May 30, 2023

Medacta International S.A.
℅ Chris Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K220706
Trade/Device Name: MyPAO Guides
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: PBF
Dated: March 9, 2022
Received: March 10, 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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
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OHT6: Office of Orthopedic Devices
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)*
K220706

Device Name
MyPAO Guides

Indications for Use *(Describe)*
MyPAO patient-specific guides are devices intended to be used as anatomical guides. The guides are specifically designed based on the CT images of the patient (i.e., pelvis, proximal femur, distal femur). The guides are intended to assist the surgeon in the positioning of the acetabular fragment during periacetabular osteotomies to treat patients who require to undergo periacetabular osteotomy. MyPAO guides are intended for single use only.

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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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, Medacta USA
Date Prepared: March 09, 2022
Date Revised: May 30, 2023

II. Device

Device Proprietary Name:	MyPAO Guides
Common or Usual Name:	Orthopaedic Surgical Planning And Instrument Guides
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Primary Product Code:	PBF
Regulation Number:	21 CFR 888.3030
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate devices:
Primary predicate device:

- VSP Orthopedics System, K190044, 3D Systems, Inc.

Reference device :

- MySpine MySpine S2-Alar/Alar-Iliac Pedicle Screw Placement Guides, K200792, Medacta International SA
- MyPAO Planning Report, K200589, Medacta International SA

IV. Device Description

The MyPAO Guides enlarge Medacta's MyPAO realignment system, already including MyPAO Planning report, in order to provide the surgeons a further help in the realignment phase after a Periacetabular Osteotomy.
Specifically, the current submission aims at obtaining the clearance for the changes made to MyPAO Planning report and for the following new devices:

- Reposition PSI guides (Pre-op drill guide, Ilium and Acetabulum Rep Guides, Realignment Arc);
- Preoperative and postoperative bone models;
- Reusable instruments to be used with the guides.

MyPAO Guides are patient specific guides designed on the basis of the patient's preoperative CT scan and subsequent preoperative planning and they aim at replicating the desired correction before the final fixation of the acetabular fragment.
The MyPAO Guides as well as their bone models are single-use and they are provided non-sterile.

The 3D pre-operative planning based on the patient's CT scans is performed through MyPAO software that is the same software already used to generate MyPAO Planning Report. The only change made to the already cleared MyPAO Planning report (K200589) regards the addition of two parameters in the report, i.e. 3D femoral head coverage and acetabular anteversion.

V. Indications for Use

MyPAO patient-specific guides are devices intended to be used as anatomical guides. The guides are specifically designed based on the CT images of the patient (i.e., pelvis, proximal femur, distal femur). The guides are intended to assist the surgeon in the positioning of the acetabular fragment during periacetabular osteotomies to treat patients who require to undergo periacetabular osteotomy. MyPAO guides are intended for single use only.

The indications for use differ because the predicate is indicated for use in non-joint replacing osteotomies in the non-sacrum pelvis area, whereas the subject device has specific indications for use in periacetabular osteotomy (a type of non-joint replacement, non-sacrum pelvis indication). This specificity does not change the intended use of the instruments for guided orthopedic corrections of the pelvis.

VI. Comparison of Technological Characteristics

The subject and primary predicate device (K190044) indications for use are substantially equivalent: both are intended to be used as a surgical instrument to assist the surgeon during non-joint replacing osteotomies.

Both the subject and the predicate device include single use patient matched guides. The subject device differs from the predicate because it allows orientation of one mobile bone fragment to the remaining pelvic bone, whereas the predicate allows for orientation of instruments to bone.

Discussion
The subject and primary predicate device (K190044) indications for use are substantially equivalent: both are intended to be used as a surgical instrument to assist the surgeon during non-joint replacing osteotomies.
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 MyPAO Guides to the identified predicate devices.

The only change made to the already cleared MyPAO Planning report (K200589) has not any impact on device's safety and effectiveness since it simply regards the addition of two parameters in the report, i.e. 3D femoral head coverage and acetabular anteversion.

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 validation
- MyPAO Design validation to validate functionality and usability
- MyPAO Design validation to demonstrate the ability of MyPAO guides to replicate preoperative planning
- MyPAO guides positioning variability - Cadaveric test validation

Biocompatibility data submitted in support of the reference device (K200792) was leveraged.

Clinical Studies:

- 10 patients were treated by three surgeons using the MyPAO surgical planning software and guides. The primary safety and effectiveness data included a surgeon formative evaluation and comparison of the preoperative planned correction as compared to the post-operative correction results. 2D planar x-rays were used to measure the final lateral center edge angle and acetabular index.
    - This was a single-arm study with a literature control. The study was conducted outside of the United States.
    - The acceptance criteria was a mean error of 4 degrees or less for the lateral center edge angle and acetabular index. This criteria was identified based on literature for conventional surgical technique accuracy.
    - The clinical data set met the acceptance criteria.
- The 10 patients included:
    - 8 female
    - 2 male
    - Ages: from 18 to 53

- There were no observed adverse effects or complications.

VIII. Conclusion

The information provided above supports that the MyPAO Guides are substantially equivalent to the identified predicate devices.