August 16, 2022

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

Re: K222169
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: July 20, 2022
Received: July 21, 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,

For,

Laura C. Rose, PhD
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)*

K222169

Device Name

Fairfix Adjustable Button System

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 Extenders are 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.

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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, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: July 20, 2022
Date Revised: August 16, 2022

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 primary predicate device:

- FairFix Adjustable Button System, K203259, Medacta International SA

IV. Device Description

The FairFix Adjustable Button Extender Round implants are a Medacta SportsMed devices line extension providing alternative implantable fixation devices to be used during knee ligament reconstruction surgery for the fixation of the graft in association with the FairFix Adjustable Buttons (cleared within K203259 and K221389) in case of large tunnel conditions (e.g. cortical blowout, revision cases, full tunnel).

The subject FairFix Adjustable Button System implants are available in three different sizes and they consist of a circular metal plate provided with a recess specifically designed to house the FairFix Adjustable Button.

V. Indications for Use

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 Extenders are 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.

VI. Comparison of Technological Characteristics

The subject devices are substantially equivalent to the predicate, FairFix Adjustable Button Extender (K203259), with regards to the following characteristics:

- indications for use;
- materials;
- biocompatibility;
- device usage;
- sterilization;
- shelf-life; and
- packaging.

The only difference between the subject implants and the predicate, FairFix Adjustable Button Extender (K203259), is related to the shape and dimensions.

Discussion
Medacta International SA has not made any change to the indications for use, material, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the predicate device.

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 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:

<u>Non-Clinical Studies</u>

- *PERFORMANCE TESTING*
  - The mechanical test related to lengthening under cyclic loading and load to failure performed on the predicate (K203259) is leveraged for the subject devices based on a worst case 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 evaluation*
- *SHELF-LIFE evaluation*

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the FairFix Adjustable Button System implants are substantially equivalent to the predicate device.