June 13, 2022

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

Re: K221389
Trade/Device Name: FairFix AM Adjustable Button
FairFix PSP Adjustable Button
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI

Dear Christopher Lussier:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 8, 2022. Specifically, FDA is updating this SE Letter due to a typographical error in the trade name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Laura C. Rose, Ph.D., OHT6: Office of Orthopedic Devices, by phone (301) 348-1947 or email at Laura.Rose@fda.hhs.gov.

Sincerely,

Melissa A. Ramcharan -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

June 8, 2022

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

Re: K221389
Trade/Device Name: FairFix AM - Adjustable Button
FairFax PSP – Adjustable Button
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 12, 2022
Received: May 13, 2022

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,

Melissa A. Ramcharan -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)*

K221389

Device Name
FairFix AM – Adjustable Button

Indications for Use *(Describe)*

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

FairFix Extender is intended to be used in association with any FairFix Adjustable Button configuration 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.**

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."*

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)*

K221389

Device Name
FairFix PSP – Adjustable Button

Indications for Use *(Describe)*
Reconstructive treatment of ruptured anterior and posterior cruciate ligaments by means of autologous grafts.

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

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, Sr. Director, Quality, Regulatory, and Clinical, Medacta USA
Date Prepared: May 12, 2022
Date Revised: June 7, 2022

## II. Device

| | |
|---|---|
| Device Proprietary Name: | FairFix AM - Adjustable Button |
| | FairFix PSP - Adjustable Button |
| 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 device:

- FairFix Adjustable Button System, K203259, Medacta International SA

Additional predicate device:

- M-ARS ACL, K171640, Medacta International SA

## IV. Device Description

The subject FairFix Adjustable Button System Extension is a Medacta SportsMed devices line extension providing two new implantable fixation devices with an adjustable suture loop used during knee ligament reconstruction surgery for the fixation of the graft by means of an extra cortical suspensory fixation.

Specifically, the current submission includes:

- FairFix AM Adjustable Button, a metal button with a pre-assembled, nonabsorbable 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; and
- FairFix PSP Adjustable Button, an extra-cortical fixation device pre-assembled with a non-absorbable adjustable suture loop indicated for the extracortical fixation of the graft on the tibial side.

Both the devices are provided pre-assembled on a dedicated card, aiming to facilitate device handling and connection to the graft.

## V. Indications for Use

- FairFix AM – Adjustable Button

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

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

- FairFix PSP – Adjustable Button

Reconstructive treatment of ruptured anterior and posterior cruciate ligaments by means of autologous grafts.

## VI. Comparison of Technological Characteristics

The subject devices are substantially equivalent to the predicate (K203259 for the FairFix AM and K171640 for the FairFix PSP) with regards to the following characteristics:

- indications for use;
- buttons shapes and dimensions;
- adjustable loop dimension;
- pulling and flipping suture of the FairFix AM;
- materials;
- biocompatibility;
- device usage;
- shelf-life; and
- packaging.

The subject implants differ from the predicate devices (K203259 for the FairFix AM and K171640 for the FairFix PSP) as follows:

- adjustable loop - shape and mechanism; and
- sterilization method of the FairFix PSP Adjustable Button with respect to M-ARS ACL - Pull Suture Plate (K171640).

*Discussion*
Medacta International SA has not made any change to the indications for use, general design and shape, materials, 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 FairFix Adjustable Button System Extension implants to the identified predicate devices.

## 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*
  - FairFix Design Validation, Cadaver Lab
  - FairFix AM Adjustable Button Mechanical Behavior Validation Rationale
  - FairFix PSP Adjustable Button Mechanical Behavior Validation Rationale
  - MR safety evaluations

- *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 FairFix Adjustable Button System Extension implants are substantially equivalent to the predicate devices.