February 6, 2020

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

Re: K193461
Trade/Device Name: MectaLock All-Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 11, 2019
Received: December 16, 2019

Dear Mr. 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,

Laura C. Rose, Ph.D.
Acting 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)*

Device Name
MectaLock-All Suture Anchors

Indications for Use *(Describe)*
The MectaLock All-Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of suture (soft tissue) to bone in the hip and shoulder in the following procedures:

- Hip: acetabular labral repair
- Shoulder: glenoid labrum repair; cuff rotator 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.

2.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Director of Quality and Regulatory, Medacta USA
Date Prepared: December 11, 2019
Date Revised: January 31, 2020

II. Device

Device Proprietary Name:	MectaLock All-Suture Anchors
Common or Usual Name:	Soft Tissue Fixation Device
Classification Name:	Fastener, Fixation, Non-degradable, Soft tissue
Product Codes:	MBI
Regulation Number:	21 CFR 888.3040
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- JuggerKnot Soft Anchors, K150768, Biomet Manufacturing Corp.

The following device is referenced in the submission:

- MectaLock PEEK Suture Anchor, K190474, Medacta International SA

IV. Device Description

The MectaLock All-Suture Anchors are implantable, knotted, devices composed entirely of ultra-high molecular weight polyethylene (UHMWPE) specifically arranged and braided to create an anchoring point within the bone after deployment. The sutures that compose the anchor are also used to secure soft tissues to a supporting structure (i.e., bone).

The sterile, individually packaged, devices consist of the all-suture anchor and a disposable stainless steel driver with a plastic handle. The all-suture anchor is pre-loaded on the disposable driver.
MectaLock All-Suture Anchors are available in six (6) different configurations depending on anchor size (size 1 and size 2), driver length (long and short), and typology of preloaded floating sutures (standard or tape sutures).

V. Indications for Use

The MectaLock All-Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of suture (soft tissue) to bone in the hip and shoulder in the following procedures:

- Hip: acetabular labral repair
- Shoulder: glenoid labrum repair; cuff rotator repair

VI. Comparison of Technological Characteristics

The MectaLock All-Suture Anchors and the predicate device share the following characteristics:

- anchor deployment and fixation mechanism;
- driver design and material;
- driver handle design and material; and
- sterilization method.

The MectaLock All-Suture Anchors and the predicate devices are technologically different with respect to suture size and types of sutures provided with each configuration.

Discussion

Based on the comparison of technological characteristics and performance data provided within this submission, the MectaLock All-Suture Anchors are substantially equivalent to the identified predicate device. Technological differences related to suture size and types of sutures provided are addressed through performance testing.

VII. Performance Data

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

<u>Non-Clinical Studies</u>

- DESIGN VALIDATION
  - Design Validation, according to Medacta Design Validation Protocol A1 (Cadaver Workshop) M07.85.003 and Evaluation forms. Test Report A1.

- MR compatibility, MR Safety Evaluation – All-Suture Anchors
- CHARACTERIZATION TESTING
  - Cyclic and load-to–failure properties of All-Suture Anchors – according to Empa Test Report No. 5214'022'720e and Medacta Protocol IL 07.09.575. Test report A2.

- PYROGENICITY
  - Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and pyrogen test according to USP chapter <151> for pyrogenicity determination
  - the subject devices are not labeled as non-pyrogenic or pyrogen free

- BIOCOMPATIBILITY

- STERILIZATION

- SHELF-LIFE

Clinical Studies

- No clinical studies were conducted

VIII. Conclusion

The information provided with this submission supports that the MectaLock All-Suture Anchors are substantially equivalent to the predicate device. Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance evaluations.