



February 24, 2022

Henan Nursecare Biotechnology Co., Ltd  
% Johnson Liu  
Consultant  
Cnmed Consultant  
31 Archer St  
Upper MT Gravatt, 4122 Au

Re: K212949

Trade/Device Name: Sterile Syringe with Safety Needle for Single Use, Sterile Syringe with Needle for Single Use, Sterile Syringe for Single Use, Sterile Safety Needle for Single Use, Sterile Needle for Single Use

Regulation Number: 21 CFR 880.5440

Regulation Name: Intravascular Administration Set

Regulatory Class: Class II

Product Code: FPA

Dated: January 20, 2022

Received: January 27, 2022

Dear Johnson Liu:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gang Peng for  
Alan Stevens  
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)

K212949

Device Name

Sterile Safety Needle for Single Use, Sterile Syringe with safety needle for Single Use, Sterile Needle for Single Use, Sterile Syringe with needle for Single Use, Sterile Syringe for Single Use.

Indications for Use (Describe)

Sterile Syringe with Safety needle for Single Use is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety mechanism can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.

Sterile Syringe with needle for Single Use is intended for use in the aspiration and injection of fluids for medical purpose.

Sterile Syringe for Single Use is a sterile luer lock or luer slip syringe which is intended to be used with a hypodermic needle for the aspiration and injection of fluids for medical purpose.

Sterile Safety Needle for Single Use is intended to be used with a luer lock or luer slip syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety mechanism can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.

Sterile Needle for Single Use is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose.

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.

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