May 1, 2024

Hangzhou Qiantang Longyue Biotechnology Co., Ltd
% Esther Zhang
Regulatory Affairs
Shanghai Ling Fu Technology Co., Ltd.
4F No. 585-2, Wanyuan Rd. Minhang District
Shanghai, Shanghai 201102
China

Re: K233284
Trade/Device Name: Vial Adapter with Filter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: April 3, 2024
Received: April 3, 2024

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) 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.

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,

Porsche Bennett

Porsche Bennett
For David 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233284

Device Name
Vial Adapter with Filter

Indications for Use *(Describe)*
The Vial adapter with filter is intended for use by Healthcare Professionals for the transfer and mixing of drugs contained in vials within clinical, hospital, or healthcare environments.

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.

K233284- 510(k) Summary

I Submitter

Device submitter:	Hangzhou Qiantang Longyue Biotechnology Co., LTD 104, 301, 302, building 12, building 1,619 WangMei Roadinping street, Linping Dlstrict, Hangzhou
Contact person:	Chunyu Wang Quality Assurance Manager Phone: 0086-13965638723 Email: chunyu_wang@nextech-x.com
Prepare Date:	April 26, 2024

II Correspondent

Company	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

III Subject Device

Trade Name of Device: Vial Adapter with Filter
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

IV Predicate Device

Trade name:	Vial Adapter
Regulation Name:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Classification:	Class II
Product Code:	LHI
Premarket Notification:	K222718
Manufacturer:	Hangzhou Qiantang Longyue Biotechnology Co., LTD

V Device description

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 the vial adapter. The connector on opposite side of the vented vial adapter is for the connection of a standard luer syringe for the reconstitution and removal of the contents of the drug vial.

The device is intended for use by Healthcare Professionals (HCPs) in a clinical, hospital, or other healthcare environment. The subject device is available by prescription use only and has no known contraindications.

The proposed vented vial adapter is available in 13mm, 20mm diameter to accommodate respective sizes of drug vials.

VI Indications for use

The Vial adapter with filter is intended for use by Healthcare Professionals for the transfer and mixing of drugs contained in vials within clinical, hospital, or healthcare environments.

VII Comparison of technological characteristics with the predicate devices

The Vial Adapter intended use, technological characteristics, design and performance specifications are either identical or substantially equivalent to the existing legally marketed predicate device. The differences between the subject and predicate devices do not raise different questions of safety and effectiveness.

Device feature	Subject Device K233284	Predicate Device K222718	Comments
Indications for use	The Vial adapter with filter is intended for use by Healthcare Professionals for the transfer and mixing of drugs contained in vials within clinical, hospital, or healthcare environments.	The Vial Adapter 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	13mm, 20mm, 28mm	Different Comment 1
Material	Polycarbonate, Polyethylene, Acrylic, Polyamide	Polycarbonate	Different Comment 2
Connector	Female Luer fitting	Female Luer fitting; Male Luer fitting	Different Comment 3
Piercing Spike	Plastic - Single Lumen	Plastic - Single Lumen	Identical
Filter	Yes	No	Different Comment 4
Performance	Performance test of: - Penetration force. - Detachment force from Drug Vial. - Spike Tip Ductility. - Fluid Leakage. - Liquid Filtration	Performance test of: - Penetration force; - Detachment force from Drug Vial; - Spike Tip Ductility; - Fluid Leakage.	Different Comment 5
Vial Adapter Fit (Vial Side)	Snap Fit to Vial	Snap Fit to Vial	Identical
Sterilization Method	Electron beam Irradiation	Electron beam Irradiation	Identical
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 and mixing instructions	Proposed device labeling (IFU) includes transfer and mixing instructions	Identical
Shelf life	4 years	3 years	Different Comment 6

Discussion:

Comment 1

The subject device consists of Vial Adapters that are 13mm, 20mm for different diameter standard vials. The size of Vial Adapter with filter was demonstrated to meet specification according to internal performance standards. This difference does not raise new questions of safety and effectiveness.

Comment 2

The material of the subject device is polycarbonate, polyethylene, acrylic/polyamide, and the predicate device material is polycarbonate. Although there is a difference in the material, the biocompatibility test of the subject device complies with the standard requirements. This difference does not raise new questions of safety and effectiveness.

Comment 3

The connector of the Vial Adapter with filter have only one type, while the predicated device has two types. This difference was addressed through ISO 80369-7 testing and therefore, this difference does not raise new questions of safety and effectiveness.

Comment 4

The inclusion of a Filtration Membrane in the subject device (K233284) differentiates it from the predicate device (K222718), which does not include a filter. Despite this difference, the additional filtration functionality in K233284 does not raise new questions of safety and effectiveness. It is supported by adherence to standards detailed below, which set requirements for transfer sets and infusion equipment, including the performance of fluid filters. The subject device has been tested to ensure that the filter performs adequately. Testing includes visual inspection for defects, dimensional measurements of the membrane, and filtration efficiency tests, all of which the device has passed. Therefore, the difference does not raise different questions of safety and effectiveness.

Comment 5

Performance testing of the Vial adapter with filter inlet and outlet functions demonstrates that the difference does not raise new questions of safety and effectiveness.

Comment 6

The shelf life of the subject device is 4 years which is longer than the predicated device; however, performance testing after accelerated aging passed all applicable and internal test methods. The difference does not raise new questions of substantially equivalence on safety

and effectiveness.

VIII Performance data

The following performance 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 10993-23: 2021
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
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare

applications Part 7: Connectors for intravascular or hypodermic applications

- ISO 8536-4:2019 Infusion equipment for medical use Part 4: Infusion sets for single use, gravity feed
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

Performance testing

Performance testing Summary

Items		Testing standard	Result
Appearance		Internal performance standards	Pass
Particulate		ISO 22413 -2021	Pass
Tensile strength		ISO 22413 -2021	Pass
Leakage		ISO 22413 -2021	Pass
Unobstructed		ISO 22413 -2021	Pass
Piercing Spike		ISO 22413 -2021	Pass
Puncture force		ISO 22413 -2021	Pass
puncture chip		ISO 22413 -2021	Pass
Dimension		Internal performance standards	Pass
Housing		ISO 22413 -2021	Pass
Luer Connector		ISO 80369-7	Pass
Detachment force		Internal performance standards	Pass
Spike tip ductility		Internal performance standards	Pass
Filtration rate		ISO 22413 -2021	Pass
Chemical property		ISO 8536-4:2019	Pass
Chemical Properties	Reducing substances (easy oxides)	Internal performance standards	Pass
	Metal ions		
	pH		
	Evaporation residues		
	UV absorbance		
Sterile		USP46-NF41	Pass
Bacterial endotoxin		USP-NF<71>	Pass

IX Clinical Data

Clinical data was not conducted to support a substantial equivalence determination.

X Conclusion

The Vial Adapter with Filter are substantially equivalent to the predicate device (Vial Adapter). The non-clinical testing demonstrates that the differences between the subject and

predicate device do not raise different questions of safety and effectiveness.