April 24, 2025

A.M.I. Agency for Medical Innovations GmbH
Anke Ristow
Regulatory Affairs Specialist
Im Letten 1
Feldkirch, 6800
AUSTRIA

Re: K243821
Trade/Device Name: i-Cut
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic Laparoscope and accessories
Regulatory Class: II
Product Code: HET
Dated: December 10, 2024
Received: March 27, 2025

Dear Anke Ristow:

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,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243821

Device Name
i-Cut

Indications for Use *(Describe)*
The i-Cut system is indicated for morcellating and extracting tissue in laparoscopic, gynecologic surgical procedures.

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.

510(k) Summary
K243821

SUBMITTER INFORMATION

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Official Contact: Tanja Kinzl, Regulatory Affairs Specialist, PRRC
DATE PREPARED: April 24, 2025

DEVICE INFORMATION

Proprietary Name/Trade Name:	i-Cut
Common Name:	Power Morcellator
Regulation Name:	Gynecologic Laparoscope And Accessories
Regulation Number:	21 CFR § 884.1720
Regulatory Class:	Class II
Product Code:	HET
Review Panel:	Obstetrics/Gynecology

PREDICATE DEVICE IDENTIFICATION

510(k) Number	Predicate Device Name / Manufacturer	Primary Predicate
K101458	LiNA eXcise / LiNA Medical ApS	yes

A search for recalls was performed in the FDA recall database (Medical Device Recalls, advanced search). For the predicate device, no design-related or safety recall was identified.

DEVICE DESCRIPTION

The i-Cut is a single use laparoscopic power morcellator. It is provided sterile.
The i-Cut consists of a rotating cutting tube with a trocar that provides protection against the cutting blade when locked in the “CLOSED” position. The device comes with an obturator for placement into the patient’s body and a locking clip that keeps the trocar in the “closed” position during insertion. The activation button must be pressed to cut tissue.
The lumen of the device is designed for use with a standard grasper or Tenaculum forceps with a diameter between 10 to 14 mm. The i-Cut is designed to be used with surgical instruments of diameters between 10 to 14 mm. The lumen is fitted with a silicone valve to prevent gas loss during use of the device.
The i-Cut is electrically operated by a DC Motor which is powered by a 24V AC/DC mains adapter. The non-sterile i-Cut Power Supply with power cord is supplied separately to power the device.

INDICATIONS FOR USE

The i-Cut system is indicated for morcellating and extracting tissue in laparoscopic, gynecologic surgical procedures.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Device & Predicate Device(s):	K243821	K101458	Comparison
Device Name	**i-Cut**	LiNA Xcise	
Design features	Hand controlled mains powered morcellator with cutting tube. 2 Trocar positions: closed, cut handle button control. Build in gearing and motor	Hand controlled battery powered morcellator with cutting tube. 3 Trocar positions: Safe, Cut1, Cut2 handle button control. Build in battery package, gearing and motor	Different
Inner diameter	Ø14.95mm	Ø14.6mm	Different
Outer diameter	Ø19mm	Ø17mm	Different
Shaft length	100mm	155mm	Different
Speed	1100rpm	650rpm	Different
Cutting rate	>21.5g/min	---	No data available for the predicate device
Power source	24V DC (mains)	9V Battery	Different
Use life	Motor/gear lifetime approx. 60min (continuous operation)	Battery lifetime no load: 150 min	Different

Tool compatibility	Laparoscopic tools 10-14mm diameter	Laparoscopic tools 10-12mm diameter (5mm, with reducer cap)	Different

The differences in technological characteristics do not raise different questions of safety and effectiveness.

SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following non-clinical testing has been performed on the i-Cut in order to demonstrate equivalence to the predicate device:

- Sterilization validation per ANSI/AAMI/ISO 11135:2014
- Shelf-life validation per ASTM F1980-21:2023 (package integrity and device performance support 5 year shelf life)
- Simulated shipping per ASTM D4332-22:2022, ASTM D4169-22:2022, ASTM F1886/F1886-16:2017
- ASTM F88/F88M-21:2022, ASTM F1929-15:2015, and ASTM F2096-11:2013
- Biocompatibility testing:
    - Cytotoxicity per ISO 10993-5:2009
    - Sensitization per ISO 10993-10:2021
    - Intracutaneous irritation per ISO 10993-23:2021
    - Acute systemic toxicity per ISO 10993-11:2017
- Electrical Safety and electromagnetic compatibility (EMC)
    - Electrical safety per IEC 60601-1:2020
    - EMC per IEC 60601-1-2:2020

- Performance testing (bench): The subject device passed the following tests:
    - Load test: Evaluate if the morcellator can withstand expected load without failure
    - Gas tightness test: Determine if pneumoperitoneum is maintained in clinical use conditions
    - Obturator abrasion test: Demonstrate that no abrasion of obturator occurs during insertion and removal from the device (no visible wear marks)
    - Liquid tightness test: Evaluate if liquid tightness requirements were met after load test
    - Grip of the housing surface test: Assess the surgeon’s ability to properly grip the device during use
    - Surface reflection test: Determine whether the cutting blade caused reflections under bright light that impeded visibility during morcellation
    - Trocar sleeve – pull-off force test: Evaluate pull-off force of the trocar sleeve to demonstrate the connection of trocar sleeve and device is suitable for the application
    - Functional test: Simulated use testing to evaluate if the device can morcellate and extract tissue in a model specimen within a containment system under expected use conditions.
    - Insertion test: Measure of the force needed to expose the cutting blade when the device is in the “Closed” position to prevent accidental exposure of the cutting surface
    - Usability testing: Simulated use testing with surgeons of different experience with laparoscopic morcellators to demonstrate compatibility of the morcellator with the

labeled containment system. The test evaluated device use related to potential containment system failures as well as assessment of containment system integrity.

CONCLUSION

The performance testing summarized above support that the subject device is as safe and effective as the predicate device.

The similar intended use, technological characteristics, and performance characteristics for the proposed i-Cut device are substantially equivalent to the predicate device.