May 3, 2024

Medacta International S.A.
℅ Christopher Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta International SA
6386 Global Drive, Suite 101
Memphis, Tennessee 38141

Re: K232733
Trade/Device Name: Mbrace Cable
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: April 4, 2024
Received: April 4, 2024

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 (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.

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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.

Submission Number *(if known)*

K232733

Device Name

Mbrace Cable

Indications for Use *(Describe)*

The Mbrace Cable is designed as a cerclage system for long bones and to reattach the greater trochanter in case of fractures or osteotomies. The device is intended for long-term implantation inside the human body for single use only. The Mbrace Cable is not intended for use as a suture cable in soft tissue approximation and/or ligation.

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, Sr. Director, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: September 7, 2023
Date Revised: April 26, 2024

II. Device

Device Proprietary Name:	Mbrace Cable
Common or Usual Name:	Cerclage, Fixation
Classification Name:	Bone fixation cerclage
Primary Product Code	JDQ
Regulation Number:	21 CFR 888.3010
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- Titanium alloy Songer cable system, K920201, SOFAMOR DANEK MFG., Inc.

Additional Predicate device:

- HS Fiber, K100006, Riverpoint Medical

IV. Device Description

The Mbrace cable is an implantable flexible braided cable made of UHMWPE and designed as a cerclage bone system.

The Mbrace cable is provided individually packed, sterile and single-use.

V. Indications for Use

The Mbrace Cable is designed as a cerclage system for long bones and to reattach the greater trochanter in case of fractures or osteotomies. The device is intended for long-term implantation inside the human body for single use only. The Mbrace Cable is not intended for use as a suture cable in soft tissue approximation and/or ligation.

VI. Comparison of Technological Characteristics

The subject Mbrace cable and the predicate Titanium alloy Songer cable system (K920201) are substantially equivalent with respect to the following characteristics:

- General design;
- Biocompatibility;
- Device usage; and
- Packaging.

The subject Mbrace cable is technologically different from the predicate Titanium alloy Songer cable system (K920201) as follows:

- Diameter and fixation;
- Material; and
- Sterilization.

Discussion

The different diameter and fixation method of the subject Mbrace cable with respect to the predicate Titanium alloy Songer cable system (K920201), as well as the different material, do not raise any new issue related to safety and effectiveness as demonstrated by the results of the mechanical test. The different sterilization method between the subject and the predicate devices is due to the different materials, but it has not any impact on device's safety and effectiveness since the ETO sterilization method of the subject device is fully validated. The subject Mbrace cable, in its final finished form, is identical to the additional predicate (HS Fiber, K100006) with regards to materials of construction, processing, geometry, sterilization method and shelf-life, thus the biocompatibility of the subject and additional predicate device can be considered the same even if the subject device is intended to be used in long bones and greater trochanter, while the additional predicate is intended for use in soft tissues.

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

VII. Performance Data

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

Non-Clinical Studies

- *DESIGN VALIDATION*
  - Mbrace cable design validation - sawbone workshop to evaluate device's suitability.

- *PERFORMANCE TESTING*
  - Quasi-static load to failure properties of Mbrace cable comparing subject and predicate devices ultimate strengths and evaluating the related maximum displacement.
  - Dynamic resistance properties of Mbrace cable to assess the endurance properties of the subject Mbrace Cable and demonstrate that the subject device is able to pass 1 million load cycles without any signs of failure, thus ensuring its safe and effective clinical use.

- *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 device is substantially equivalent to the predicate devices.