



November 19, 2025

Medacta International S.A.
% Christopher Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
6386 Global Drive, Suite 101
Memphis, Tennessee 38141

Re: K242603

Trade/Device Name: MyPAO SA 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 12, 2025

Received: October 16, 2025

Dear Christopher 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K242603

Device Name
MyPAO SA Guides

Indications for Use (Describe)

MyPAO SA 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 SA 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, Senior Director, Quality, Regulatory, and Clinical Research, Medacta USA

Date Prepared: 30 August, 2024

Date Revised: 13 November, 2025

II. Device

Device Proprietary Name:	MyPAO SA 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 device:

- MyPAO guides cleared within K220706

IV. Device Description

The MyPAO SA guides are a set of patient specific 3D printed guides produced using patients' CT scans, intended to assist the surgeon in reaching the desired level of correction during periacetabular osteotomies.

The MyPAO SA guides represent a range extension as well as a simplified approach with respect to the already existing MyPAO guides cleared within K220706. The MyPAO SA guides, and their related preoperative and postoperative 3D printed bone models, are single-use surgical instruments provided non-sterile to the end-user.

The MyPAO SA Realignment System is composed of:

- One Preop SA guide used to mark the path of the planned line and to drill holes that facilitate placement and fixation of the Realignment SA Guide during the realignment phase.
- One Realignment SA Guide placed on the acetabular and iliac fragments after osteotomy, allowing for intraoperatively assessing the positioning of the acetabular bone fragment.
- 3D printed bone models of the preoperative and postoperative condition of the patient.

The MyPAO SA guides are available in two configurations, allowing to perform both right and left hip surgeries.

Given their design, the MyPao SA guides require a less invasive surgical access with respect to the predicates MyPao guides (K220706). On the other hand, the new MyPao SA guides are not indicated in case of reverse PAO corrections.

V. Indications for Use

MyPAO SA 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 SA guides are intended for single use only.

VI. Comparison of Technological Characteristics

The MyPAO SA guides are identical to the MyPAO guides cleared within K220706 in terms of intended use and general technological characteristics. In particular, subject and predicate device share the following:

- functional features;
- anchoring points;
- production process flow;
- material;
- biocompatibility;
- device usage;
- packaging;
- shelf-life;
- sterilization (non-sterile);

The only differences between subject and predicate devices (K220706) are related to slight design changes implemented on both pre and post-osteotomy guides, in order to allow a less invasive surgical approach, preserving the insertion of the Rectus Femoris on the Anterior Inferior Iliac Spine (AIIS) during Periacetabular Osteotomy surgeries.

Discussion

These changes do not pose any additional risks in terms of safety and performance as the unique positioning of the MyPAO SA guides on the bone is still guaranteed, since the guides are designed according to patient's bone anatomy. Also, being the Post-op Realignment System a single component, the stiffness of the construct is not affected by external factors such as connecting elements, while its stability is still ensured by fixation through the two pins inserted into the bone with non-parallel directions.

VII. Performance Data

Based on the risk analysis, testing activities were conducted to written protocols.

Non-Clinical Studies

- Substantial Equivalence Assessment between the subject and predicate devices to demonstrate that no new worst cases are introduced in terms of technical characteristics, thus pre-clinical and clinical evaluations performed on the predicate devices can be leveraged for the subject devices;
- Guides positioning variability assessment demonstrating the substantial equivalence between the subject and predicate devices in terms of clinical, technological and biological characteristics as well as usability of the system;
- Designers variability assessment demonstrating minimal inter- and intra-designer variability.

Clinical Studies:

- Design Validation by using real-world clinical data collected for the subject devices and compared to the ones of the predicate devices has been used.

In detail, patients representative of the intended user population were treated according to real clinical treatment by operating surgeons across Europe (France and Switzerland).

Primary Effectiveness Endpoint

The subject devices' effectiveness (ability to replicate pre-operative planning) was assessed by demonstrating substantial equivalent performance of the subject devices with respect to the predicate devices (K220706) and by collecting intra-operative surgeons' feedback.

Effectiveness Results

- Performance Equivalence Assessment: Different angles of interest have been measured. The mean absolute errors were within the respective predefined acceptability margin and lower for the MyPAO SA System compared to the predicate device. Variability was comparable between the two systems.
- Intra-operative surgeon feedback: Formative evaluation feedback from surgeons consistently expressed full intra-operative satisfaction with the correction achieved using the system.

Primary Safety Endpoint

The safety of the subject system was evaluated by assessing the occurrence of complications or adverse events related to device use, both during surgery and throughout the patient's post-

operative follow-up period. The analysis was deemed successful if no device-related complications or adverse events were reported.

Safety Results

No device-related complications or adverse events reported intra-operatively nor during the post-operative follow-up period.

Summary

The clinical performance demonstrated that the subject MyPAO SA System is a safe and effective device for its intended clinical application.

VIII. Conclusion

The information provided above supports that the subject device is substantially equivalent to the predicate device.