May 28, 2019

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

Re: K190474
Trade/Device Name: MectaLock PEEK Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 25, 2019
Received: February 27, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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)*
K190474

Device Name
MectaLock PEEK Suture Anchor

Indications for Use *(Describe)*
The MectaLock PEEK Suture anchors are intended for use in arthroscopic or open surgical approaches for fixation of suture (soft tissue) to bone in the shoulder and hip in the following procedures:
• Hip: acetabular labral repair; and
• Shoulder: glenoid labrum repair.

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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2.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: Feb 25, 2019
Date Revised: Apr 18, 2019
Date Revised: Apr 29, 2019

II. Device

Device Proprietary Name:	MectaLock PEEK® Suture Anchor
Common or Usual Name:	Suture Anchor
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Primary Product Code:	MBI
Regulation Number:	21 CFR 888.3040
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

Primary predicate device:
- PushLock™ K061863 – Arthrex.

Reference devices:
- MectaLIF Anterior Stand-Alone, K160605 – Medacta International
- MectaLIF Anterior Stand-Alone, K170455 – Medacta International
- MectaLIF Posterior Extension, K181970 – Medacta International
- Hs Fiber (Polyblend), River Bond, Riversilk (Silk), Riverpro (Polypropylene), Riverlon (Nylon) Model Veries By Size/Need, K100006 – Riverpoint Medical

IV. Device Description

The purpose of this submission is to gain clearance for the MectaLock PEEK® Suture Anchor. The MectaLock PEEK® Suture Anchor is an implantable device used for soft tissue re-fixation (i.e.: muscles, tendons, ligaments...) composed of an anchoring component (PEEK® anchor) and an Ultra High Molecular Weight PolyEthylene non-absorbable braided suture.

The MectaLock PEEK® Suture Anchor is a knotless device provided mounted on the tip of a dedicated disposable driver which allows the surgeon to insert the anchor into a pilot hole, previously drilled in the desired position into the patient's bone. The surgeon must combine the MectaLock PEEK® Suture Anchor with the provided non-absorbable UHMWPE suture, packaged and included in the whole product's blister. The driver can be disposed immediately after the implant has been placed.
The MectaLock PEEK® Suture Anchor portfolio is composed of three anchor sizes: ø2.4, ø2.9, and ø3.4mm combined with two driver lengths: short and long.

V. Indications for Use

The MectaLock PEEK Suture anchors are intended for use in arthroscopic or open surgical approaches for fixation of suture (soft tissue) to bone in the shoulder and hip in the following procedures:
• Hip: acetabular labral repair; and
• Shoulder: glenoid labrum repair.

VI. Comparison of Technological Characteristics

The MectaLock PEEK® Suture Anchor and the predicate devices share the following characteristics:

- Materials (Anchor: PEEK® and Suture: Ultra-High molecular weight polyethylene)
- Provided Sterile (EtO sterilization - overkill approach)
- Device Usage
- Disposable driver design (materials and geometrical concepts)
- Interference mechanism: external shape (Cylindrical body with circumferential ribs)
- Diameters
- Manual sutures engagement
- Shelf life (5 years)

The MectaLock PEEK® Suture Anchor is technologically different from the predicate devices as follows:

- Suture engagement: eyelet

The materials used in the MectaLock PEEK® Suture Anchor product are:

- Anchor: PEEK® according to ASTM F2026
- Suture: Ultra High Molecular Weight PolyEthylene
- Disposable driver: Stainless steel and Polycarbonate medical grade

All of these materials were chosen in alignment with the predicate device and in according with the most common equivalent products in the orthopedic field.
Due to the extensive history of use in currently marketed medical devices, additional biocompatibility testing was deemed unnecessary for the MectaLock PEEK® Suture Anchor components.

Discussion
The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness. The MectaLock PEEK® Suture Anchor is the same or similar to the predicate devices in terms of materials of construction, Interference mechanism device usage, Suture typology and sterility.

Although there are some differences in the design of the eyelet dedicated to suture engagement, the intended use and functionality of the component are the same. In detail the sutures engagement is performed manually with an equivalent procedure, both for the MectaLock PEEK® Suture Anchor and for the predicate device. The eyelet functions to both keep the sutures connected and push them into the pilot pre-drilled hole in a way that, after the anchor's insertion is complete, the sutures are mechanically locked against the surrounding bone. While in the MectaLock PEEK® Suture Anchor the eyelet is monoblock with the anchor's body, the PushLock® eyelet is a separated body connected to the driver. Nevertheless, once the anchor and eyelet are released from the driver, the final configuration of anchor + eyelet is pushed into the pilot hole in the bone, realizing an equivalent system. Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the MectaLock PEEK® Suture Anchor to the identified predicate 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) M07.85.003 and Evaluation form J-Lock & Aimers. *Test Report A1.*
  - MR compatibility, *MR Safety Evaluation – MectaLock PEEK Suture Anchors*

- *CHARACTERIZATION TESTING*
  - Cyclic and load-to–failure properties of suture anchors – according to Empa Test report No. 18-06-25_5214019237_1e_Anchor-test_final.pdf, according to Medacta Protocol IL 07.09.488_rev.0. *Test report A2.*
  - MectaLock PEEK® Suture Anchors suitability assessment. *Rationale A3_Rev0*

- *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.

- *STERILIZATION:*
  - ISO 11135:2014 Sterilization of health-care products - Ethylene Oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.
  - ISO 10993-7:2008 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the MectaLock PEEK® Suture Anchor is as safe and effective as the predicate devices. Therefore, it is concluded that the MectaLock PEEK® Suture Anchor is substantially equivalent to the predicate devices.