July 25, 2023

Escala Medical
% Lina R. Kontos
Partner
Hogan Lovells
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K230730
Trade/Device Name: Apyx
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: PBQ
Dated: June 26, 2023
Received: June 27, 2023

Dear Lina R. 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 (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,

Reginald K. Avery -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

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)*
K230730

Device Name
Apyx

Indications for Use *(Describe)*
The Apyx is intended for attaching sutures to ligaments of the pelvic floor.

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

Escala Apyx

Submitter

Escala Medical LTD.
17 Tchelet St. Misgav Business Park
2017400 Israel

Phone: +972.72.260.7000

Contact Person: Edit Goldberg, CEO

Date Prepared: July 13, 2023

Name of Device: Apyx

Common or Usual Name: Fixation device for the pelvic floor

Classification Number: 884.4530

Classification Name: Obstetric-gynecologic specialized manual instrument

Regulatory Class: II

Product Code: PBQ

Product Code Name: Fixation, Non-Absorbable or Absorbable, For Pelvic Use

Predicate Device: Escala Medical Ltd., Apyx, K213783

The predicate device has not been subject to a design-related recall.

Device Description

The Apyx 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 use retriever may be used to remove the anchor in the event of sub-optimal placement of an Anchor during the index procedure. The Apyx 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 Apyx device is a single use device which is supplied sterile.

Intended Use / Indications for Use

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

Summary 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 Apyx 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. The difference between the subject device and the predicate device is the inclusion of the securement element. The inclusion of this optional component is evaluated with similar testing as the predicate device and accordingly does not raise different questions of safety or effectiveness.

	Subject Device Apyx (K230730)	**Predicate Device Apyx (K213783)**
Anchor design	4 prongs	4 prongs
Anchor materials	Nitinol and optional stainless steel securement element	Nitinol
Suture	Polypropylene or Polydioxanone	Polypropylene or Polydioxanone
Applicator	Yes – shaft (applicator cartridge) and handle	Yes – shaft (applicator cartridge) and handle
Securement element	Yes (optional – per physician discretion)	No
Retriever for device removal	Yes (optional – per physician discretion)	Yes (optional – per physician discretion)

Performance Data

Testing to support the modified device with the optional securement element included:

- Biocompatibility testing in accordance with the 2020 FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* and ISO 10993 consistent with intended duration of contact:
  - Cytotoxicity
  - Sensitization
  - Pyrogenicity
  - Irritation
  - Intracutaneous reactivity
- Chemical Characterization and toxicological risk assessment in accordance with ISO 10993-18 to address biocompatibility endpoints of:
  - Genotoxicity
  - Acute systemic toxicity
  - Chronic systemic toxicity
  - Carcinogenicity
  - Developmental/reproductive toxicity
- Corrosion resistance
- Packaging validation
- Shelf-life validation
- Securement element pull out

Cadaver Testing

Cadaver model testing was conducted to demonstrate that the Apyx instructions for use and critical operation tasks can be performed. Following the system instructions, users delivered the anchor through a transvaginal approach and then retrieved the applied anchors from their implantation site. No complications or unanticipated risks were observed throughout all anchor delivery and retrieval procedures. All anchors were accurately delivered into the target ligament and no damage to any of the surrounding structures was observed. All anchors were secured using the securement element and were noted to be properly fixed at the desired position with ease. It was therefore concluded that the Apyx device meets the design requirements and is suitable for its intended use.

Conclusions

The Apyx has the same intended use and identical indications, and substantially similar technological characteristics, and principles of operation as its predicate device. The sole difference between the Apyx and its predicate device (optional securement element) does not raise any different questions of safety or effectiveness. Performance data demonstrates that the Apyx with the optional securement element is as safe and effective as the predicate device to support a substantial equivalence determination.