March 4, 2026

Escala Medical , Ltd.
% Lina Kontos
Regulatory Counsel
Hogan Lovells US LLP
555 Thirteenth St. NW
Washington, District of Columbia 20004

Re: K260380
Trade/Device Name: Mendit
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: PBQ
Dated: February 5, 2026
Received: February 5, 2026

Dear Lina Kontos:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

JASON ROBERTS -S

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260380

Please provide the device trade name(s).

Mendit

Please provide your Indications for Use below.

The Mendit device is intended for attaching sutures to ligaments of the pelvic floor.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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510(k) Summary

Escala Mendit

Date Prepared: February 23, 2026

Submitter Information:
Escala Medical Ltd.
17 Tchelet Street, Misgav Business Park, 2017400, Israel
Phone: +972-72-2607000
Contact: Monique Robas, QA/RA Director
Email: monique@escalamedical.com

Device Information:
Trade Name: Mendit
Common Name: Fixation Device for Pelvic Floor
Classification Name: Fixation, Permanent (Non-Absorbable) or Absorbable, For Pelvic Use
Regulation Number: 21 CFR 884.4530
Product Code: PBQ
Regulatory Class: II

Predicate Devices:
Apyx (K230730) – Escala Medical Ltd.

Device Description:
The Mendit device is indicated for anchoring sutures to ligaments of the pelvic floor. The device consists of an implantable nitinol anchor with 4 prongs configured with either non-absorbable or resorbable suture.

The anchor-suture assembly is contained within a cartridge, wherein the anchor/suture assembly is deployed to the target site from the cartridge with an applicator.
An optional retriever may be used to remove the anchor in the event of sub-optimal placement of an anchor during the index procedure. An optional suture passer accessory may be used to facilitate threading of an extension suture to enable use of the retriever after the sutures have been tied and cut.

The device also includes an optional securement element which may be used as a suture retention device to distribute suture tension over a larger tissue area and aid in wound healing.

The optional Securement Element has undergone a geometric design modification to facilitate controlled retrieval of the Securement Element if needed. The material (316L stainless steel), sterilization method (ethylene oxide), patient contact characteristics remain unchanged.

The sterile barrier system was updated from a tray-based configuration to a preformed PETG blister sealed with Tyvek and aluminum lids. The sterilization method (ethylene oxide), sterility assurance level, and shelf life remain unchanged.

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Intended Use:
The Mendit device is intended for attaching sutures to ligaments of the pelvic floor.

Comparison of Technological Characteristics
Both the subject and predicate devices are indicated for attaching sutures to ligaments of the pelvic floor. The technological characteristics of the Mendit are identical to that of the previously cleared Apyx device, i.e., the predicate device. Both devices include a nitinol anchor, which is provided with the attached suture and delivered using an applicator. The devices are supplied sterile by ethylene oxide and are pre-loaded with the anchor-suture assembly.

Predicate Device – Apyx (K230730)	Subject Device – Mendit
Anchor design: 4 prongs	Anchor design: 4 prongs
Anchor materials: Nitinol	Anchor materials: Nitinol
Suture: Polypropylene or Polydioxanone	Suture: Polypropylene, Polydioxanone, or expanded polytetrafluoroethylene (ePTFE)
Applicator: Yes – shaft (applicator cartridge) and handle	Applicator: Yes – shaft (applicator cartridge) and handle
Securement element: Yes (optional)	Securement element: Yes (optional)
Retriever for device removal: Yes (optional)	Retriever for device removal: Yes (optional)

The Mendit system includes an optional suture passer accessory and an additional permanent suture option (expanded polytetrafluoroethylene, ePTFE) beyond the cleared Apyx device. These additions do not alter the intended use, indications for use, or fundamental technology of the device and therefore do not affect the substantial equivalence determination.

Performance Data:
The company applied their design control procedures including risk analysis to evaluate the modifications to the device which are the subject of this 510(k). The modifications in the subject device did not raise different questions of safety and effectiveness.

Verification and validation testing was conducted under design controls to evaluate the modified Securement Element geometry and confirm that the design modification does not adversely affect safety or performance.

Testing included:

- Mechanical performance testing, including suture retention and tensile evaluation
- Functional securement stability testing
- Controlled release and removal testing to confirm no damage to suture integrity
- Dimensional and visual inspection
- Simulated-use usability evaluation with intended users

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All predefined acceptance criteria were met. No new materials were introduced, and no new risks or different questions of safety or effectiveness were identified.

Conclusion:
The subject Mendit device is substantially equivalent to the predicate Escala Apyx device (K230730), as it has the same intended use, indications for use, and substantially similar technological characteristics, and principles of operation.

Performance data demonstrates that the Mendit device meets its specifications and has comparable safety and performance to the predicate device, supporting a determination of substantial equivalence.