February 10, 2020

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

Re: K193165
Trade/Device Name: MectaFix CL Fixation Button with Continuous Loop
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, HWC, JDR
Dated: November 14, 2019
Received: November 15, 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,

Laura C. Rose, PhD
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)*
K193165

Device Name
MectaFix CL Fixation Button with Continuous Loop

Indications for Use *(Describe)*

The MectaFix CL Fixation Button with Continuous Loop is indicated for use in reconstructive treatment and extracortical femoral fixation of an implanted anterior cruciate ligament reconstruction.

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 and Compliance Director, Medacta International SA
Date Prepared: November 12, 2019
Date Revised: January 28, 2020

II. Device

Device Proprietary Name:	MectaFix CL Fixation Button with Continuous Loop
Common or Usual Name:	Suture retention device, Non-absorbable surgical suture
Classification Name:	Fastener, Fixation, Non-degradable, Soft tissue, Non-absorbable surgical suture
Product Codes:	MBI (primary), HWC (secondary), JDR (secondary)
Regulation Number:	21 CFR 888.3040, 21 CFR 888.3030
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Endobutton Continuous Loop, K081098, Smith & Nephew, Inc., Endoscopy Division

The following device is referenced in the submission:

- MectaLock Ti Suture Anchor, K191300, Medacta International SA

IV. Device Description

The MectaFix CL Fixation Button with Continuous Loop is an implantable fixation button with a continuous loop used for the femoral fixation of the anterior cruciate ligament (ACL) graft by means of an extra-cortical suspensory fixation. It consists of a metal elongated button (Ti6Al4V ELI), a continuous loop (UHMWPE) ranging in length from 15 mm to 60 mm to be coupled with the graft, and a pulling suture (UHMWPE) to pull the construct through the prepared bone tunnel and to subsequently flip the button after passing the femoral lateral cortex.

The MectaFix CL Fixation Button with Continuous Loop implants are provided sterile and are provided in single-use packages.

V. Indications for Use

The MectaFix CL Fixation Button with Continuous Loop is indicated for use in reconstructive treatment and extracortical femoral fixation of an implanted anterior cruciate ligament reconstruction.

VI. Comparison of Technological Characteristics

The MectaFix CL Fixation Button with Continuous Loop implants and the predicate device share the following characteristics:

- shape;
- dimension;
- loop sizes; and
- button material of construction.

The MectaFix CL Fixation Button with Continuous Loop implants and the predicate devices are technologically different with respect to:

- number of sutures; and
- suture materials.

Discussion

Based on the comparison of technological characteristics and performance data provided within this submission, the MectaFix CL Fixation Button with Continuous Loop implants are substantially equivalent to the identified predicate device.

VII. Performance Data

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following mechanical studies were performed on worst-case implants in support of a substantial equivalence determination:

Non-Clinical Studies:

- cyclic loading
- tensile strength per ASTM D2256/D2256M-10
- Cadaver testing
- Sterilization validation
- Shelf-life testing
- 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

VIII. Conclusion

The information provided with this submission supports that the MectaFix CL Fixation Button with Continuous Loop 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.