November 26, 2025

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

Re: K252260
Trade/Device Name: RELIEEV HSG Catheter (HSG7FA1)
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: July 18, 2025
Received: October 27, 2025

Dear Jago Chen:

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 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,

Monica D. Garcia -S

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)*
K252260

Device Name
RELIEEV HSG Catheter (HSG7FA1)

Indications for Use *(Describe)*
The RELIEEV HSG Catheter (HSG7FA1) is for the delivery of contrast media or saline into the uterine cavity during hysterosalpingography or sonohysterography for examination of the uterus and fallopian tubes.

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 – K252260

I. SUBMITTER INFORMATION

Submitter:	LI Medical Corporation LTD. 2F., No. 43, Zhongxing Rd., Xizhi Dist., New Taipei City 221012, Taiwan
Submission Correspondent:	Jago Chen, CEO 2F., No. 43, Zhongxing Rd., Xizhi Dist., New Taipei City 221012, Taiwan Phone： +886-2-86461999 Fax：+886-2-26471999 Email：jago.chen@li-med.com.tw

Date Summary Prepared:	November 25, 2025

II. DEVICE INFORMATION

Device Trade Name:	RELIEEV HSG Catheter (HSG7FA1)
Common Name:	HSG Catheter
Regulation Number:	21 CFR 884.4530
Regulation Name:	Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class:	Class II
Product Code:	LKF (Cannula, Manipulator/Injector, Uterine)

III. PREDICATE DEVICE INFORMATION

Predicate Device:	PANPAC HSG Catheter Set
Company Name:	PANPAC
Submission number:	K092983

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

IV. DEVICE DESCRIPTION

The RELIEEV HSG Catheter (HSG7FA1) is a 7 French (Fr) dual lumen polyurethane catheter with a working length of 30 cm. RELIEEV HSG Catheter (HSG7FA1) is available with a closed-end tip with two side ports. The catheter consists of two lumens: an open lumen used to inflate the balloon and an open lumen used to inject diagnostic media into the uterus. The silicone balloon is designed with a balloon volume of 3.5 mL. When the balloon is inflated inside the uterus, the subject device seals the cervix. The catheter features a proximal fitting of a double-lumen polyurethane hub with a polycarbonate stopcock attached. Both the hub and stopcock accept a standard Luer lock. A stopcock is provided at the proximal end of the device to allow inflation of the balloon with a syringe. The center lumen is open through the device to the distal end, and the device has a luer connector at the proximal end for injecting fluids. An introducing sheath is placed over the tube as a guide and into the endocervix to the level of the internal os (opening of the cervix) with no dilatation required; therefore, allowing the catheter to pass easily through the cervix and into the uterine cavity.

The RELIEEV HSG Catheter (HSG7FA1) consists of a balloon catheter and a 5 mL syringe. The subject device is supplied sterile and is single-use.

V. INDICATIONS FOR USE

The RELIEEV HSG Catheter (HSG7FA1) is for the delivery of contrast media or saline into the uterine cavity during hysterosalpingography or sonohysterography for examination of the uterus and fallopian tubes.

VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND PREDICATE DEVICE

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 1. Comparison to Predicate Device

Device Attribute	**Proposed Device** RELIEEV HSG Catheter (HSG7FA1) **(Subject Device: K252260)**	**Predicate Device** PANPAC HSG Catheter Set **(Predicate Device: K092983)**	**Comparison**
Classification	Intrauterine Catheter	Intrauterine Catheter	Same
Regulation	Class II, 21 CFR	Class II, 21 CFR	Same

	884.4530	884.4530	
Product code	LKF	LKF	Same
Indications for Use	The RELIEEV HSG Catheter (HSG7FA1) is for the delivery of contrast media or saline into the uterine cavity during hysterosalpingography or sonohysterography for examination of the uterus and fallopian tubes.	PANPAC HSG Catheter Sets are indicated to evaluate the causes of abnormal uterine bleeding, menstrual disorders, recurring pregnancy loss, or unexplained infertility. They can also be used to assess uterine pathology and patients on tamoxifen therapy. HSG type catheter sets are used to infuse a fluid (either a contrast media or a sterile saline) into the uterine cavity while blocking the external cervical as to retain the fluid in the uterus during the procedure.	***Different***: The differences in the Indications for Use statement between the subject device and predicate device do not alter the intended use of the subject device.
Manufacturer	LI Medical Corporation LTD.	PANPAC Medical Corporation	-
Device name	RELIEEV HSG Catheter (HSG7FA1)	PANPAC HSG Catheter Set	-
Prescription medical device	YES	YES	Same
Single patient use	YES	YES	Same
Reusable	NO	NO	Same
Contraindications	HSG procedures are contraindicated in cases of pregnancy, suspected pregnancy,	HSG procedures are contraindicated in cases of pregnancy, suspected pregnancy,	Similar

	active pelvic infections, recent pelvic infections, severe uterine bleeding, gynecologic malignancies, or if the patient is allergic to the contrast media. This device should not be used for intrafallopian procedures.	active pelvic infections, recent pelvic infections, severe uterine bleeding.	
Technical Characteristics			
Lumen Number	2, dual lumen (for contrast and air inflated balloon)	2, dual lumen (for contrast and air inflated balloon)	Same
Catheter Tip Diameter	7 Fr	5 Fr 7 Fr	***Different***: The differences in the catheter tip diameters are supported by testing (e.g., performance testing).
Size of Catheter Tube	O.D. (7.0 French (Fr))	O.D. (7.0 French (Fr))	Same
ID of Tube (Air)	Ø0.8mm	Ø0.8mm	Same
ID of Tube (Liquid)	1.3*0.8mm	1.3*0.8mm	Same
Catheter Tip Shape	Closed and round	Closed and round	Same
Working Length	30 cm	30 cm	Same
TPU Tube flexible	YES	YES	Same
Capacity of Inflated Balloon	3.5 mL	5 Fr 1.5 ml 7 Fr 3.0 ml	***Different***: The differences in the balloon volume are

			supported by testing (e.g., performance testing).
Balloon Shape	Spherical	Spherical	Same
Operation Principle	Manual insert and inflate the balloon with a sterile syringe by a trained physician.	Manual insert and inflate the balloon with a sterile syringe by a trained physician.	Same
Removal Mechanism	Deflate the balloon with a syringe and remove the catheter.	Deflate the balloon with a syringe and remove the catheter.	Same
Media Expelled (Contrast or Saline Injection)	Via catheter side port	Via catheter side port	Same
Materials	Catheter tube: Thermoplastic polyurethane (TPU) 75D; Balloon material: Silicone; Guide Sleeve: Polypropylene (PP)	Catheter tube: Polyurethane (PU) 75D; Balloon material: Silicone; Guide Sleeve: Polypropylene (PP)	***Different***: The differences in the materials are supported by testing (e.g., biocompatibility testing, shelf-life testing, performance testing, etc.).
Biocompatibility	Surface device, in contact with mucosal tissue, with limited contact (≤ 24h)	Surface device, in contact with mucosal tissue, with limited contact (≤ 24h)	Same
Single Patient Use	YES	YES	Same
Reusable	NO (Single use)	NO (Single use)	Same
Anatomical Site	Uterine cavity	Uterine cavity	Same
Target Patient	Patient undergoing SHG or HSG	Patient undergoing SHG or HSG	Same

	procedure	procedure	
Clinical purpose on Clinical environment	The catheter is to be used for sonohysterography procedure that aid in the analysis of uterine pathology.	The catheter is to be used for sonohysterography procedure that aid in the analysis of uterine pathology.	Same
Sterilized Method	Ethylene Oxide (EO) gas	Ethylene Oxide (EO) gas	Same
Packaging	Medical grade paper pouch and PET film	Dupont Tyvek	***Different***: The differences in the packaging material are supported by testing (e.g., biocompatibility testing, shelf-life testing, etc.).
Shelf life	3 years	3 years	Same

The indications for use of the subject and predicate device are not identical. However, the intended use of the subject and predicate is the same (i.e., delivery of contrast medium or saline to the uterine cavity for HSG and SHG procedures). The subject and predicate device have the same designs and dimensions, shelf life, and sterilization method. The predicate and subject device differ in catheter tip sizes, tube material, maximum balloon inflation, and packaging materials. The differences identified do not raise different questions of safety and effectiveness as compared to the predicate device.

VIII. PERFORMANCE DATA

The following testing was performed to demonstrate that the RELIEEV HSG Catheter (HSG7FA1) met applicable design and performance requirements. All predetermined acceptance criteria were met in the following tests:

Bench Testing

Physical bench testing was performed to confirm that the device performs according to the product specifications. Device evaluation consisted of physical and functional testing including:

- Balloon Diameter and Maximum Balloon Volume Testing,

- Balloon Failure Test,
- Lumen Patency and Liquid Leakage Test:
- Tensile Testing (luer to tube, stopcock to tube, balloon adhesive catheter tube)

The subject device test results were compared with the predicate device and passed all functional bench testing.

Biocompatibility Testing

Per the indications for use, the RELIEEV HSG Catheter (HSG7FA1) is categorized as a surface device contacting mucosal membranes for a limited duration (≤ 24 hours). According to the 2023 FDA Guidance Document, *Use of International Standard ISO10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, the following endpoints were testing for the subject device:

Test Description	Method	Results
Cytotoxicity	ISO 10993-5: 2009, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	Non-cytotoxic
Sensitization	ISO 10993-10: 2021, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Non-sensitizer
Vaginal Irritation	ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation	Non-irritant

Sterilization Validation

The subject device is sterilized via Ethylene Oxide (EO) to achieve a Sterility Assurance Level (SAL) of 10^{-6}. Sterilization validation was conducted as per ISO 11135:2014 *Sterilization of health-care products –Ethylene oxide requirement for the development, validation, and routine control of a sterilization process for medical devices*. Sterility testing and documentation were provided as outlined in the 2024 FDA Guidance Document, *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*.

Shelf Life

The RELIEEV HSG Catheter (HSG7FA1) has a shelf life of 3 years (36-months). Shelf life studies have been conducted to demonstrate that the subject device can maintain functionality and

the packaging in will maintain its sterile barrier over the entirety of the intended shelf life.

The devices were subjected to environmental conditioning per ASTM D4332-22:2022, *Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing*, and simulated shipping distribution per ASTM D4169-22: 2022, Distribution Cycle 2, *Standard Practice for Performance Testing of Shipping Containers and Systems*. Sterile barrier packaging testing was performed per ISO 11607-1:2019, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*, and ISO 11607-2:2019, *Packaging for Terminally Sterilized Medical Devices -Part 2: Validation requirements for forming, sealing and assembly processes*. Following accelerated aging, per ASTM F1980-21: 2023, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*, and simulated shipping distribution, the following package integrity tests were completed:

- Visual Inspection per ASTM F1886/F1886M-16: 2017, *Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection*
- Seal Strength per ASTM F88/F88M-23: 2023, *Standard Test Method for Seal Strength of Flexible Barrier Materials*
- Dye Penetration per ASTM F1929-23: 2024, *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*

IX. CONCLUSION

The results of the testing described above demonstrate that the RELIEEV HSG Catheter (HSG7FA1) is as safe and effective as the predicate device and supports a determination of substantial equivalence.