October 6, 2023

Shanghai Ling Fu Technology Co., Ltd.
Esther Zhang
Regulatory Affairs
4F, No.585-2 Wanyuan Road, Minhang District
Shanghai, Shanghai 201102
China

Re: K232055
Trade/Device Name: Vial Adapter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: July 7, 2023
Received: July 11, 2023

Dear Esther Zhang:

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).

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.

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,

Daivd Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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)*
K232055

Device Name
Vial Adapter

Indications for Use *(Describe)*
The Vial Adapter is indicated for the transfer and mixing of drugs contained in vials.

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- K232055

I Submitter

Device submitter:	Shanghai Ling Fu Technology Co., Ltd. 4F, No.585-2 Wanyuan Road, Minhang District, Shanghai, P.R.China
Contact person:	Esther ZHANG Regulatory affairs Phone: 0086-13771505757 Email: Esther.zhang@llins-tech.com
Prepare Date:	October 6, 2023

II Device

Trade Name of Device: Vial Adapter
Common Name: Fluid Transfer IV Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product code: LHI
Review Panel: General Hospital

III Predicate Devices

Trade name:	Vial Adapter 15mm
Common name:	Set, I.V. Fluid Transfer
Classification/Regulation Number:	Class II, 21 CFR 880.5440
Regulation Name:	Intravascular Administration Set
Product Code:	LHI
Premarket Notification:	K171796
Manufacturer:	Medimop Medical Projects Ltd

IV Device description

The Vial Adapter consists of luer connector, housing and piercing spike, all of which are made of polycarbonate (PC). The sterile device pierces the elastomeric septum of a drug vial with its integrated piercing spike. The device is then pushed fully onto the drug vial and seats securely around the ferrule of the drug vial utilizing the housing of Vial Adapter. The connector on opposite side of the Vial Adapter is for the connection

of a standard Luer needle free syringe for the reconstitution and removal of the contents of the drug vial.

The proposed Vial Adapter is available in 13mm, 20mm and 28mm diameter configurations to accommodate respective size of drug vials. The device is intended for use in healthcare facilities or in the home environment by the patient or care-giver to aid and support prescribed treatment and therapy.

V Indications for use

The Vial Adapter is indicated for the transfer and mixing of drugs contained in vials.

VI Comparison of technological characteristic with the predicate device

The Vial Adapter has the same intended use as the legally marketed predicate device. The differences in technological characteristics between the subject and predicate device do not raise new or different questions of safety and effectiveness.

Device feature	Subject Device K232055	Predicate Device K171796	Comments
Indications for use	The Vial Adapter is indicated for the transfer and mixing of drugs contained in vials.	The Vial Adapter 15mm is indicated for the transfer and mixing of drugs contained in vials	Identical
Product code	LHI	LHI	Identical
Regulation number	21 CFR 880.5440	21 CFR 880.5440	Identical
Class	CLASS II	CLASS II	Identical
Principle of operation	Single use	Single use	Identical
Size	13mm, 20mm, 28mm	15mm	Different Comment 1
Material	Polycarbonate	Polycarbonate	Identical
Connector	Female Luer fitting; Male Luer fitting	Luer fitting	Different Comment 2
Piercing Spike	Plastic - Single Lumen	Plastic - Single Lumen	Identical
Vial Adapter Fit (Vial Side)	Snap Fit to Vial	Snap Fit to Vial	Identical
Sterilization Method	Electron beam Irradiation	Gamma Irradiation	Different Comment 3
Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	Identical
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993	Identical
Labeling	Proposed device labeling (IFU) includes transfer	Proposed device labeling (IFU) includes transfer	Identical

	and mixing instructions	and mixing instructions	
Expiration Date	3 years	5 years	Different Comment 4

Discussion:

Comment 1

There are differences in the size of Vial Adapters of the subject device which consist of 13mm, 20mm, 28mm configurations. The different sizes are for different diameter standard vials. The subject device performance testing demonstrates that the difference does not affect the intended use and does not raise new questions of safety and effectiveness.

Comment 2

The connector of Vial Adapter was divided into a female Luer fitting and a male Luer fitting, while the predicated device has only one luer fitting. This difference was addressed through ISO 80369-7 as well as biocompatibility, sterility and performance testing. The difference does not raise new or different questions of safety and effectiveness.

Comment 3

The Vial Adapter is provided sterilized by an Electron beam Irradiation method rather than gamma irradiation for the predicate device. However, the validation of the sterilization process in compliance with ISO 11137-1 and ISO 11137-2 ensures the device is adequately sterilized. Therefore, the difference does not raise new or different questions of safety and effectiveness.

Comment 4

The expiration date of subject device is 3 years which is shorter than the predicated device. The performance of the device over the proposed shelf life was tested to demonstrate that the difference does not affect the intended use and does not raise new questions of safety and effectiveness.

VII Data

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

Biocompatibility testing

Biocompatibility of the Vial Adapter was evaluated in accordance with ISO 10993-1:2018 for the body contact category of “External communication device – Blood path

indirect" with a contact duration of "Limited (< 24 hours)". The following tests were performed, as recommended:

Cytotoxicity	ISO 10993-5: 2009
Skin sensitization	ISO 10993-10: 2010
Hemolysis	ISO 10993-4: 2017
Intracutaneous reactivity	ISO 10993-10: 2010
Acute systemic toxicity	ISO 10993-11: 2017
Pyrogenicity	ISO 10993-11: 2017

Sterilization and shelf life testing

The sterilization method has been validated to ISO 11137-1 and ISO 11137-2, which has thereby determined the routine control and monitoring parameters. The sterilization process is validated to a minimum SAL 10^{-6}.

The shelf life of the Vial Adapter is determined based on stability study which includes ageing test. The testing is performed according to the following standards:

- ISO 11607-1: 2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2: 2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Performance testing

Performance testing Summary

Items		Testing standard	Result
Appearance		Internal performance standards	Pass
Particulate		Internal performance standards	Pass
Tensile strength		Internal performance standards	Pass
Leakage		Internal performance standards	Pass
Unobstructed		Internal performance standards	Pass
Piercing Spike		Internal performance standards	Pass
Puncture force		Internal performance standards	Pass
Chips after puncture		Internal performance standards	Pass
Housing		Internal performance standards	Pass
Luer Connector		ISO 80369-7	Pass
Chemical Properties	Reducing substances (easy oxides)	Internal performance standards	Pass
	Metal ions		
	pH		
	Evaporation residues		
	UV absorbance		
Sterile		Internal performance standards	Pass
Bacterial endotoxin		Internal performance standards	Pass

Simulated transportation testing

The transportation package has been tested according to ASTM D4169-DC13 test procedure to ensure its integrity during transportation.

VIII Conclusion

The Vial Adapter is substantially equivalent to the predicate device, Vial Adapter 15mm cleared under K171796. The non-clinical testing demonstrates that the device is as safe and effective as the predicate device and that the differences in technological characteristics do not raise new or different questions of safety and effectiveness.