February 3, 2022

Medacta International SA
% Chris Lussier
Senior Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K203335
Trade/Device Name: MectaScrew Extension
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 3, 2022
Received: January 5, 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,

for

Laura C. Rose, Ph.D.
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

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)*
K203335

Device Name
MectaScrew Extension

Indications for Use *(Describe)*
Reconstructive treatment of ruptured anterior and posterior cruciate ligaments by means of auto- and allografts.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

## I. Submitter

Medacta International SA
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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: November 12, 2020
Date Revised: February 2, 2022

## II. Device

| | |
|---|---|
| Device Proprietary Name: | MectaScrew Extension |
| 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 primary predicate device:

- KSEA Megafix-C Bioabsorbable Composite Interference Screw, K071437, Karl Storz Endoscopy – America, Inc

Substantial equivalence is claimed to the following secondary predicate device:

- MectaScrew PEEK, K190892, Medacta International SA

## IV. Device Description

The MectaScrew Extension includes implantable devices used for the tibial and the femoral fixation of the graft in reconstructive treatment of knee ligament ruptures. They have been developed to provide interference between a ligament graft and a bone tunnel in the ligament reconstruction surgery.

The MectaScrew Extension implants includes MectaScrew C, a composite interference screw made of RESOMER® Composite LR 706S β-TCP, a mixture of 70 % RESOMER® LR 706 S and 30 % β-TCP.

MectaScrew C is available in 19 different configurations ranging from 6 to 12 mm in diameter and 15 to 35 mm in length.

## V. Indications for Use

Reconstructive treatment of ruptured anterior and posterior cruciate ligaments by means of auto- and allografts.

## VI. Comparison of Technological Characteristics

The MectaScrew Extension implants and the predicate device (K071437) share the following characteristics:

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

The MectaScrew Extension implants differ from the predicate device (K071437) with respect to:

- screw diameters;
- screw lengths; and
- driver connection.

## 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*
    - MectaScrew C Design Validation Report – *Test Report A8* according to Design Validation Protocol M07.85.003 Nr. A8
- *PERFORMANCE TESTING*
    - MR Safety evaluation - Composite Interference Screw

- Torque resistance of graft fixation device for ACL reconstruction: interference screw, according to Test Protocol IL 07.09.485 Rev.2 and Empa Test Reports No. 5214022874 and 5214025594/1e
- Pull out strength of graft fixation device for ACL reconstruction: interference screw, Rationale A3
- MectaScrew C - Endurance properties with respect to the degradation phenomena, Rationale A2

- *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.

- *BIOCOMPATIBILITY*
  - Biocompatibility assessment as per ISO 10993 series and FDA Biocompatibility Guidance document Use of International Standard ISO 10993-1, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.*

Clinical Studies:

- No clinical studies were conducted.

## VIII. Conclusion

Based on the information provided within this submission, the MectaScrew Extension implants are substantially equivalent to the identified predicate devices. Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance evaluations.