April 12, 2021

Medacta International SA
% Chris Lussier
Senior Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 83118

Re: K210456
Trade/Device Name: Ligament Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: February 12, 2021
Received: February 16, 2021

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,

Pooja Panigrahi -S

for

Laura C. Rose, Ph.D.
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)*

K210456

Device Name

Ligament Staple

Indications for Use *(Describe)*

The Medacta Ligament Staple is intended for use in medial collateral ligament (MCL) and lateral collateral ligament (LCL) reconstruction.

Reconstructive treatment of ruptured or damaged MCL and LCL.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Submitter

Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director of Quality and Regulatory, Medacta USA
Date Prepared: February 12, 2021
Date Revised: March 31, 2021

II. Device

Device Proprietary Name:	Ligament Staple
Common or Usual Name:	Staple, fixation bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Primary Product Code:	JDR
Regulation Number:	21 CFR 888.3030
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- Arcus Staple System (K151160), Nextremity Solution

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

- Richards Staple (pre-amendment device), Smith and Nephew
- MectaScrew PEEK Interference Screw (K190892), Medacta International SA
- MectaLock Ti Suture Anchor (K191300), Medacta International SA

IV. Device Description

Medacta Ligament Staple is a single size (ø11 mm) extra cortical fixation device which is impacted on the Medial Collateral Ligament (MCL) or on the Lateral Collateral Ligament (LCL) for soft tissue to bone refixation by means of a dedicated impactor. The device consists of a circular plate with

protruding tapered serrated legs, made of titanium alloy (Ti6Al4V ELI according to ISO 5832-3 and ASTM F136), and a staple inlay, made of PEEK according to ASTM F2026, for pressing the graft down to the bone, featuring a lower spike patterned surface for increasing soft tissue fixation.

V. Indications for Use

The Medacta Ligament Staple is intended for use in medial collateral ligament (MCL) and lateral collateral ligament (LCL) reconstruction.
Reconstructive treatment of ruptured or damaged MCL and LCL.

VI. Comparison of Technological Characteristics

The Ligament Staple and the predicate Arcus Staple share the following characteristics:

- staple material;
- biocompatibility;
- device usage;
- sterility; and
- packaging.

The Ligament Staple differs from the predicate Arcus Staple as follow:

- size; and
- design.

Discussion
Medacta International SA has not made any change to the indication for use, material, device usage, biocompatibility, sterility and packaging of the subject device respect to the predicate device.
The comparison of technological characteristics and performance data provided within this submission, shows that there are no new risks associated with the subject devices and supports the substantial equivalence of the Ligament Staple to the identified predicate devices.

VII. Performance Data

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

Non-Clinical Studies

- *DESIGN VALIDATION*
  - Ligament staple Porcine bone workshop, verifying the performance of the subject device
  - Ligament staple wetlab, validating the subject device for the intended population and purpose

- *CHARACTERIZATION TESTING*
  - Cyclic and load-to-failure properties of ligament staple device for soft tissue fixation
  - Ligament staple MR safety evaluation and testing according to ASTM F2052-15, ASTM F2213-17, ASTM F2182-11a and ASTM F2119-07 (2013)

- *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
  - The subject devices are not labeled as non-pyrogenic or pyrogen free.

- *BIOCOMPATIBILITY evaluation* according to ISO 10993

- *SHELF-LIFE testing* according to ISO 11607-1 and ISO 11607-2

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the Ligament Staple is substantially equivalent to the identified predicate devices.