Medacta International SA
% Ms. Elizabeth Rose
Manager, Regulatory Affairs
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

October 23, 2017

Re: K171640
Trade/Device Name: M-ARS ACL: Anatomic Ribbon Surgery System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 11, 2017
Received: September 12, 2017

Dear Ms. Rose:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171640

Device Name
M-ARS ACL: Anatomic Ribbon Surgery System

Indications for Use *(Describe)*
M-ARS ACL: Anatomic Ribbon Surgery System - M-ARS ACL Tibial Pull Suture Plate (PSP):
Reconstructive treatment of ruptured anterior and posterior cruciate ligaments by means of autologous grafts.

M-ARS ACL: Anatomic Ribbon Surgery System: M-ARS ACL Extracortical Femoral Button:
Reconstructive therapy of ruptures to the anterior and posterior cruciate ligament 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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3.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: June 01, 2017
Date Revised: October 17, 2017

II. Device

Device Proprietary Name:	M-ARS ACL: Anatomic Ribbon Surgery System
Common or Usual Name:	Suture Anchor
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Primary Product Code:	MBI
Regulation Number:	21 CFR 888.3040
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- KSEA Flipptack, K982571, Karl Storz Endoscopy – America, Inc. (also referred to as Karl Storz's Flipptack)
- Endotack, K022853, Karl Storz Endoscopy – America, Inc.

The following reference devices are cited within the submission:

- M.U.S.T. Extension, K132878, Medacta International SA
- M.U.S.T. Pedicle Screw System, K141988, Medacta International SA
- M.U.S.T. Pedicle Screw System, K153664, Medacta International SA
- M.U.S.T. Pedicle Screw System, K162061, Medacta International SA

IV. Device Description

The purpose of this submission is to gain clearance for the M-ARS ACL: Anatomic Ribbon Surgery System. The M-ARS ACL: Anatomic Ribbon Surgery System components are implantable devices used for the reconstructive treatment of ligament ruptures as well as the fixation of an implanted Anterior Cruciate Ligament graft by means of suspensory extracortical fixation.

The M-ARS ACL: Anatomic Ribbon Surgery System Extracortical Fixation Button component is an implantable extracortical suspension device used to secure the graft fixation on the femoral side during ACL reconstruction surgery. The M-ARS ACL: Anatomic Ribbon Surgery System Tibial Pull Suture Plate (PSP) component is an implantable extracortical suspension device used to secure the graft fixation on the tibial side during ACL reconstruction surgery.

The M-ARS ACL: Anatomic Ribbon Surgery System Extracortical Fixation Button and Tibial Pull Suture Plate are manufactured with Titanium-6 Aluminum-4 Vanadium Extra Low Interstitial (Ti-6Al-4V ELI).

V. Indications for Use

M-ARS ACL Extracortical Femoral Button

Reconstructive therapy of ruptures to the anterior and posterior cruciate ligament by means of autologous grafts.

M-ARS ACL Tibial Pull Suture Plate (PSP)

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

VI. Comparison of Technological Characteristics

The M-ARS ACL: Anatomic Ribbon Surgery System and the predicate devices share the following characteristics:

- Material;
- Sterile;
- device usage; and
- Extracortical Fixation Button;
    - length;
    - width;
    - thickness;
    - number and purpose of holes; and
    - critical section thickness.

The M-ARS ACL: Anatomic Ribbon Surgery System is technologically different from the predicate devices as follows:

- Tibial Pull Suture Plate, and
    - length;
    - width;
    - thickness;
    - number and purpose of holes;
    - geometry; and
    - critical section dimensions
- Extracortical Fixation Button
    - critical section width.

The M-ARS ACL: Anatomic Ribbon Surgery System Extracortical Fixation Button and Tibial Pull Suture Plate are manufactured with Titanium-6 Aluminum-4 Vanadium Extra Low Interstitial Alloy according to ISO 5832-3:1996 Implants For Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy and ASTM F136-13 Standard Specification For Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy For Surgical Implant Applications.

This material, used with Karl Storz's Flipptack (K982571) and Karl Storz's Endotack (K022853), has an extensive biocompatibility history and has been previously reviewed by FDA.

Due to the extensive history of use in currently marketed medical devices, additional biocompatibility testing was deemed unnecessary for the M-ARS ACL: Anatomic Ribbon Surgery System components. In addition, manufacturing processes for the subject devices are identical or similar to the reference devices the M.U.S.T. Pedicle Screw Systems (K162061, K153664, K141988, and K132878).

The tables below compare key technological features between the subject and predicate devices.

Technological comparison

Parameters	**M-ARS ACL: Anatomic Ribbon Surgery System Extracortical Fixation Button (Subject Device)**	**Karl Storz's Flipptack K982571 (Predicate Device)**
Material	Titanium Alloy (ELI)	Titanium Alloy
Length	12.3 mm	12.3 mm
Width	4 mm	4 mm
Thickness	1.5 mm	1.5 mm
Holes	2 for suture loop for graft fixation 1 lateral hole for suture used to flip implant 1 lateral hole for suture used to pull construct	2 for suture loop for graft fixation 1 lateral hole for suture used to flip implant 1 lateral hole for suture used to pull construct
Critical Section Dimensions	Thickness: 1.5 mm Width: 1.7 mm	Thickness: 1.5 mm Width: 1.3 mm
Device Usage	Single Use	Single Use
Biocompatibility	Implant with permanent > 30 day	Implant with permanent > 30 day
Sterilization	Sterile	Sterile

Parameters	M-ARS ACL: Anatomic Ribbon Surgery System Tibial Pull Suture Plate (Subject Device)	Karl Storz's Endotack K022853 (Predicate Device)
Material	Titanium Alloy (ELI)	Titanium Alloy
Length	20 mm	16 mm
Width	13 mm	10 mm
Thickness	1.2 mm	2 mm
Holes	2 central holes for adjustable suture loop 2 lateral holes for additional sutures, graft fixation and tension	2 holes used for graft fixation and tension
Geometry	C-Shape	Round Shape
Critical Section Dimensions	Thickness: 2 mm Width: 2.84 mm	Thickness: 3 mm Width: 2 mm
Device Usage	Single Use	Single Use
Biocompatibility	Implant with permanent > 30 day	Implant with permanent > 30 day
Sterilization	Sterile	Sterile

Discussion
As seen above, the technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness. The M-ARS ACL: Anatomic Ribbon Surgery System is the same or similar to the predicate devices in terms of materials of construction, device usage, and sterility. Although there are some differences in the design attributes of the Tibial Pull Suture Plate, the intended use and functionality of the component are the same. Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the M-ARS ACL: Anatomic Ribbon Surgery System to the identified predicate devices.

VII. Performance Data

Risks were identified based on the proposed design and testing was conducted to mitigate those risks. Based on the risk analysis, the following studies were performed in support of a substantial equivalence determination:

Non-Clinical Studies

- design comparison: geometrical and comparative analysis between the M-ARS ACL: Anatomic Ribbon Surgery System and the predicate devices to show mechanical equivalence;
- cadaver workshop: surgeon evaluations to verify the design features and surgical technique; and
- substantial equivalence evaluation: a comparative analysis between the M-ARS ACL: Anatomic Ribbon Surgery System Tibial Pull Suture Plate and the predicate device.

Pyrogenicity

- Medacta uses both the Bacterial Endotoxin Test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and the Pyrogen Test according to USP chapter <151> for pyrogenicity determination.
- Medacta does not intend to label the subject devices as non-pyrogenic or pyrogen free.

Clinical Studies

- No clinical studies were conducted

VIII. Conclusion

Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics as well as performance evaluations. The M-ARS ACL: Anatomic Ribbon Surgery System is as safe and effective as the predicate devices, Karl Storz's Flipptack (K982571) and Karl Storz's Endotack (K022853).