June 5, 2026

Hangzhou Qiantang Longyue Biotechnology Co., Ltd.
Meijun Chen
RA manager
Rm. 104, 201, 301, 302, Bldg. 12, Block 1, # 619
Wangmei Rd., Linping Subdistrict, Linping District
Hangzhou, Zhejiang 310000
China

Re: K260301
Trade/Device Name: Vial Adapter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: May 6, 2026
Received: May 6, 2026

Dear Meijun 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

PAPATYA KANER -S

Papatya Kaner, Ph.D.
*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

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)*
K260301

Device Name
Vial Adapter

Indications for Use *(Describe)*
Vial adapters are intended to be used for aspiration from single-dose container and multi-dose containers.
Model VA-722000, VA-722050, VA-722051, VA-742000, VA-742050, VA-742051 can be matched with a 20mm vial closure diameter and a 22mm vial body diameter (6R/8R), model VA-721000, VA-721050, VA-741000, VA-741050 can be matched with a 13mm vial closure diameter and a 16mm vial body diameter (2R/3R/4R) and model VA-720001, VA-720051, VA-740001, VA-740051 can be matched with any size containers.

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.***

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# K260301 - 510(k) Summary

## 1. Submitter


| | |
|---|---|
| Submitter name: | Hangzhou Qiantang Longyue Biotechnology Co., Ltd. |
| Submitter address: | Room 104, 201, 301, 302, Building 12, Block 1, No. 619 Wangmei Road, Linping Subdistrict,Linping District,Hangzhou City,310000 Zhejiang P.R. China. |
| Contact person: | MeiJun Chen<br>Regulatory Affairs Manager<br>Phone: +86 17775381549<br>meijun_chen@nextech-x.com |
| Date of preparation: | June 5, 2026 |


## 2. Subject 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: | Class II |
| Product code: | LHI |
| Review Panel: | General Hospital |

## 3. Predicate Devices

| | |
|---|---|
| Trade Name of Device: | Mini Spike Plus 6/8R |
| Common Name: | set, i.v. fluid transfer |
| Regulation Number: | 21 CFR 880.5440 |
| Regulation Name: | Intravascular Administration Set |
| Regulatory Class: | Class II |
| Product code: | LHI |
| Premarket Notification: | K201469 |
| Manufacturer: | B. Braun Medical Inc. |

## 4. Device description

The Vial Adapter is a sterile, single-use medical device designed to ensure the safe transfer and mixing of drugs.

The Vial Adapter consists of a closing cap, a grip plate, an air filter membrane, a drug filter membrane (optional), a piercing plate, an adapter (optional), and a protective cap (optional). The

grip plate features a luer connector, while the piercing plate features a piercing device. The product is sterilized using ethylene oxide and is intended for single-use use.

Closing cap is made of Polypropylene (PP), the grip plate and piercing plate are made of ABS, the air filter membrane is made of PTFE and PET, the drug filter membrane is made of PA and PET, the adapter is made of Polycarbonate (PC) , the protective cap is made of Polyethylene (PE). The device is sterilized using Ethylene Oxide. The Vial Adapter is intended for transferring and mixing medications in hospitals and outpatient care facilities. It is critical that the device is used only once to prevent cross-contamination and that its packaging integrity is checked before use to ensure no compromise in sterility.

## 5. Indications for use

Vial adapters are intended to be used for aspiration from single-dose container and multi-dose containers.

Model VA-722000, VA-722050, VA-722051, VA-742000, VA-742050, VA-742051 can be matched with a 20mm vial closure diameter and a 22mm vial body diameter (6R/8R), model VA-721000, VA-721050, VA-741000, VA-741050 can be matched with a 13mm vial closure diameter and a 16mm vial body diameter (2R/3R/4R) and model VA-720001, VA-720051, VA-740001, VA-740051 can be matched with any size containers.

## 6. Comparison of technological characteristics with the predicate device

The indications for use, technological characteristics, design and performance specifications of subject device are 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.

| **Characteristics** | **Subject Device (Vial adapter)** | **Predicate Device (Mini Spike Plus 6/8R, K201469)** | **Comparison result** |
|---|---|---|---|
| **General Characteristics** | | | |

| | | | |
|---|---|---|---|
| Indications for use | Vial adapters are intended to be used for aspiration from single-dose container and multi-dose containers. Model VA-722000, VA-722050, VA-722051, VA-742000, VA-742050, VA-742051 can be matched with a 20mm vial closure diameter and a 22mm vial body diameter (6R/8R), model VA-721000, VA-721050, VA-741000, VA-741050 can be matched with a 13mm vial closure diameter and a 16mm vial body diameter (2R/3R/4R) and model VA-720001, VA-720051, VA-740001, VA-740051 can be matched with any size containers. | An IV additive dispensing pin for aspiration from single-dose containers with a 20 mm vial closure diameter and a 22mm vial body diameter (6R/8R). | Identical, just wording different. See below comment 1 |
| Product Code and Regulation | LHI<br>21 CFR 880.5440 | LHI<br>21 CFR 880.5440 | Identical |
| Classification | Class II (non-exempt) | Class II (non-exempt) | Identical |
| Review Panel | General Hospital | General Hospital | Identical |
| Type of Use | Single Use | Single Use | Identical |
| Conditions of Use | Prescription use only | Prescription use only | Identical |
| Principle of Operation | The device provides two separate channels:<br>- One for injection and withdrawal of fluids<br>- One for the pressure equalization between the vial and the environment<br>When the device's spike is pierced into a rubber stopper of a drug vial, these channels enable a fluid transfer between a syringe (that is connected with the device's luer connector on the top) and the vial.<br>In addition, some models in this submission have drug filter membrane, drug filter membrane can Filter foreign matter and undissolved particles in the solution. | The device provides two separate channels:<br>- One for injection and withdrawal of fluids<br>- One for the pressure equalization between the vial and the environment<br>When the device's spike is pierced into a rubber stopper of a drug vial, these channels enable a fluid transfer between a syringe (that is connected with the device's luer connector on the top) and the vial. | Similar, see below comment 2 |
| **Material Composition** | | | |
| Material | Closing Cap: PP<br>Grip plate/Piercing plate: ABS<br>Air filter membrane: PTFE and PET<br>Drug filter membrane: PA and PET<br>Protective cap: PE<br>Adapter: PC | Snap Cap: PP<br>Upper Grip Piece: SAN/ABS<br>Piercing Spike: SAN/ABS<br>Air Filter: AVC on PA 6<br>Adapter: PS | Different, see below comment 3 |
| **Sterilization** | | | |

| | | | |
|---|---|---|---|
| Sterilization Method | EO Sterilization | EO Sterilization | Identical |
| Sterility Assurance Level | SAL $10^{-6}$ | SAL $10^{-6}$ | Identical |
| **Product Structure Design** | | | |
| Luer Connector Cover | Closing Cap | Snap cap | Identical, just wording different |
| Device User Interface | Grip plate | Grip Piece | Identical, just wording different |
| Interface to Syringe | Luer Connector | Luer Lock Connector | Identical, just wording different |
| Interface to Vial | Piercing device | Piercing spike | Identical, just wording different |
| Air Filter membrane | Yes | Yes | Identical |
| Drug Filter membrane | Yes | None | Different, see below comment 4 |
| Protective Cap | Yes | None | Different, see below comment 5 |
| Vial adapter | Model VA-722000, VA-722050, VA-722051, VA-742000, VA-742050, VA-742051 can be matched with a 20mm vial closure diameter and a 22m m vial body diameter (6R/8R), model VA-721000, VA-721050, VA-741000, VA-741050 can be matched with a 13mm vial closure diameter and a 16m m vial body diameter (2R/3R/4R) and model VA-720001, VA-720051, VA-740001, VA-740051 can be matched with any size containers due to these models have no adapter(housing). | Vial adapter keeps proposed device connected with a 20 mm vial closure diameter and a 22mm vial body diameter. | Different, see below comment 6 |
| Color | Closing cap: Red (VA-720001, VA-720051,VA-721000,VA-721050, VA-722000,VA-722050,VA-722051 applicable), Green (VA-740001, VA-741000, VA-742000 applicable), Blue(VA-740051, VA-741050, VA-742050, VA-742051 applicable).<br>Grip plate/Grip plate: White | Closing cap: Green<br>Grip Piece/Piercing spike: White | Different, see below comment 7 |

| | | | |
|---|---|---|---|
| | Protective cap: Blue | | |
| **Other Characteristics** | | | |
| Packaging – Sterile Barrier System | Thermoformed film sealed with printed medical grade paper | Thermoformed film sealed with printed medical grade paper | Identical |
| Shelf life | 5 years | 5 years | Identical |

**Discussion:**

Comment 1: Both subject device and predicate device are intended for transfer medicinal liquid for single use. They have same intended use.

For subject device, Model VA-722000, VA-722050, VA-722051, VA-742000, VA-742050, VA-742051 can be matched with a 20mm vial closure diameter and a 22mm vial body diameter (6R/8R), model VA-721000, VA-721050, VA-741000, VA-741050 can be matched with a 13mm vial closure diameter and a 16mm vial body diameter (2R/3R/4R) and model VA-720001, VA-720051, VA-740001, VA-740051 can be matched with any size containers. For predicate device, it is only connected with a 20 mm vial closure diameter and a 22mm vial body diameter. The various models of the subject device can meet different clinical requirements.

The differences in wording of indications for use between subject device and predicate device do not affect safety and effectiveness.

Comment 2: The principle or operation is similar between subject device and predicate device. Some models in this submission have filtration membrane to filter foreign matter and undissolved particles in the solution. In addition, the performance and biocompatibility of the filter has been verified in accordance with ISO 10993 series standards and ISO 8536-4. This difference does not raise any new risks.

Comment 3: The material is different between subject device and predicate device. But the subject device has been tested according to ISO 10993 series standards, the results showed that the subject device does not raise biological safety concerns.

Comment 4: The subject device has filtration membrane to filter foreign matter and undissolved particles in the solution. The performance and biocompatibility of this structure has been verified in accordance with ISO 10993 series standards and ISO 8536-4. This difference does not raise any new risks.

Comment 5: The subject device has protective cap, it is used to protect the Piercing device tip not to be damaged and prevent needle-stick injury. This part does not affect the main function of the product and does not come into contact with the drug solution. This difference does not raise any new risks.

Comment 6: Regardless of the subject device is intended for single-dose or multi-dose containers,

its intended use remains the same and consistent, which is to transfer medicinal liquid for single use. The difference lies in that the vial adapter for single-dose container is adapted to fixed-sized medicine bottles, while the vial adapter for multi-dose containers can be adapted to any size of the bottle without any restrictions. And during a single clinical use, the vial adapter for multi-dose containers is only used with a certain fixed-sized medicine bottle and does not involve multiple uses.

Additionally, the dose of the drug is determined by the drug use instructions, the subject device is only for medicinal liquid transfer.

Therefore, this difference will not cause new safety and efficacy issues.

Comment 7: For subject device, the color of Grip plate/Grip plate is white, the color of Protective cap is blue and there are 3 colors for the closing cup, they are green, red and blue. The protective cap and closing cup do not come into contact with the drug solution, the fluid-contacting components of subject device has been verified in accordance with ISO 10993 series standards. Therefore, this difference does not raise any new risks.

## 7. 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 exposure". The following tests were performed, as recommended:

| Standard | Test performed |
|---|---|
| ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity | Cytotoxicity |
| ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization | Skin sensitization |
| ISO 10993-4: 2017 Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood | Hemolysis |
| ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation | Intracutaneous reactivity |
| ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity | Acute systemic toxicity |
| ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity | Pyrogenicity |

Performance testing

| Standard | Test Performed |
|---|---|
| ISO 22413:2021<br>Transfer sets for pharmaceutical preparations — Requirements and test methods | ■ Fragmentation<br>■ Air Tightness<br>■ Free flow<br>■ Penetration Force<br>■ Tensile strength<br>■ Visual Inspection<br>■ Leakage<br>■ Chemical Performance |
| ISO 80369-7: 2021<br>Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications<br><br>ISO 80369-20: 2024<br>Small-bore connectors for liquids and gases in healthcare applications Part 20: Common test methods | ■ Luer connectors |
| USP<85> Bacterial Endotoxins Test | ■ Bacterial endotoxin |
| USP<788> Particulate Matter in Injections | ■ Particulate contamination |
| ISO 8536-4:2019<br>Infusion equipment for medical use Part 4: Infusion sets for single use, gravity feed | ■ Filtration rate |
| ISO 11607-1: 2019<br>Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems<br><br>ISO 11607-2: 2019<br>Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes<br><br>ASTM F1980-21<br>Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices<br><br>ASTM F1929-15<br>Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration<br><br>ASTM F88/F88M-23<br>Standard Test Method for Seal Strength of Flexible Barrier Materials<br><br>ASTM F 1886<br>Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection<br><br>ASTM D4169-23e1 | ■ Sterile Barrier System Validation |

| | |
|---|---|
| Standard Practice for Performance Testing of Shipping Containers and Systems | |

## 8. Clinical Data

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

## 9. Conclusion

The subject device Vial Adapter has met all established acceptance criteria for performance testing and design verification testing. Results of functional performance and biocompatibility testing demonstrate that the differences between the subject and predicate device do not raise different questions of safety and effectiveness.

Therefore, the subject device (Vial adapter) supports a substantial equivalence determination to the predicate device (Mini Spike Plus 6/8R).