July 1, 2025

Medacta International S.A.
% Christopher Lussier
Senior Director, Quality and Regulatory
Medacta USA
6386 Global Drive
Suite 101
Memphis, Tennessee 38141

Re: K251933
Trade/Device Name: SnugFit ASA Extension
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 24, 2025
Received: June 24, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251933

Please provide the device trade name(s).

SnugFit ASA Extension

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

K251933

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality and Regulatory, Medacta USA
Date Prepared: June 24, 2025

II. Device

Device Proprietary Name:	SnugFit ASA 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 predicate devices.

Primary Predicate device:

- SnugFit All-Suture Anchor extension, K230544, Medacta International SA

Additional Predicate devices:

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

IV. Device Description

The SnugFit ASA Extension is a Medacta suture anchors portfolio extension including implantable devices indicated for the treatment of hip and shoulder instability as well as shoulder rotator cuff repair and biceps tenodesis. Specifically, the purpose of this submission is to gain the clearance for:

- SnugFit All-Suture Anchor – Size 1: 1 single loaded configuration (short and long), 3 double loaded configurations (short and long and two different color options each); and
- SnugFit All-Suture Anchor – Size 2: 3 triple loaded configurations (short) and 1 double loaded configuration (short).

The subject devices are 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 devices are composed of two parts: an all-suture anchor and a driver made of a stainless-steel shaft with an over-molded plastic handle. The all-suture anchor is provided pre-loaded on the specifically designed disposable driver.

V. Indications for Use

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 subject and the predicate devices (K230544, K203485) are substantially equivalent with respect to the following characteristics:

- Indications for Use;
- Sizes;
- Deployment and fixation mechanism;
- Driver design;
- Materials;
- Biocompatibility;
- Device usage;
- Packaging;
- Shelf-life; and
- Sterilization.

The only difference between the subject and the predicate devices (K230544, K203485) is the type and number of preloaded sutures.

Discussion
The subject pre-loaded sutures have been designed to expand the portfolio providing surgeons with a broader selection of devices, but this difference has not any impact on safety and effectiveness since the subject devices functional mechanism is identical to the one of the predicate devices and no worst case is introduced with respect to pull-out force.

The comparison of technological characteristics and performance data provided within the submission supports the substantial equivalence of the subject devices respect to the predicate devices.

VII. Performance Data

Based on the risk analysis, testing activities were conducted to written protocols. The following evaluations and rationales are provided in support of the substantial equivalence determination.

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - Substantial equivalence assessment

- *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* assessment

- *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.