October 14, 2021

Azur Medical Company Inc.
Di Zhao
General Manager
6710 Everglades Dr.
Richmond, Virginia 23838

Re: K211214
Trade/Device Name: Sterile Hypodermic Needles for Single Use
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: August 9, 2021
Received: August 20, 2021

Dear Di Zhao:

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,

For CAPT 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

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)*
K211214

Device Name
Sterile Hypodermic Needles for Single Use

Indications for Use *(Describe)*
The Sterile Hypodermic Needles for Single Use are intended to be used with a luer lock or luer slip syringe and injection devices for general purpose fluid injection/aspiration.

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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K211214 510(k) summary

Preparation Date: October 14, 2021

I Submitter

Device submitter: Azur Medical Company Inc.
6710 Everglades Dr., Richmond, Virginia, VA 23838, USA

Contract manufacturer: Zhejiang Kangkang Medical-Devices CO., Ltd.
Longwang Industrial District, Chumen Town, Yuhuan, Zhejiang, 317605, China
Registration number: 3015042030

Contact person: Di Zhao
General Manager
Phone: 928-5922380
Email: dzhao@azur-ppe.com

II Device

Trade Name of Device: Sterile Hypodermic Needles for Single Use
Common Name: Hypodermic Single Lumen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product code: FMI
Review Panel: General Hospital

III Predicate Device

Trade name:	Self-destruction Safety Syringes for Single Use; Sterile Hypodermic Syringes for Single Use; Sterile Hypodermic Needles for Single Use (used as the predicate device); Sterile Safety Hypodermic Needles for Single Use
Common name:	Hypodermic single lumen needle
Classification:	Class II, 21 CFR 880.5570
Product Code:	FMI
510(K) Number:	K180417
Manufacturer:	Berpu Medical Technology Co., Ltd

IV Device description

The Sterile Hypodermic Needles for Single Use is composed of a needle hub, protective cover, needle tube and jointing. The Sterile Hypodermic Needles for Single Use is for single use only, It is provided sterile. The sterilization method is EO sterilization and the sterilization assurance level is 10^{-6}.

Table 1 specification of proposed device

Gauge / Length	30G	27G	26G	25G	24G	23G	22G	21G	20G	19G	18G
1/2"	●	●	●								
5/8"			●	●	●						
1"			●	●	●	●	●	●	●	●	●
1 1/4"						●	●	●	●	●	●
1 1/2"						●	●	●	●	●	●

V Indications for use

The Sterile Hypodermic Needles for Single Use are intended to be used with a luer lock or luer slip syringe and injection devices for general purpose fluid injection/aspiration.

VI Comparison of technological characteristics with the predicate devices

The Sterile Hypodermic Needles for Single Use have the same intended use, technology, and design; and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the Sterile Hypodermic Needles for Single Use and predicate devices do not alter suitability of the proposed device for its intended use.

Device feature	Subject Device	Predicate Device K180417
Indications for use	The Sterile Hypodermic Needles for Single Use are intended to be used with a luer lock or luer slip syringe and injection devices for general purpose fluid injection/aspiration.	The Sterile Hypodermic Needles for Single Use are intended to be used with a luer slip or luer slip syringe and injection devices for general purpose fluid injection/aspiration.
Product code	FMI	FMI
Regulation number	21 CFR 880.5570	21 CFR 880.5570
Class	II	II
Principle of operation	For manual use only	For manual use only
Intended user	Medical professionals and trained care givers	Medical professionals and trained care givers

Device feature	Subject Device		Predicate Device K180417	
Environment of use	Hospitals and clinics		Hospitals and clinics	
Needle gauge	30G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G		14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G, 30G	
Length	1/2" 、5/8"、1"、1 1/4"、1 1/2"		¼", 5/16", ½", 5/8", ¾", 1", 1 ½", 2", 2 ½"	
Type of wall	Normal wall or thin wall		Not provided	
blade angle	Short bevel or long bevel		Not provided	
Main structure and materials	Needle hub	Polypropylene	Needle hub	Polypropylene
	Needle tube	Stainless steel	Needle	Stainless steel
	Protective cover	Polypropylene	Protective cap	Polypropylene
Needle hub Color	Color-coded per ISO 6009		Color-coded per ISO 6009	
Single use	Yes		Yes	
Performance specifications	Complies with ISO 7864:2016 *Sterile hypodermic needles for single use - Requirements and test methods,* ISO 9626:2016 *Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods,* ISO 80369-7:2021 *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications,* ISO 80369-20:2015 *Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods*		Complies with ISO 7864:2016 *Sterile hypodermic needles for single use - Requirements and test methods,* ISO 9626:2016 *Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods*	
Sterilization	EO		EO	
SAL	10^{-6}		10^{-6}	
Pyrogen	Non-pyrogenic		Non-pyrogenic	
Biocompatibility	The biocompatibility evaluation for the subject device was conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical		Complies with ISO 10993. The testing is as follows: The devices meet biocompatibility endpoints for cytotoxicity, irritation, sensitization, systemic toxicity,	

Device feature	Subject Device	Predicate Device K180417
	Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA and the "Use of International Standard ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process", June 16, 2016. The syringe of testing included the following tests: Cytotoxicity; Skin sensitization; Hemolysis; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity. The evaluation of the above testing items meets the requirements	hemolysis and material-mediated pyrogens.
Labeling	Meets the requirements of 21 CFR Part 801	Meets the requirements of 21 CFR Part 801

VII Performance data

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

Biocompatibility testing

Biocompatibility of the Sterile Hypodermic Needles for Single Use, Sterile Safety Hypodermic Needles for Single Use were 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)" and USP <788>. 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

All evaluation acceptance criteria were met.

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

Sterilization and shelf-life testing

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. The shelf-life of the Sterile Hypodermic Needles for Single Use, Sterile Safety Hypodermic Needles for Single Use is determined based on stability study which includes ageing test. The shelf-life of the Sterile Hypodermic Needles for Single Use, Sterile Safety Hypodermic Needles for Single Use is five (5) years.

Sterilization Evaluation	ISO11135: 2014
EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacterial Endotoxin testing	USP42-NF37<85>
Sterile Barrier Packaging Testing & Shelf-Life Evaluation	Seal Strength ASTM F88/F88M-15 Dye Penetration ASTM F1929-15 Creep/Burst Testing ASTM F1140/F1140M-13 Gross Leakage ASTM F2096-11 Antibacterial Testing DIN 58953-6:2010

Performance testing

Performance testing is performed according to the following standards:

- ISO 7864: 2016

Cleanliness	Clause 4.3 of ISO 7864: 2016
Limits for acidity or alkalinity	Clause 4.4 of ISO 7864: 2016
Limits for extractable metals	Clause 4.5 of ISO 7864: 2016
Tubular needle designation	Clause 4.6 of ISO 7864: 2016
Colour coding	Clause 4.7 of ISO 7864: 2016
Needle hub	Clause 4.8 of ISO 7864: 2016, ISO 80369-7 and ISO 6009
Needle cap	Clause 4.9 of ISO 7864: 2016
Needle tube (Tolerance on length, Freedom from defects, Lubricant)	Clause 4.10 of ISO 7864: 2016
Needle Point	Clause 4.11 of ISO 7864: 2016
Bond between Tube and Hub	Clause 4.12 of ISO 7864: 2016
Patency of Lumen	Clause 4.13 of ISO 7864: 2016

- ISO 9626:2016

Surface finish and visual appearance	Clause 5.2 of ISO 9626:2016
Cleanliness	Clause 5.3 of ISO 9626:2016
Limits for acidity and alkalinity	Clause 5.4 of ISO 9626:2016
Size designation	Clause 5.5 of ISO 9626:2016
Dimensions	Clause 5.6 of ISO 9626:2016

Stiffness	Clause 5.8 of ISO 9626:2016
Resistance to breakage	Clause 5.9 of ISO 9626:2016
Resistance to corrosion	Clause 5.10 of ISO 9626:2016

- ISO 80369-7:2016

Dimensional requirements for luer connectors.	Clause 5 of ISO 80369-7: 2021
Fluid leakage (Positive pressure liquid leakage)	Clause 6.1.3 of ISO 80369-7: 2021
Sub-atmospheric pressure air leakage	Clause 6.2 of ISO 80369-7: 2021
Stress cracking	Clause 6.3 of ISO 80369-7: 2021
Resistance to separation from axial load	Clause 6.4 of ISO 80369-7: 2021
Resistance to separation from unscrewing	Clause 6.5 of ISO 80369-7: 2021
Resistance to overriding	Clause 6.6 of ISO 80369-7: 2021

VIII Conclusion

The Sterile Hypodermic Needles for Single Use are substantially equivalent to its predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.