



July 26, 2024

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

Re: K233287

Trade/Device Name: Vent Vial Adapter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: June 27, 2024
Received: June 27, 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

A handwritten signature in black ink that reads "Porsche Bennett". The signature is written in a cursive style. A large, light blue "FDA" watermark is visible in the background behind the signature.

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

Indications for Use

510(k) Number (if known)

K233287

Device Name

Vented Vial Adapter

Indications for Use (Describe)

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

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. This adapter is suitable for use across all age groups, including neonates, pediatrics, adults, and the elderly.

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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K233287- 510(k) Summary

I Submitter

Device submitter: Hangzhou Qiantang Longyue Biotechnology Co., LTD
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Prepare Date: July 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
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III Device

Trade Name of Device: Vented Vial Adapter

Common Name: Set, I.V. Fluid Transfer

Regulation Number: 21 CFR 880.5440

Regulation Name: Intravascular Administration Set

Regulatory Class: II

Product code: LHI

Review Panel: General Hospital

IV Predicate Devices

Trade name:	Vial Adapter
Common name:	Set, I.V. Fluid Transfer
Classification:	Class II, 21 CFR 880.5440
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 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 proposed Vented Vial Adapter is available in 13mm, 20mm diameter to accommodate respective size of drug vials.

VI Indications for use

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

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. This adapter is suitable for use across all age groups, including neonates, pediatrics, adults, and the elderly.

VII Comparison of technological characteristics with the predicate devices

The Vented Vial Adapter has the same intended use, and the technology, design, and performance specifications are either identical or substantially equivalent to the existing legally marketed predicate device. The differences between the Vented Vial Adapter and predicate device do not alter suitability of the proposed device for its intended use.

Device feature	Subject Device	Predicate Device K222718	Comments
Indications for use	The Vented vial adapter is indicated for the transfer and mixing of drugs contained in vials. 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	The Vial Adapter is indicated for the transfer and mixing of drugs contained in vials.	Identical. The predicate device is also used by Healthcare Professionals (HCPs) in a clinical, hospital, or other Healthcare environment.

Device feature	Subject Device	Predicate Device K222718	Comments
	has no known contraindications. This adapter is suitable for use across all age groups, including neonates, pediatrics, adults, and the elderly.		
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, PTFE	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
Performance	Performance test of: - Penetration force. - Detachment force from Drug Vial. - Spike Tip Ductility. - Fluid Leakage. Air filter	Performance test of: - Penetration force; - Detachment force from Drug Vial; - Spike Tip Ductility; Fluid Leakage.	Different Comment 4
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
Expiration Date	4 years	3 years	Different Comment 5

Discussion:**Comment 1**

Differences in the size of Vented vial adapter 13mm, 20mm are for different diameter standard vials, and the size of Vial Adapter was controlled by internal performance standards. This difference does not affect intended use and does not raise new questions of substantial equivalence on safety and effectiveness.

Comment 2

The Vented vial adapter is available in PC and PTFE. The predicate product is only available in PC, but the product has passed the biocompatibility test according to ISO 10993-1:2018, and the difference in raw materials does not affect the substantial equivalence of safety and efficacy.

Comment 3

The connector of Vented Vial Adapter has only one type, while the predicated device has two types. This difference was addressed through ISO 80369-7 and this does not affect substantial equivalence on safety and effectiveness.

Comment 4

The Vented vial adapter with inlet and outlet functions, was tested in accordance to internal performance standards. The difference does not affect substantial equivalence on safety and effectiveness.

Comment 5

The Expiration Date of subject device is 4 years which is longer than the predicated device, and it has been passed through the Shelf-life validation. This difference does not affect intended use and does not raise new questions of substantial 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

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
Detachment force		ISO 8536-4	Pass
Spike tip ductility		Internal performance standards	Pass
Chemical Properties	Reducing substances (easy oxides)	Internal performance standards	Pass
	Metal ions		
	pH		
	Evaporation residues		
	UV absorbance		
Sterility		Internal performance standards	Pass
Bacterial endotoxin		Internal performance standards	Pass

IX Clinical Data

Not Applicable

X Conclusion

The Vented vial adapter is substantially equivalent to the predicate device (Vial Adapter). The non-clinical testing demonstrates that the device is as safe and effective as the legally marketed device and therefore, substantially equivalent.