary Hip Arthroplasty and they are compatible with Windows and Mac OS operating system. MyHip Verifier is also compatible with Ubuntu operating system.

V. Indications for Use

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.

The MyHip Verifier software is intended to assist in the intra-operative evaluation of leg length and offset differences as well as acetabular cup positioning for anterior approach Total Hip Arthroplasty when the patient is positioned supine.

VI. Comparison of Technological Characteristics

- *MyHip Planner*

The MyHip Planner and the predicate device MediCAD 4.0 (K170702) share the following characteristics:

- design concept/principle of operation;
- user interface;
- input images;
- workflow;
- segmentation and landmark acquisition method;
- measurements output

The subject MyHip Planner and the predicate device MediCAD 4.0 (K170702) are technologically different with respect to:

- operative system compatibility;
- images importation method;
- available implants

- *MyHip Verifier*

The MyHip Verifier and the predicate device JointPoint (K160284) share the following characteristics:

- design concept/principle of operation;
- user interface;
- input images;
- workflow;
- landmark acquisition method;

- measurements output

The subject MyHip Verifier and the predicate device JointPoint (K160284) are technologically different with respect to:

- operative system compatibility;
- images importation method;
- available implants

Discussion

The subject and predicate devices are substantially equivalent with reference to the intended use, design concept, user interfaces, input images, workflow and measurements output. The slight differences in operative system compatibility, images importation methods and available implants 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 devices design, and supports the substantial equivalence of the MyHip Planner & Verifier to the identified predicate devices.

VII. Performance Data

Based on the risk analysis, software verification and validation 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

- MyHip Planner software verification and validation;
- MyHip Planner validation through retrospective analysis;
- MyHip Verifier software verification and validation;
- MyHip Verifier validation through in-vitro and cadaver testing.

Clinical Studies

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the MyHip Planner & Verifier 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 MyHip Planner & Verifier can be considered substantially equivalent to the identified predicate devices.