September 25, 2024

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

Re: K240434
Trade/Device Name: "RELIEEV" Suction Curette (Flexible 3.0/ Standard 3.6)
Regulation Number: 21 CFR 884.1175
Regulation Name: Endometrial Suction Curette and accessories
Regulatory Class: II
Product Code: HHK
Received: August 30, 2024

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: 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,

Reginald K. Avery -S

for 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)*
K240434

Device Name
"RELIEEV" Suction Curette (Flexible 3.0/ Standard 3.6)

Indications for Use *(Describe)*
The "RELIEEV" Suction Curette (Flexible 3.0/ Standard 3.6) is used to remove samples of materials from the uterus and from the mucosal lining of the uterus by scraping or vacuum suction. These devices obtain tissue samples for purposes of biopsy precancer screening or they can be used for menstrual extraction.

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

510(K) Number: K240434

I. SUBMITTER

LI Medical Corporation LTD.
2F., No. 43, Zhongxing Rd., Xizhi Dist.,
New Taipei City 221012, Taiwan
Phone: +886-2-86461999
Fax: +886-2-26471999
Contact Person: Jago Chen, CEO
Email: jago.chen@li-med.com.tw
Date Prepared: Sep. 24, 2024

II. DEVICE

Device Name：	“RELIEEV” Suction Curette (Flexible 3.0/ Standard 3.6)
Trade/Proprietary Name：	RELIEEV
Common Name：	Endometrial suction curette
Regulation Number：	21 CFR 884.1175
Regulation Name：	Endometrial suction curette and accessories
Regulatory Class：	Class II
Product Code：	HHK

III. PREDICATE DEVICES REFERENCED IN THE SUBMISSION

Predicate Device：	The PANPAC SUCTION CURETTE
Company Name：	PANPAC
510(k) number:	K092982

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

IV. DEVICE DESCRIPTION

The “RELIEEV” Suction Curette is a sterile, disposable, single-use device used to obtain a sample from the uterine mucosal lining. It is available in two models – Flexible 3.0 and Standard 3.6 with outer diameters of 3.0 mm and 3.6 mm respectively. The device consists of a tube and piston made of polypropylene (PP) with a silicone O-ring. The subject device is packaged in medical paper grade pouch (60g).

V. INDICATIONS FOR USE

The "RELIEEV" Suction Curette (Flexible 3.0/ Standard 3.6) is used to remove samples of materials from the uterus and from the mucosal lining of the uterus by scraping or vacuum suction. These devices obtain tissue samples for purposes of biopsy precancer screening or they can be used for menstrual extraction.

VII. COMPARISON TO PREDICATE DEVICES

	Subject Device (K240434)	**Predicate Device (K092982)**	COMPARISON
Manufacture	LI Medical Corporation LTD.	PANPAC Medical Corporation	
Device name	“RELIEEV” Suction Curette (Flexible 3.0/ Standard 3.6)	The PANPAC Suction Curette	
Model	Model 1: ESC30A1 (Flexible 3.0) Model 2: ESC36A1 (Standard 3.6)	The Preferred Curette (Standard 3.0- Model M0014)	
Common name	Endometrial Suction Curette	Endometrial Suction Curette	Same
Regulation number	21 CFR 884.1175	21 CFR 884.1175	Same
Product code	HHK	HHK	Same
Classification	Class II	Class II	Same
Prescription medical device	Yes	Yes	Same
Single patient use	Yes	Yes	Same
Sterile device	Yes	Yes	Same
Disposable device	Yes	Yes	Same
Sterilization method	Ethylene Oxide (EtO)	EtO	Same
Hole on the tube	YES (1 hole on the side of the tube)	YES (1 hole on the side of the tube)	Same
Indications for Use	The "RELIEEV" Suction Curette (Flexible 3.0/ Standard 3.6) is used to remove samples of materials from the uterus and from the mucosal lining of the uterus by	An endometrial suction curette, such as the curette and preferred curette (available in 2.5 and 3.0 mm outer diameters) are devices	Same

	scraping or vacuum suction. These devices obtain tissue samples for purposes of biopsy precancer screening or they can be used for menstrual extraction.	used to remove samples of materials from the uterus and from the mucosal lining of the uterus by scraping or vacuum suction. These devices obtain tissue samples for purposes of biopsy precancer screening or they can be used for menstrual extraction.	
Length	<u>Flexible 3.0</u> PP tube: 240.0 ± 3.0 mm Piston: 264.0 ± 3.0 mm <u>Standard 3.6</u> PP tube: 240.0 ± 3.0 mm Piston: 264.0 ± 3.0 mm	M0014 (Model M0014) Curette Length-240 mm	Same
Dimensions	<u>Flexible 3.0</u> PP tube O.D: 3.0 + 0.10/-0.03 mm Piston cover with O-ring O.D.: 2.7 ± 0.05mm <u>Standard 3.6</u> PP tube O.D: 3.6 +0.10/-0.03 mm Piston cover with O-ring O.D.: 2.7 ± 0.05mm	M0014 PP tube O.D: 3.0 mm Piston O.D: 2.2 mm	Different
Material	<u>Flexible 3.0 and Standard 3.6</u> Tube: Polypropylene	M0014 Tube: Polypropylene	Different

	Piston: Polypropylene O-ring: Silicone (Purple pigment)	Piston: Polypropylene O-ring: Silicone (blue color)	
Scale marked on the tube	Laser engraving	Ink printed	Different
Packaging	Medical paper grade pouch (60g)	Tyvek pouch	Different
Shelf life	3 years	3 years	Same

The subject and predicate device differ in the dimensions, materials, scale marking and packaging. These technological differences do not raise different questions of safety and effectiveness and are addressed with performance testing.

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

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:

- Dimensional Analysis,
- Suction Force,
- Marker readability after bending, and
- Bending Force

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

Biocompatibility Testing

The biocompatibility testing was conducted in accordance with 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 “RELIEEV” Suction Curette is considered mucosal tissue contacting for less than 24 hours and the testing included the following tests with passing results.

Test name	Results	Standards
Cytotoxicity	Non-cytotoxic	ISO 10993-5:2009
Sensitization	Non-sensitizer	ISO 10993-10:2021
Irritation	Non-irritant	ISO 10993-23:2021

Packaging and Shipping Validation

Packaging and shipping validation were conducted on the subject device in order to confirm that the packaging materials are capable of withstanding the distribution environment during the rigors of shipping and handling.

For the simulated shipping distribution testing the environmental conditions were selected in accordance with ASTM D4332-22 and then the simulated shipping distribution was conducted per ASTM D4169-22, DC 13.

Packaging integrity testing consisting of seal peel test per ASTM F88/F88M-23, dye penetration per ASTM F1929-15, and visual inspection per ASTM F1886/F1886M-16 were completed with passing results.

Sterilization validation

The subject device is sterilized via ethylene oxide. 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

Shelf life testing was performed to support a shelf life of 3 years. Accelerated aging was conducted as per ASTM F1980-21 and package integrity testing for seal integrity and seal strength was completed using the methods under ASTM F1929-15. Bench testing, as described above, were completed on aged devices to support device functionality after aging. The results of these tests support the 3-year shelf-life claim.

IX. CONCLUSIONS

Subject and predicate devices share the same intended use and fundamental scientific technology, including principles of operation and mechanism of action. Differences in design between the subject and predicate devices do not raise different questions of safety and effectiveness. The results of performance testing demonstrate that the subject device is as safe and effective as the predicate devices to support a substantial equivalence determination.