September 12, 2025

Medacta International S.A.
% Christopher Lussier
Senior Director, Quality and Regulatory
Medacta USA
6386 Global Drive
Suite 101
Memphis, Tennessee 38141

Re: K252225
Trade/Device Name: PowerKnot High Strength Sutures
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: July 16, 2025
Received: July 16, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control 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)*
K252225

Device Name
PowerKnot High Strength Sutures

Indications for Use *(Describe)*
PowerKnot High Strength Suture is indicated for soft tissue approximation and/or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.

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."

510(k) Summary

K252225

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, Senior Director, Quality and Regulatory, Medacta USA
Date Prepared: July 16, 2025
Date Revised: September 11, 2025

II. Device

Device Proprietary Name:	PowerKnot High Strength Sutures
Common or Usual Name:	Suture, Nonabsorbable, Synthetic, Polyethylene
Classification Name:	Nonabsorbable poly(ethylene terephthalate) surgical suture
Primary Product Code	GAT
Regulation Number:	21 CFR 878.5000
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- Arthrex FiberWire, K071622, Arthrex Inc.

Additionally, the following reference devices are used:

- Polyester Non-absorbable Surgical Suture, Polyblend Non-absorbable Surgical Suture, Silk Non-absorbable Surgical Suture, Polypropylene Surgical Suture, Nylon Non-absorbable Surgical Suture, K100006, Riverpoint Medical
- HS Fiber Suture, K190817, Riverpoint Medical

IV. Device Description

PowerKnot High Strength Sutures are non-absorbable braided suture constructs made of 100% UHMWPE. They consist of a multifilament core yarn with a braided sheath and they are available in various color options, with or without a stainless steel needle. The PowerKnot High Strength Sutures portfolio also includes a Running Direction Indicator (RDI) surface of the suture, aiding the surgeon when applying the suture.

PowerKnot High Strength Sutures are designed to support soft tissue approximation and/or ligation. These sutures may be incorporated as components into surgeries where constructs, including those with allograft or autograft tissues, are used for repair.

V. Indications for Use

PowerKnot High Strength Suture is indicated for soft tissue approximation and/or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.

VI. Comparison of Technological Characteristics

The subject and predicate device (K071622) are substantially equivalent in terms of intended use and technological characteristics. The table below provides a comparison of the intended use and key features:

Parameters	**PowerKnot High Strength Sutures K252225 (Subject Device)**	**Arthrex FiberWire® [K071622] (Predicate Device)**	**Comparison**
Indications for Use	The Medacta PowerKnot Suture is intended for use in soft tissue approximation and/or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.	The Arthrex FiberWire® Suture is intended for use in soft tissue approximation and or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.	Same
Shape and Dimension (Suture Ø and length)	The Medacta PowerKnot Suture meets or exceeds U.S. and European Pharmacopeia standards for non-absorbable surgical sutures (except for diameter requirements). • Range of Ø according to USP #2: 0.50 – 0.599 mm • Effective Ø: 0.65 – 0.68 mm	The Arthrex FiberWire® sutures meet or exceed U.S. and European Pharmacopeia standards for non-absorbable surgical sutures (except for diameter requirements). • Range of Ø according to USP #2: 0.50 – 0.599 mm • Effective Ø: 0.67 mm	The suture diameter and the overall length are comparable to the one of the predicate device and can therefore be considered substantially equivalent. The slight difference in suture diameter has no negative impact on the subject device's safety and effectiveness as demonstrated by mechanical testing. The

	Overall length of the Medacta PowerKnot Sutures: Length: 990 mm / 38.97”	Overall length of the Arthrex FiberWire®: Length: 965 mm / 38”	slight difference in suture length also does not introduce any risks in terms of safety and effectiveness and is aimed at improving usability.
Shape and Dimension (Needle)	Some Medacta PowerKnot Suture configurations include a needle with the following design parameters: • Needle Ø: 1.28 • Needle length: 26 mm • Needle shape: ½ circle • Needle tip design: taper point • Needle to suture attachment: crimp (joining)	The Arthrex FiberWire® includes a needle with the following design parameters: • Needle Ø: 1.32 • Needle length: 26.5 mm • Needle shape: ½ circle • Needle tip design: taper point • Needle to suture attachment: crimp (joining)	The slight differences do not have any negative impact on the subject devices safety and effectiveness as demonstrated by the bench testing. The Suture/Needle Attachment Strength has been successfully tested under quasi-static loading and wetlab tests demonstrated the safety and performance of the device and that no new clinical risks are introduced.
Configurations	The Medacta PowerKnot Sutures #2 will be available in various colour options with and w/o needle: • White/blue w/ needle • White/blue • White/black w/ needle • White/black • Black/blue/white w/ needle RDI configuration • Black/blue/white RDI configuration	The Arthrex FiberWire® USP #2 is available in the following configurations: • Blue w/needle • Blue • White/black w/needle • White/black • White w/ needle • White • Blue/black	The colour and needle options are substantially equivalent. The presence of the RDI feature, supporting the surgeon in visually identifying the running direction under an arthroscopic view of the subject devices does not introduce new risks and does not impact safety and effectiveness as demonstrated during cadaver labs. Moreover, the mechanical properties of the Medacta PowerKnot Suture device have been successfully tested under cyclic and quasi-static loading and wetlab tests demonstrated the safety and performance of the

			device and that no new clinical risks are introduced.
Braiding Design	Medacta PowerKnot Suture consists of a tubular braiding with yarn core and is braided on a 16-bobbin maypole braiding machine in a normal occupation resulting in a "2 over / 2 under" braiding pattern. The braiding angle is approximately 25°	The Arthrex FiberWire® consists of a tubular braiding with yarn core and is braided on a 16-bobbin braiding machine in a normal occupation resulting in a "2 over / 2 under" braiding pattern. The braiding angle is approximately 25°	Same
Material	The Medacta PowerKnot Suture consists of the following materials: **Suture core:** • UHMWPE **Suture sheath:** • UHMWPE **Suture coating:** • n/a **Suture Dyes:** • Blue: Chromium-cobalt-aluminum oxide • Black: D&C Black No.4 (high purity carbon) **Needle:** • Stainless Steel acc. to ASTM F899	The Arthrex FiberWire® predicate device consists of the following materials: **Suture core:** • UHMWPE **Suture sheath:** • UHMWPE & Polyester **Suture coating:** • Silicone elastomer **Suture Dyes:** • D&C Blue No. 6, • Logwood Black **Needle:** • Stainless Steel	The material used for the suture core and needle is equivalent. The sheath of the Medacta PowerKnot Suture is made 100% of UHMWPE while the predicate device's is made of UHMWPE and polyester. No coating is applied to the Medacta PowerKnot Suture, but this difference does not raise any new issue related to safety and effectiveness since the mechanical properties of the subject devices have been validated through performance testing. Partially different sutures dyes comply with 21 CFR § 73.1015 and 21 CFR § 74.3054, they do not raise any new issues related to safety and effectiveness and are the same as the ones used in the reference devices.
Biocompatibility	Implant with permanent contact (>30 days)	Implant with permanent contact (>30 days)	Same
Device usage	Single use	Single use	Same
Packaging	Individual packaging	Individual packaging	Same

Shelf life	5 years	Unknown	No impact on safety and effectiveness since the subject devices have been tested for the defined shelf-life.
Sterilization	EtO sterilization	EtO sterilization	Same

Discussion
The slight difference in suture diameter and length and in the needle shape and dimension between the subject and the predicate device has no negative impact on the subject device's safety and effectiveness, as demonstrated through performance testing.

The presence of the RDI feature of the subject devices in addition to the configurations already available in the predicate device does not introduce new risks and does not impact safety and effectiveness as demonstrated during cadaver labs and mechanical evaluations.

The slight differences in the suture sheath materials between the subject and the predicate device and the absence of a suture coating in the subject device do not raise any new issue related to safety and effectiveness since the mechanical properties of the subject devices have validated through tests.

The dye utilized in the subject device suture consists of Chromium-cobalt-aluminum oxide (blue) and D&C Black No.4 (black) and differ from the ones used in the predicate device. However, the differences in the suture dyes used in the subject and the predicate device do not raise any new issues related to safety and effectiveness since the colorants meet the requirements of 21 CFR 70.5(c) and are shared with reference devices.

The comparison of technological characteristics and performance data provided within the submission supports the substantial equivalence of the subject devices with 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 VALDATION*
  - PowerKnot High Strength Suture Design Validation

- *PERFORMANCE TESTING*
  - Testing of quasi-static load-to-failure properties of surgical suture:
    - Sutures/Needle Attachment Strength Test according to USP <871>
    - Knot-Pull Tensile Strength Test according to USP <881>

- Quasi-static straight-pull tensile strength test on single strands (without knot) according to ASTM D2256/D2256M – 10
- Testing of cyclic and load-to-failure properties of knotted suture loops, according to ASTM D2256/D2256M – 10
- MR Safety Evaluation

- *PYROGENICITY*
  - Bacterial endotoxin test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85> and USP <161>)
  - 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 devices are substantially equivalent to the predicate devices.