April 17, 2023

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

Re: K230544
Trade/Device Name: SnugFit All-Suture Anchor extension
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 28, 2023
Received: March 20, 2023

Dear Christopher 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

Sara S. Thompson, D.V.M.
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230544

Device Name

SnugFit All-Suture Anchor extension

Indications for Use *(Describe)*

- MectaLock All-Suture Anchor
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

- SnugFit All-Suture Anchor
The SnugFit All-Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of soft tissue to bone in the hip and shoulder in the following procedures:
 - Hip: acetabular labral repair
 - Shoulder: glenoid labrum repair; rotator cuff repair, biceps tendon 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.

510(k) Summary

I. Submitter

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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: February 28, 2023

II. Device

Device Proprietary Name:	SnugFit All-Suture Anchor extension
Common or Usual Name:	Soft Tissue Fixation Device
Classification Name:	Fastener, Fixation, Non-degradable, 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 primary predicate device:

- SnugFit All-Suture Anchor, K203485, Medacta International SA.

In addition, the following predicate devices are mentioned within the submission:

- MectaLock All-Suture Anchor, K193461, Medacta International SA
- MectaLock TI Triple Loaded Suture Anchor, K223582, Medacta International SA

IV. Device Description

The purpose of this submission is to gain clearance for the change in driver design of the already cleared MectaLock All-Suture Anchor (K193461) and SnugFit All-Suture Anchor size 2 (K203485), and to add new size 1 implants to SnugFit All-Suture Anchor, as a line extension.
The subject devices are implantable devices indicated for the treatment of hip and shoulder instability.
The subject SnugFit All-Suture Anchor size 1 is entirely composed of sutures, made up of ultra-high molecular weight polyethylene (UHMWPE) and polyester (PET), which are specifically arranged and

braided to create an anchoring point within the bone, after their deployment. The sutures themselves, are also used to secure soft tissues to a supporting structure, i.e. bone.
The sterile, individually packaged, subject device is composed of two parts: an all-suture anchor and a driver made of a stainless-steel shaft with an over-moulded plastic handle. The all-suture anchor is provided pre-loaded on the specifically designed disposable driver.
The new SnugFit All-Suture Anchor size 1 is available in two (2) different configurations depending on the driver length (long and short).

V. Indications for Use

- **MectaLock All-Suture Anchor**

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

- **SnugFit All-Suture Anchor**

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

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

VI. Comparison of Technological Characteristics

The only differences between the subject MectaLock All-Suture Anchor and the SnugFit All-Suture Anchor size 2, with respect to their related predicate devices (K193461 and K203485, respectively), lie in the driver design (suture locking system and interface between the plastic handle and the metal shaft), that has not any impact on devices' safety and performance.

The subject SnugFit All-Suture Anchor size 1 is substantially equivalent to the predicate device, SnugFit All-Suture Anchor (K203485), with regards to the following characteristics:

- Indication for use;
- Size;
- Pre-loaded sutures;
- Deployment and fixation mechanism;
- Materials (except for the driver clipping mechanism);
- Biocompatibility;
- Device usage;
- Sterility;
- Shelf-life;
- Packaging.

The subject SnugFit All-Suture Anchor size 1 differs respect to the predicate, SnugFit All-Suture Anchor (K203485), with regards to the following characteristics:

- Anchors diameter;

- 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, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices with respect to the predicate devices.
Based on the comparison of technological characteristics and performance data provided within this submission, no new risks are associated with the driver design change of the MectaLock All-Suture Anchor (K193461) and SnugFit All-Suture Anchor size 2 (K203485), and the data supports the substantial equivalence of the new SnugFit All-Suture Anchor Size 1 implants 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*
  - SnugFit Size 1 - Ø1.8 and SnugFit Size 1 – Ø1.4 Substantial Equivalence Assessment;
  - MR Safety evaluation - SnugFit All-Suture Anchor.

- *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 subject devices are substantially equivalent to the predicate devices.