February 24, 2023

Medacta International S.A.
% Chris Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K223582
Trade/Device Name: MectaLock TI Triple Loaded 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: November 23, 2022
Received: December 1, 2022

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,

Sara S. Thompson -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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K223582

Device Name
MectaLock TI Triple Loaded Suture Anchor

Indications for Use *(Describe)*

The MectaLock TI Triple Loaded 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: rotator cuff 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.**

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.***

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# 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, Quality, Regulatory, and Clinical Research, Medacta USA

Date Prepared: November 30, 2022
Date Revised: February 21, 2023

## II. Device

| | |
|---|---|
| Device Proprietary Name: | MectaLock TI Triple Loaded Suture Anchor |
| Common or Usual Name: | Fastener, Fixation, Nondegradable, Soft Tissue |
| Classification Name: | Smooth or threaded metallic bone fixation fastener |
| Primary Product Code | MBI |
| Regulation Number: | 21 CFR 888.3040 |
| Device Classification | II |

## III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- MectaLock TI Suture Anchor, K191300, Medacta International SA

## IV. Device Description

The MectaLock TI Triple Loaded Suture Anchor is a line extension to the MectaLock TI Suture Anchor cleared within K191300.
The MectaLock TI Triple Loaded Suture Anchors are implantable devices used for soft tissue refixation within the shoulder joint (rotator cuff repair, biceps tenodesis). They are composed of an anchoring component (Titanium alloy anchor) and preloaded with UHMWPE non-absorbable braided sutures.
This implantable assembly, is provided sterile and individually packaged, mounted on a dedicated disposable stainless steel driver with a plastic handle, allowing the surgeon to insert and place the MectaLock TI Triple Loaded Suture Anchor into the patient.

The MectaLock TI Triple Loaded Suture Anchor are available in 4 different configurations depending on anchor size (Ø5.0 or Ø6.5 mm) and typology of preloaded sutures.

## V. Indications for Use

The MectaLock TI Triple Loaded 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: rotator cuff repair and biceps tenodesis.

## VI. Comparison of Technological Characteristics

The subject devices are substantially equivalent to the predicate, MectaLock TI Suture Anchor (K191300), with regards to the following characteristics:

- indications for use;
- anchor diameters;
- anchor tip and thread shape;
- materials;
- biocompatibility;
- device usage;
- sterilization;
- shelf-life; and
- packaging.

The subject devices differ respect to the predicate, MectaLock TI Suture Anchor (K191300), with regards to the following characteristics:

- anchors length;
- anchor eyelet and driver connection;
- preloaded suture; and
- driver design.

*Discussion*
The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness.
Medacta International SA has not made any change to the indications for use, anchor diameters, anchor external design, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the predicate devices.
Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the MectaLock TI Triple Loaded Anchors to the identified predicate device.

## VII. Performance Data

Based on the risk analysis, performance testing was conducted to written protocols. The following tests and rationales are provided in support of the substantial equivalence determination:

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - MectaLock TI Triple Loaded Suture Anchor Design validation, cadaver lab
  - MectaLock TI and MectaLock TI Triple Loaded Suture Anchor – Substantial Equivalence Assessment
  - MR safety evaluation

- *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*

- *SHELF-LIFE evaluation*

Clinical Studies:

- No clinical studies were conducted.

## VIII. Conclusion

The information provided above supports that the MectaLock TI Triple Loaded Suture Anchors are substantially equivalent to the predicate devices.