May 10, 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: K233277
Trade/Device Name: Filter Needle for Single Use
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPB
Dated: April 10, 2024
Received: April 11, 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,

David Wolloscheck

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233277

Device Name
Filter Needle for Single Use

Indications for Use *(Describe)*
This product is intended for the aspiration, filtration and preparation of medical fluid, not including injection.

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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K233277_510(k) summary

I Submitter

Device submitter:	Hangzhou Qiantang Longyue Biotechnology Co., LTD 104, 301, 302, building 12, building 1,619 WangMei Road Linping street, Linping Dlstrict, Hangzhou
Contact person:	Chunyu Wang Quality Assurance Manager Phone: 0086-571-89150121 Email: chunyu_wang@nextech-x.com Fax: 86-571-89150091
Prepare Date:	May 10, 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 Device

Trade Name of Device: Filter Needle for Single Use
Common Name: Infusion Line Filter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product code: FPB
Review Panel: General Hospital

IV Predicate Devices

Trade name:	B-D FILTER NEEDLE
Common name:	Infusion Line Filter
Classification:	Class II, 21 CFR 880.5440
Product Code:	FPB
Premarket Notification:	K801343
Manufacturer:	BD BECTON DICKINSON VACUTAINER SYSTEMS PREANALYTIC

V Device description

The Filter Needle for Single Use is a single use, irradiation sterilized device that is designed to be used for use in conjunction with luer taper infusion sets conforming to EN ISO 80369-7 for the extraction, filtration and configuration of medicinal solutions and is not intended for injection purposes. Filter Needle for Single Use consists of cap, needle cannula, needle hub, sheath and filter. The cap, needle hub and sheath are made of polycarbonate (PC), the needle tube is made of medical stainless steel (SUS304), and filter is made of polyamide (PA).

The needle holder is a 6% standard tapered connector with good connectivity to the infusion apparatus.

Model Number	Description
FN-B1838RW	18 Gauge, 38 mm length
FN-B1850RW	18 Gauge, 50 mm length
FN-L1938TW	19 Gauge, 38 mm length
FN-L1950TW	19 Gauge, 50 mm length

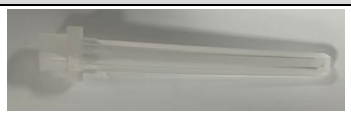
VI Indications for use

This product is intended for the aspiration, filtration and preparation of medical fluid, not including injection.

VII Comparison of technological characteristics with the predicate devices

The Filter Needle for Single Use 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 Filter Needle for Single Use and predicate devices do not alter suitability of the proposed device for its intended use.

Device feature	Subject Device	Predicate Device K801343	Comments
Product code	FPB	FPB	Identical
Regulation number	21 CFR 880.5440	21 CFR 880.5440	Identical
Class	CLASS II	CLASS II	Identical
Number of uses	Single use Rx only	Single use Rx only	Identical
Material	Needle holder material of polycarbonate (PC), needle tube material of stainless steel (SUS304), filter membrane material of polyamide (PA)	Needle holder material (PC), Needle tube material (SUS304), Filter membrane material (PA)	Identical

Device feature	Subject Device	Predicate Device K801343	Comments
Sheath			Different Comment 1
Indications for Use	This product is intended for the aspiration, filtration and preparation of medical fluid, not including injection.	The B-D FILTER NEEDLE is intended for the aspiration, filtration and preparation of medical fluid, not including injection.	Identical
Operating principles	Manual	Manual	Identical
Design specifications	Needle Gauge: 18G, 19G Length: 38 mm,50 mm	Gauge: 18 G Length (mm): 40 Length (inch): 1 1/2”	Different Comment 2
Performance	Conforms to the standard requirements of ISO 7864:2016 and ISO 22413:2021	Conforms to the standard requirements of ISO 7864:2016 and ISO 22413:2021	Identical
Biocompatibility	Biocompatible The finished device’s patient contacting parts were assessed in accordance with tests recommended in the FDA Guidance - Use of International Standard ISO-10993- 1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.”	Biocompatible The finished device’s patient contacting parts were assessed in accordance with tests recommended in the FDA Guidance - Use of International Standard ISO-10993- 1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.”	Identical
Sterilization method	Irradiation sterilization	Irradiation sterilization	Identical
Bacterial endotoxin	USP <85>	USP <85>	Identical
Expiration Date	4 years	5 years	Different Comment 3

Discussion:

Comment 1

Although there are differences in the size and design of the two sheaths of needle, their general forms are essentially the same. Since the structure and intended use of the body of the subject and predicate device remain unchanged, modifications to the sheath do not raise different safety concerns or new ones.

Comment 2

Needle length specification our needle length specification is 38mm and 50mm, and BD needle length specification is 40mm. Tests on the varying needle lengths of the subj are performed per ISO 7864:2016. These test results confirm that the differences in needle lengths do not impact the safety or effectiveness.

Comment 3

Our products are valid for 4 years and BD' products are valid for 5 years. We have implemented validation of our products, and the safety and validity of our products meet the requirements within the validity period.

In conclusion, there is no substantial difference between our products and similar products currently marketed in the United States.

VIII Performance data

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

Biocompatibility testing

Biocompatibility of the Filter Needle for Single Use 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: 2021
Hemolysis	ISO 10993-4: 2017
Intracutaneous reactivity	ISO 10993-23: 2021
Acute systemic toxicity	ISO 10993-11: 2017
Pyrogenicity	ISO 10993-11: 2017

In addition to the above tests, particulate contamination was evaluated to ensure compliance with particulate cleanliness requirements. The particulate testing was conducted following:

Particulate Testing Standard: ISO 8536-4:2019 and USP 788.

Sterilization and shelf-life testing

The sterilization method has been validated to ISO 11137, 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 Filter Needle for Single Use 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 F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F1929-2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

Performance testing

Performance testing Summary

Number	Item	Testing standard	Result
1.	Exterior Condition	ISO 7864:2016	Pass
2.	Needle Length	ISO 7864:2016	Pass
3.	Needle Holder Tapered Fittings	ISO 7864:2016	Pass
4.	Uprightness	ISO 7864:2016	Pass
5.	Firmness of Connection	ISO 7864:2016	Pass
6.	Particulate Contamination	ISO 22413-2021	Pass
7.	Tightness	ISO 22413-2021	Pass
8.	Piercing Force	ISO 22413-2021	Pass
9.	Puncture Chip	ISO 22413-2021	Pass
10.	Filtration Rate	ISO 22413-2021	Pass
11.	Seat to Sheath Mating	ISO 7864:2016	Pass
12.	Chemical Property	ISO 7864:2016	Pass
13.	Sterility	United States Pharmacopeia	Pass
14.	Bacterial Endotoxin	USP <85>	Pass

IX Conclusion

The Filter Needle for Single Use are substantially equivalent to its predicate device (B-D FILTER NEEDLE). The non-clinical testing demonstrates that the device is as safe and as effective as the legally marketed predicate device.