January 29, 2020

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

Re: K191677
Trade/Device Name: MectaTap TI 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: January 7, 2020
Received: January 9, 2020

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,

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)*
K191677

Device Name
MectaTap TI Suture Anchor

Indications for Use *(Describe)*
The MectaTap TI Suture Anchors are intended for use in arthroscopic or open surgical approaches for fixation of suture (soft tissue) to bone in shoulder in the following procedure:
Shoulder: cuff rotator repair and biceps tenodesis.

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: Christopher Lussier, Director of Quality and Regulatory, Medacta USA
Date Prepared: Jun 21, 2019
Date Revised: January 15, 2020

II. Device

Device Proprietary Name:	MectaTap TI 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:

- ConMed Linvatec, SuperRevo® Herculine ™ Suture Anchor (K041713).

In addition, the following Reference devices is cited within the submission:

- Medacta International SA, M-ARS ACL: Anatomic Ribbon Surgery System (K171640)
- Riverpoint Medical, HS FIBER (POLYBLEND), RIVER BOND, RIVERSILK (SILK), RIVERPRO (POLYPROPYLENE), RIVERLON (NYLON) MODEL VERIES BY SIZE/NEED (K100006)
- DePuy Mitek, FASTIN RC Anchor (K060664)

IV. Device Description

The MectaTap TI – Suture anchor is an implantable knotted device used for the soft tissues refixation (i.e.: muscles, tendons, ligaments...) composed of a titanium alloy anchoring component preloaded with two Ultra High Molecular Weight PolyEthylene non-absorbable braided sutures and assembled on a disposable inserter.

Due to its specific design, the MectaTap TI – Suture anchor is implanted by tapping on the plastic handle of the inserter: the modularity between the internal eyelet and the external sleeve translates the axial movement of tapping into rotation of the anchor's body into the bone.

The MectaTap TI Suture anchor comes in two different sizes: ø5.0 and ø6.5mm (maximum external diameter) with a fixed length of 15mm, to cover the intended population and bone quality.

V. Indications for Use

The MectaTap TI Suture Anchors are intended for use in arthroscopic or open surgical approaches for fixation of suture (soft tissue) to bone in shoulder in the following procedure:

- Shoulder: cuff rotator repair and biceps tenodesis.

VI. Comparison of Technological Characteristics

The MectaTap TI Suture Anchor and the predicate device share the following characteristics:

- Materials (Anchor: Ti 6Al-4V ELI [ASTM F136 & ISO 5832-3] and Suture: Ultra-High molecular weight polyethylene)
- Provided Sterile
- Suture typology
- Device Usage
- Shelf-life
- Biocompatibility

The MectaTap TI Suture Anchor is technologically different from the predicate device as follows:

- Diameters
- External shape (Thread profile and Tip)
- Inner shape (Eyelet and Driver connection)

The materials used in the MectaTap TI Suture Anchor product are:

- Anchor: Ti 6Al-4V ELI according to ASTM F136 & ISO 5832-3
- 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 MectaTap TI Suture Anchor components.

The MectaTap TI Suture Anchor will be labelled with a 5 year shelf life.

Discussion

The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness. The MectaTap TI Suture Anchor is the same or similar to the predicate device in terms of materials of construction, device usage, suture typology and disposable driver design and sterility.

Although there is a difference in the modularity and position of the eyelet (free to rotate and internal for the MectaTap TI Suture anchor, while monoblock and external for the predicate device), and in the Driver connection, the intended use and functionality of the component are the same.

Moreover, even if the external shape of the implant is not identical to the predicate, the general external geometric features are equivalent for the expected use and application. Both devices have similar dimensions and the wrap of the external contour creates the same geometrical volume, so that the final encumbrance of the two devices is equivalent.

The product range is shared with the reference device DePuy Mitek, FASTIN RC Anchor (K060664).

Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the MectaTap TI 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 (Wetlab) M07.85.003 and Evaluation form Titanium impaction anchor. *Test Report A1.*
  - Impaction Test. *Test Report A3.*
  - MR compatibility*, MR Safety Evaluation – MectaTap TI - Titanium Impaction Suture anchor*

- *CHARACTERIZATION TESTING*
  - Cyclic and load-to–failure testing – according to Empa Test report No. 18-11-14_5214020346_1e_final.pdf, according to Medacta Protocol IL 07.09.488_rev.1. *Test report A2.*
  - Hitting force assessment – Workshop. *Test Report A4.*

- Mectatap Ti: Mechanical Evaluation During Assembly, A Finite Element Study. Test Report A5.

- *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 MectaTap TI Suture Anchor is as safe and effective as the predicate devices. Therefore, it is concluded that the MectaTap TI Suture Anchor is substantially equivalent to the predicate device.