March 26, 2021

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

Re: K203259/S001
Trade/Device Name: FairFix Adjustable Button System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 22, 2021
Received: February 26, 2021

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, 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)*

K203259

Device Name

FairFix Adjustable Button System

Indications for Use *(Describe)*

FairFix Adjustable Button is intended to be used during a knee ligament (i.e. anterior cruciate ligament and posterior cruciate ligament) reconstruction surgery when a Ø4.5mm tunnel is realized.

FairFix Extender is intended to be used in association with FairFix Adjustable Button during a knee ligament (i.e. anterior cruciate ligament and posterior cruciate ligament) reconstruction surgery with a Ø 6 – 11 mm tunnel.

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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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 of Quality and Regulatory, Medacta USA
Date Prepared: November 4, 2020
Date Revised: March 26, 2021

II. Device

Device Proprietary Name:	FairFix Adjustable Button System
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 devices:

Primary Predicate:

- ACL TightRope, K112990, Arthrex Inc.

Secondary Predicate:

- GraftMax Cradle, K151037, Conmed Corporation

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

- OrthoButton AL, K171060, Riverpoint Medical
- M-ARS ACL, K171640, Medacta International SA

IV. Device Description

The FairFix Adjustable Button System includes implantable devices indicated for knee ligament (i.e. ACL, PCL) reconstructive surgery for the fixation of tendons and ligaments by means of a suspensory fixation with an adjustable suture loop.
The FairFix Adjustable Button consists of a metal button with a pre-assembled, non-absorbable adjustable suture loop to be coupled with the graft, a pulling suture (blue) to pull the construct through

the bone tunnel and a flipping suture (white) to flip the button once the extracortical side has been reached.
The device is provided pre-assembled on a dedicated graft preparation card, aiming to facilitate implant-graft connection.
The FairFix Adjustable Button Extender is intended to be used in association with the FairFix Adjustable Button in case of large tunnel conditions (e.g. cortical blowout, revision cases, full tunnel). It consists of an elongated metal plate with a recess to house the FairFix Adjustable Button and a lateral slot to allow suture passage.

V. Indications for Use

FairFix Adjustable Button is intended to be used during a knee ligament (i.e. anterior cruciate ligament and posterior cruciate ligament) reconstruction surgery when a Ø4.5mm tunnel is realized.
FairFix Extender is intended to be used in association with FairFix Adjustable Button during a knee ligament (i.e. anterior cruciate ligament and posterior cruciate ligament) reconstruction surgery with a Ø 6 – 11 mm tunnel.

VI. Comparison of Technological Characteristics

- FairFix Adjustable Button

The subject FairFix Adjustable Button and the predicate, ACL TightRope (K112990), share the following characteristics:

- pulling suture dimension;
- materials;
- biocompatibility;
- device usage;
- sterility; and
- packaging.

The subject FairFix Adjustable Button and the predicate, ACL TightRope (K112990), differ with regards to the following characteristics:

- button shape and dimension;
- adjustable loop dimension and shape/mechanism; and
- flipping suture.

- FairFix Adjustable Button Extender

The subject FairFix Adjustable Button Extender and the predicate, GraftMax Cradle (K151037), share the following characteristics:

- shape and dimension;
- biocompatibility;
- device usage; and
- packaging.

The subject FairFix Adjustable Button Extender and the predicate, GraftMax Cradle (K151037), only differ with regards to the sterilization method.

Discussion
Medacta International SA has not made any change to the intended use, device usage, materials, biocompatibility, sterility and packaging of the subject FairFix Adjustable Button System.

The comparison of technological characteristics and performance data provided within this submission, shows that there are no new risks associated with the subject FairFix Adjustable Button System design, and supports the substantial equivalence of the FairFix Adjustable Button System 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*
  - FairFix Adjustable Button System Design Validation
  - FairFix Adjustable Button Protective Card Design Validation

- *CHARACTERIZATION TESTING*
  - Extracortical fixation devices: Lengthening under Cyclic Loading and Load to Failure
  - FairFix Adjustable Button System MR Safety Evaluation and Testing

- *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:*
  - Biocompatibility assessment as per ISO 10993 series and FDA Biocompatibility Guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the FairFix Adjustable Button System is substantially equivalent to the predicate devices. Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance evaluations.