March 10, 2023

Hangzhou Qiantang Longyue Biotechnology Co., LTD
Zhengxu Xiang
Quality Manager
302,building 12, building 1,619 WangMei Road,Linping street,
Linping District, Hangzhou
Hangzhou, Zhejiang 311199
China

Re: K222718
Trade/Device Name: Vial Adapter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: February 8, 2023
Received: February 8, 2023

Dear Zhengxu Xiang:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

David Wolloscheck, Ph.D.
Acting 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)*
K222718

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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K222718 - 510(k) summary

I Submitter

Device submitter:	Hangzhou Qiantang Longyue Biotechnology Co., LTD 302, building 12, building 1,619 WangMei Road, Linping street, Linping DIstrict, Hangzhou
Contact person:	Zhengxu Xiang Quality Manager Phone: 13757329925 Email: 1599564180@qq.com

Prepare Date:	Mar 09, 2023
Prior submission:	No prior submission of the device.

II Device

Trade Name of Device: 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

III Predicate Devices

Trade name:	Vial Adapter 15mm
Common name:	Set, I.V. Fluid Transfer
Classification:	Class II, 21 CFR 880.5440
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 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 to accommodate respective size of drug vials. And it is intended for use in healthcare facilities or in home environment by the patient or caregiver to aid and support prescribed treatment and therapy.

The device is intended for use on population of all ages.

V Indications for use

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

VI Comparison of technological characteristics with the predicate devices

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

Device feature	Subject Device	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
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
Performance	Performance test of: - Penetration force; - Detachment force from Drug Vial; - Spike Tip Ductility; - Fluid Leakage.	Performance test of: - Penetration force; - Detachment force from Drug Vial; - Spike Tip Ductility; - Fluid Leakage.	Identical

Device feature	Subject Device	Predicate Device K171796	Comments
Sterilization Method	Electron beam Irradiation	Gamma Irradiation	Different Comment 3
Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	Identical
Labeling	Proposed device labeling (IFU) includes transfer and mixing instructions	Proposed device labeling (IFU) includes transfer and mixing instructions	Identical
Expiration Date	3 years	5 years	Different Comment 4

Discussion:

Comment 1

Differences in the size of Vial Adapters 13mm, 20mm, 28mm 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 no raise new questions of substantially equivalence on safety and effectiveness.

Comment 2

The connector of Vial Adapter was divided into female Luer fitting and male Luer fitting, while the predicated device has only one type. This difference was addressed through ISO 80369-7 and this does not affect substantially equivalence on safety and effectiveness.

Comment 3

The Vial Adapter was provided sterilized by Electron beam Irradiation method rather gamma irradiation. However, the validation of sterilization process in compliance with ISO 11137-1 and ISO 11137-2 to ensure the sterility of device. Therefore, the difference does not affect substantially equivalence on safety and effectiveness.

Comment 4

The Expiration Date of subject device is 3 years which is shorter than the predicated device, and it has been verified through the Shelf-life validation. This difference does not affect intended use and does no raise new questions of substantially equivalence on safety and effectiveness.

VII 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 10993-10: 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

Detachment force		Internal performance standards	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		
Sterile		Internal performance standards	Pass
Bacterial endotoxin		Internal performance standards	Pass

VIII Clinical data

Not applicable

IX Conclusion

The Vial Adapter are substantially equivalent to the predicate device (Vial Adapter 15mm). The non-clinical testing demonstrates that the device is as safe and effective as the legally marketed device.