June 4, 2019

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

Re: K190892
Trade/Device Name: MectaScrew PEEK Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 4, 2019
Received: April 5, 2019

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,

Laurence D. Coyne, Ph.D.
Assistant Director
DHT6C: Division of Stereotaxic, Trauma and Restorative 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)*
K190892

Device Name
MectaScrew PEEK Interference Screw

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

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

K190892

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: April 04, 2019
Date Revised: May 29, 2019

II. Device

Device Proprietary Name:	MectaScrew PEEK®
Common or Usual Name:	Screw, fixation, bone
Classification Name:	Smooth or threaded metallic bone fixation Fastener
Primary Product Code:	MBI
Regulation Number:	21 CFR 888.3040
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- Smith&Nephew BIOSURE PK® Interference screw (K083635).

Reference device:

- Conmed MATRYX® Interference Screw (K063588).

IV. Device Description

The purpose of this submission is to gain clearance for the MectaScrew PEEK®. The MectaScrew PEEK® is an implantable device used for the reconstructive treatment of knee ligament ruptures.

The primary purpose of the MectaScrew PEEK interference screw is to provide, via interference between the graft and the bone tunnel, a suitable and secure intra - tunnel graft fixation of the implanted ligament replacement giving stability, pain relief due to restoration of the normal anatomy, and improving articular functionality for patients treated.

The MectaScrew PEEK® portfolio is composed of 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 allo- grafts.

VI. Comparison of Technological Characteristics

The MectaScrew PEEK® interference screws and the primary predicate device BIOSURE PK® Interference screw (K083635) share the following characteristics:

- Range of product (diameter)
- External shape
- Materials (PEEK®)
- Provided Sterile
- Device Usage

In addition, the following characteristic is shared with the reference device MATRYX® Interference Screw (K063588)

- Range of product (length)

The MectaScrew PEEK® interference screw is technologically different from both the predicate and reference devices as follows:

- Driver connection

The material used in the MectaScrew PEEK® product is PEEK® according to ASTM F2026, in alignment with the predicate device and in according with the most common equivalent products in the orthopedic field.

Discussion
The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness. The MectaScrew PEEK® interference screw is substantially equivalent to the predicate device in terms of materials of construction, external shape (graft fixation and screw insertion), device usage, range of product (diameter), and sterility. Moreover, the subject product shares the range of product (length) with the above mentioned reference device.

The MectaScrew PEEK® driver connection has been designed in order to minimize the stress concentration and maximize the torque transmission. Since it is different, even if comparable, to the predicate device, the endurance properties in terms of torque resistance during screw insertion of the MectaScrew PEEK® have been successfully tested, showing that the different driver connection have no impact on the safety and performance of the device

Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the MectaScrew PEEK® interference screw to the identified predicate and reference devices.

VII. Performance Data

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

Non-Clinical Studies

- *DESIGN VALIDATION*
  - Design Validation, according to Medacta Design Validation Protocol A1 (Cadaver Workshop) M07.85.004 and six (6) Evaluation forms Single Bundle ACL Implants. *Test Report A1*.
  - MR compatibility, *MR Safety Evaluation – MectaScrew PEEK®*

- *CHARACTERIZATION TESTING*
  - Pull Out Strength of Graft Fixation Device for ACL Reconstruction: Interference Screw– according to Empa Test report No. 5214019117/1e Rev.1, according to Medacta Protocol IL 07.09.484 Rev.0. *Test report A2.*
  - Torque Resistance of Graft Fixation Device for ACL Reconstruction: Interference Screw - according to Empa Test report No 5214019116/1e, according to Medacta Protocol IL 07.09.485 Rev.0. *Test report A3.*

- *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.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the MectaScrew PEEK® is as safe and effective as the predicate and reference devices. Therefore, it is concluded that the MectaScrew PEEK® is substantially equivalent to the predicate device Smith&Nephew BIOSURE PK® Interference screw (K083635) and to the reference device Conmed MATRYX® Interference Screw (K063588).