August 7, 2026

Hangzhou Qiantang Longyue Biotechnology Co., Ltd.
℅ Ren Jiangfeng
Regulatory Affairs Manager
Shanghai Lingfu Technology Co., Ltd.
Rm. 1115, Block A, Xuhui Vanke Centre, # 55 Ding'An Rd., Xuhui District
Shanghai, Shanghai 200235, China

Re: K260933
Trade/Device Name: Safety Sterile Hypodermic Needles (NR-S1816R, NR-S1916R, NR-S1925R, NR-S1938R, NR-S2016R, NR-S2025R, NR-S2038R, NR-S2051R, NR-S2116R, NR-S2125R, NR-S2138R, NR-S2151R, NR-S2216R, NR-S2225R, NR-S2238R, NR-S2251R, NR-S2316R, NR-S2325R, NR-S2338R, NR-S2351R, NR-S2516R, NR-S2525R, NR-S2538R, NR-S2551R, NR-S2516T, NR-S2525T, NR-S2538T, NR-S2551T)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: July 8, 2026
Received: July 8, 2026

Dear Ren Jiangfeng:

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,

SHRUTI N. MISTRY -S

Shruti Mistry
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260933

Please provide the device trade name(s).

Safety Sterile Hypodermic Needles (NR-S1816R, NR-S1916R, NR-S1925R, NR-S1938R, NR-S2016R, NR-S2025R, NR-S2038R, NR-S2051R, NR-S2116R, NR-S2125R, NR-S2138R, NR-S2151R, NR-S2216R, NR-S2225R, NR-S2238R, NR-S2251R, NR-S2316R, NR-S2325R, NR-S2338R, NR-S2351R, NR-S2516R, NR-S2525R, NR-S2538R, NR-S2551R, NR-S2516T, NR-S2525T, NR-S2538T, NR-S2551T)

Please provide your Indications for Use below.

This product is intended for use in the withdrawal and injection of fluids for medical purposes. This product is compatible for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached needle safety sheath can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K260933

510(k) Summary

Prepared on: 2026-08-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Hangzhou Qiantang Longyue Biotechnology Co., LTD
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Correspondent Name	Shanghai Ling Fu Technology Co., Ltd.
Correspondent Address	Room 1115, Block A, Xuhui Vanke Centre, No. 55 Ding'an Road, Xuhui District Shanghai Shanghai 200235 China
Correspondent Contact Telephone	86-21-33561520
Correspondent Contact	Ren Jiangfeng
Correspondent Contact Email	jiangfeng.ren@llins-tech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Safety Sterile Hypodermic Needles (NR-S1816R, NR-S1916R, NR-S1925R, NR-S1938R, NR-S2016R, NR-S2025R, NR-S2038R, NR-S2051R, NR-S2116R, NR-S2125R, NR-S2138R, NR-S2151R, NR-S2216R, NR-S2225R, NR-S2238R, NR-S2251R, NR-S2316R, NR-S2325R, NR-S2338R, NR-S2351R, NR-S2516R, NR-S2525R, NR-S2538R, NR-S2551R, NR-S2516T, NR-S2525T, NR-S2538T, NR-S2551T)
Common Name	Hypodermic single lumen needle
Classification Name	Needle, Hypodermic, Single Lumen
Regulation Number	880.5570
Product Code(s)	FMI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K152362	Terumo SurGuard 3 Safety Hypodermic Needle	FMI

Device Description Summary

21 CFR 807.92(a)(4)

The Safety Sterile Hypodermic Needles are single-use medical devices intended for the injection of medicinal liquids into human intradermal, subcutaneous, or intramuscular tissues. The device primarily consists of a safety cover, needle hub, needle tube, protective

sheath, and hinge.
The needle hub is equipped with a 6% Luer female conical connector that conforms to ISO 80369-7. This connector allows the device to be securely connected to a syringe equipped with a compatible 6% Luer male conical connector. The device is manufactured primarily from medical-grade polypropylene (PP) and SUS304 stainless steel.
To reduce the risk of accidental needlestick injury after use, the device incorporates a manually activated needle safety feature. Prior to removing the protective sheath, the user must manually pivot the safety cover away from the needle to allow access for use. After completion of the injection, the user must again manually pivot the safety cover over the exposed needle until it engages and locks in place, thereby fully shielding the needle. The safety mechanism is not automatically or passively activated and requires deliberate user action to engage.
The Safety Sterile Hypodermic Needles are supplied sterile and are sterilized using electron beam irradiation. The devices have a shelf life of five years. They are available in various sizes to accommodate different clinical needs, including needle gauges ranging from 18G to 25G and nominal needle lengths ranging from 16 mm to 51 mm, in both Regular Wall (RW) and Thin Wall (TW) configurations.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This product is intended for use in the withdrawal and injection of fluids for medical purposes. This product is compatible for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached needle safety sheath can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use for the subject device, Safety Sterile Hypodermic Needles, and the predicate device, Terumo SurGuard 3 Safety Hypodermic Needle (K152362), are not identical in exact wording, but they share the exact same fundamental intended use.
Both devices are intended to interface with standard Luer syringes for the fluid delivery into the body, and both incorporate a manually activated safety shield to minimize the risk of accidental needlestick injuries after the procedure is complete.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device, the Safety Sterile Hypodermic Needles , has the same basic technological characteristics, design, materials, and principle of operation as the legally marketed predicate device, the Terumo SurGuard 3 Safety Hypodermic Needle (K152362).
The minor dimensional differences between the subject and predicate devices merely provide healthcare professionals with a broader range of options to accommodate varying clinical needs (e.g., deeper tissue injections or varying fluid viscosities). These size variations do not alter the fundamental scientific technology, principle of operation, or intended therapeutic effect of the device. Comprehensive bench testing has demonstrated that the subject device's various dimensions perform safely and effectively. Therefore, the technological characteristics of the subject device are substantially equivalent to the predicate device and do not raise any different questions regarding safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The subject device underwent a comprehensive suite of nonclinical tests to verify its safety and effectiveness for its intended use. The performance evaluation encompassed the following broad categories:
1) Physical, Mechanical, and Chemical Performance
Testing evaluated needle appearance, dimensions, stiffness, resistance to breakage, corrosion resistance, bond strength between the hub and needle tube, lumen patency, particulate contamination, color coding, and applicable chemical properties. The testing referenced EN ISO 7864:2016, ISO 9626:2016, ISO 6009:2016, and EN ISO 8536-4:2020.
2) Needlestick Prevention Mechanism
The safety mechanism was evaluated for activation force, resistance to premature activation, strength after activation, drop impact resistance, puncture resistance, and simulated clinical use. The simulated clinical evaluation referenced FDA's Medical Devices with Sharps Injury Prevention Features — Guidance for Industry and FDA Staff.
3) Luer Connector Compatibility
The 6% Luer female connector was evaluated for liquid leakage, air leakage, stress cracking, axial separation, torque resistance, and resistance to thread overriding in accordance with ISO 80369-7:2021.
4) Sterility and Bacterial Endotoxins
Electron-beam sterilization was evaluated in accordance with EN ISO 11137-2:2015 to support a Sterility Assurance Level of 10^{-6}.
Bacterial endotoxin testing was performed according to the applicable EP/USP requirements, with an acceptance criterion of less than 20 EU per device.
5) Biological Evaluation
The biological safety evaluation was conducted in accordance with the following standards:
- ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 10993-4:2017 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices — Part 10: Tests for skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

• ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation
The biological evaluation included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, pyrogen, and hemocompatibility/hemolysis evaluations using a representative worst-case model.

Clinical Data: Not Applicable

The Safety Sterile Hypodermic Needles are substantially equivalent to the predicate device (Terumo SurGuard 3 Safety Hypodermic Needle). The non-clinical testing demonstrates that the device is as safe and effective as the legally marketed device.