August 6, 2021

Medacta International SA
% Chris Lussier
Senior Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 83118

Re: K211435
Trade/Device Name: PAO Cortical Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 7, 2021
Received: May 10, 2021

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,

Shumaya Ali, MPH
Assistant Director
DHT6A: 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

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)*

K211435

Device Name
PAO Cortical Screw

Indications for Use *(Describe)*
The PAO cortical screws are intended to refixate the acetabular fragment to the ilium, after Periacetabular osteotomy.

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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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 of Quality and Regulatory, Medacta USA
Date Prepared: May 7, 2021
Date Revised: August 5, 2021

II. Device

Device Proprietary Name:	PAO Cortical Screw
Common or Usual Name:	Screw, Fixation, Bone
Classification Name:	Smooth or threaded metallic bone fixation fastener
Primary Product Code:	HWC
Regulation Number:	21 CFR 888.3040
Device Classification	II

III. Predicate Device

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

- DePuy Synthes 4.5 mm Cortex Screws, K161616, Synthes USA Products, LLC

Other predicate devices:

- DePuy Synthes 3.5 mm Cortex Screws, K112583, Synthes USA Products, LLC
- AAP CANNULATED SCREWS, K111316, AAP IMPLANTATE AG

In addition the following reference devices are cited within the submission:

- Pelvic Trauma Screws, K171595, Medacta International SA
- Ligament Staple, K210456, Medacta International SA

IV. Device Description

The PAO cortical screws are implantable devices for acetabular refixation after a Periacetabular osteotomy. They are provided sterile and single-packaged, for single use only.

The PAO cortical screws are designed in two different sizes (Ø3.5mm and Ø4.5mm), both available in different working lengths (from 20mm to 140mm and from 50mm to 140mm respectively) to be suitable to treat all the desired population.

The PAO Cortical Screws are made of Stainless Steel AISI 316 LVM according to ISO 5832-1.

V. Indications for Use

The PAO cortical screws are intended to refixate the acetabular fragment to the ilium, after Periacetabular osteotomy.

VI. Comparison of Technological Characteristics

The PAO Cortical Screw implants and the predicate devices share the following characteristics:

- shape and design;
- biocompatibility;
- device usage;
- sterility; and
- packaging.

The PAO Cortical Screw implants differ from the predicate devices as follow:

- sizes; and
- material.

Discussion
Medacta International SA has not made any change to the shape and design, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the predicate devices.

The indications for use of the subject and predicate devices can be considered substantially equivalent since the indications for use of the subject devices is totally included in the predicate device indications for use: both the subject and the predicate devices share the same indications with regards to the fixation of osteotomies.
The expanded range of sizes of the predicate devices with respect to the subject devices does not raise new questions of safety and effectiveness since the subject device's sizes are included in the predicate devices' range of products.
The different material of the subject and predicate devices does not introduce new questions of safety and effectiveness as well, since the AISI 316LVM according to ISO 5832-1 of the PAO Cortical Screw implants is shared with the reference devices, Pelvic Trauma Screws (K171595).

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 PAO cortical screws implants to the identified predicate devices.

VII. Performance Data

Based on the risk analysis, design validation and performance testing were conducted to written protocols. The following validation and tests are being provided in support of the substantial equivalence determination:

Non-Clinical Studies

- *DESIGN VALIDATION*
  - PAO cortical Screws Design validation

- *PERFORMANCE TESTING*
  - PAO Cortical Screws – Static test according to ASTM F543-17 *Standard Specification and Test Methods for Metallic Medical Bone Screws* including the evaluation and testing of:
    - Torsional properties,
    - Driving torque,
    - Axial pull-out strength, and
    - Self-tapping performance.

- *PYROGENICITY:*
  - Bacterial endotoxin test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>)
  - Pyrogen test according to USP chapter <151> for pyrogenicity determination
  - The subject devices are not labeled as non-pyrogenic or pyrogen free.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the PAO cortical screws implants are substantially equivalent to the predicate devices.