October 16, 2024

LI Medical Corporation Ltd.
Chen Jago
CEO
2F., No. 43, Zhongxing Rd.
Xizhi District, New Taipei City 221012
TAIWAN

Re: K240364
Trade/Device Name: "RELIEEV" Uterine Manipulator Injector
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: September 14, 2024
Received: September 16, 2024

Dear Chen Jago:

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,

Michael T. Bailey -S

for
Monica D. Garcia, 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)*
K240364

Device Name
"RELIEEV" Uterine Manipulator Injector

Indications for Use *(Describe)*
Use of the RELIEEV Uterine Manipulator Injector is indicated in Diagnostic Laparoscopy, Minilaparotomy, Fertility Exams, and Salpingoplasty procedures where manipulation of the uterus is required.

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 – K240364

"RELIEEV" Uterine Manipulator Injector

I. Submitter Information

Company Name:	LI Medical Corporation LTD.
Company Address:	2F., No. 43, Zhongxing Rd., Xizhi Dist., New Taipei City 221012, Taiwan
Telephone:	+886-2-86461999
Contact Person:	Jago Chen, CEO
Email:	jago.chen@li-med.com.tw
Date Prepared:	October 10, 2024

II. Device Information:

Trade Name:	"RELIEEV" Uterine Manipulator Injector
Common Name:	Uterine Manipulator Injector
Regulation Name:	Obstetric-gynecologic specialized manual instrument
Regulation Number:	884.4530
Regulatory Class:	II
Product Code:	LKF (Cannula, Manipulator/Injector, Uterine)

III. Predicate Device Information:

Panpac Uterine Manipulator Injector, Model Umi 4.5 (K092980), manufactured by Panpac Medical Corporation. The predicate device has not been subject to a design-related recall

IV. Device Description:

The "RELIEEV" Uterine Manipulator Injector is intended to be used during medical procedures where manipulation of the uterus or injection of fluids into the uterine lumen are needed. This device is a sterile, single use product consisting of a plastic (PVC) insertion tube that includes two lumens, one for inflation of a 10 mL intrauterine balloon (cuff) at the distal end of the insertion tube via the inflation valve using the provided 10 mL syringe and the other for injection of fluid through a distal end-port using a user-provided syringe via the Leur fitting. The device also includes a movable/removable rigid handle that allows alteration of the device insertion depth and includes a cervical stop, laser etched depth markings to aid in setting the insertion depth, and a pilot balloon to assess maintenance of cuff inflation. The device is curved to facilitate forward uterine manipulation. The device has an overall length of 36 cm and an outer diameter of the catheter component of 5.0 mm. When inflated with 10 mL of air, the balloon has a diameter of 23.0-24.9 mm.

V. Indications for Use:

Use of the "RELIEEV" Uterine Manipulator Injector is indicated in Diagnostic Laparoscopy, Minilaparotomy, Fertility Exams, and Salpingoplasty procedures where manipulation of the uterus is required.

VI. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Device

A comparison of the intended use and technological characteristics of the subject and predicate device are included in the table below.

Attribute	**Subject** **RELIEEV" Uterine Manipulator Injector**	**Predicate** **Panpac Uterine Manipulator Injector, Model Umi 4.5 (K092980)**	**Comparison**
Model	CUMI 5.0	UMI 4.5K	NA
Indications for Use	Use of the "RELIEEV" Uterine Manipulator Injector is indicated in Diagnostic Laparoscopy, Minilaparotomy, Fertility Exams, and Salpingoplasty procedures where manipulation of the uterus is required.	This Uterine Manipulator Injector (Model UMI-4.5) is indicated for use in Diagnostic Laparotorny, Minilaparotonny, Fertility Examinations, and Salpingoplastic procedures where manipulation of the uterus is required. This product also facilitates the sealing of cervical os while providing a fluid injection port.	The Indications for Use statements of the subject and predicate devices are not identical. However, the intended uses are the same (i.e., for use in medical procedures where manipulation of the uterus is needed and for delivering fluid to the uterine lumen).
Prescription Medical Device	Yes	Yes	**Same**
Single Patient Use	Yes	Yes	**Same**
Sterile Device	Yes; EO sterilization	Yes; EO sterilization	**Same**
Shelf life	3 years	3 years	**Same**
Not Made With Natural Rubber Latex	Yes	Yes	**Same**
Device Lumens	2 (1 inflation channel and 1 media channel)	2 (1 inflation channel and 1 media channel)	**Same**
Shape	The shape of handle and rigid tube are curved. The handle can be adjustable for physician use.	The shape of handle and rigid tube are curved. The handle can be adjustable for physician use.	**Same**
Insertion Depth Indicator	Laser engraving	Not publicly available	**Different:** Differences in insertion depth markers do not raise different questions of safety and effectiveness (S&E).
Pilot Balloon	Yes	Not publicly available	**Different:** Differences in the inclusion of a pilot ballon to assess cuff inflation maintenance does not raise different questions of S&E.

Balloon Inflation Volume	10cc	Not publicly available	**Different:** Differences in balloon inflation volume do not raise different questions of S&E.
Materials	PVC - Rigid Tube, Balloon (Cuff), HUB-3 Way, HUB-2 Way, Pilot Balloon, Inflation Valve, Leur Lock POM and Stainless Steel – Handle TPU – Cuff Inflation Line PP – 10 mL syringe UV Acrylic Adhesive	Not publicly available	**Different:** Differences in device materials do not raise different questions of S&E.
Dimensions	Total Length - 360.0 mm Curved Tube Length: 335.0 mm Curved Tube Diameter: 5 mm Balloon Length: 33.5 mm Balloon (Cuff) Outer Diameter 10 mL – 23.0-24.9 mm Handle Length – 220.0 mm	Not publicly available	**Different:** Differences in device dimensions do not raise different questions of S&E.

As shown in the table above, there are differences in the indications for use statements that do not represent a new intended use. In addition, there are technological differences between the subject and predicate device (e.g., device materials, dimensions, depth markers, etc.). However, the technological differences noted in the table do not raise different questions of safety and effectiveness.

VII. Performance Data

The following studies have been performed to support of the substantial equivalence to the predicate device:

- Sterilization validation testing:
  - ISO 11135-1:2014
  - ISO 10993-7: 2008

- Package integrity testing:
  - Visual inspection per ASTM F1886/F1886M-16
  - Seal Strength testing per ASTM F88/ F88M-23
  - Dye Penetration test per ASTM F1929-15

- Transportation Simulation testing per ASTM D4169-23

- Biocompatibility studies conducted in accordance with the 2023 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." Testing included the following assessments:

  - Cytotoxicity per ISO 10993-5: 2009
  - Sensitization ISO 10993-10: 2021
  - Irritation per ISO 10993-23: 2021
  - Acute Systemic Toxicity per ISO 10993-11:2017
  - Material Mediated Pyrogenicity Testing per USP <151>

  Testing showed the device material to be non-cytotoxic, non-sensitizing, non-irritating, non-systemically toxic and non-pyrogenic.

- Bench performance studies before and after accelerated aging to the equivalent of three-years of real-time aging in accordance with ASTM F1980-21 demonstrated that all predetermined acceptance criteria were met in the following tests:
  - Dimensional specifications
  - Bend test (Force to tip deflection)
  - Cuff Burst Test
  - Tensile strength testing (all joints/connections)
  - Repeated cuff inflation
  - Prolonged inflation
  - Insertion depth marker integrity testing
  - Handle locking mechanism testing to determine force needed to move the handle from its set position.

VIII. Conclusion

The results of the testing described above demonstrate that the "RELIEEV" Uterine Manipulator Injector is as safe and effective as the predicate device and supports a determination of substantial equivalence.