October 7, 2021

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

Re: K211211
Trade/Device Name: Sterile syringes for single use with/without needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 26, 2021
Received: September 1, 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)*
K211211

Device Name
Sterile syringes for single use with/without needle

Indications for Use *(Describe)*
The Sterile syringes for single use with/without needle are intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

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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K211211 510(k) summary

Date Prepared: 10.07.2021

510(K) Number: K211211

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 syringes for single use with/without needle
Common Name: Piston Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product code: FMF
Review Panel: General Hospital

Traditional 510(k) – New device, no prior submission.

III Predicate Devices

Trade name:	Sterile Hypodermic Syringe for Single use with/without Needle
Common name:	Piston Syringe
Classification:	Class II, 21 CFR 880.5860
Product Code:	FMF
Premarket Notification:	K112057
Manufacturer:	Shanghai Kindly Enterprise Division Group Company

IV Device description

The Sterile Syringes for Single Use with/without Needle is a three-piece, sterile, single use hypodermic syringe with a 6% (Luer) male connector/lock fitting in various sizes. The

syringe assembly consists of a lubricated polypropylene barrel with a graduated scale, a lubricated synthetic rubber stopper and a polypropylene plunger rod. The plunger rod is pulled back to aspirate fluids or depressed to inject or expel fluids.

V Indications for use

The Sterile syringes for single use with/without needle are intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

VI Comparison of technological characteristics with the predicate devices

The Sterile Syringes for Single Use with/without Needle have 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 Sterile Syringes for Single Use with/without Needle and predicate devices do not alter suitability of the proposed device for its intended use.

Table 5-1 Substantial equivalence discussion – Sterile syringes for single use with/without needle

Device feature	Subject Device	Predicate Device K112057	Comments
Indications for use	The Sterile Syringes for Single Use with/without Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	Same
Product code	FMF	FMF	Same
Regulation number	21 CFR 880.5860	21 CFR 880.5860	Same
Principle of operation	For manual use only	For manual use only	Same
Intended user	Medical professionals and trained care givers	Medical professionals and trained care givers	Same
Environment of use	Hospitals and clinics	Hospitals and clinics	Same
Nozzle type	Luer slip; Luer lock	Luer slip; Luer lock	Same
Lubricant for barrel	Silicone oil	Silicone oil	Same
Barrel transparency	Transparent and clear	Transparent and clear	Same
Gradations legibility	Legible	Legible	Same
Syringe volume	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml, 100ml	1ml, 3ml, 5ml, 6ml, 10ml, 20ml, 30ml, 35ml and 50ml	Difference 1
Needle gauge	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 30G	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	

Needle length	$^{1}/_{2}$", $^{5}/_{8}$", 1", $1\,^{1}/_{4}$", $1\,^{1}/_{2}$"	Not available	
Needle hub	Color-coded per ISO 6009	Color-coded per ISO 6009	Same
Single use	Yes	Yes	Same
Performance specifications	Complies with ISO 7886-1:2017 Sterile Hypodermic syringes for single use - Part 1: Syringes for manual use	Complies with ISO 7886-1:2017 Sterile Hypodermic syringes for single use - Part 1: Syringes for manual use	Same
Sterilization	EO	EO	Same
SAL	10^{-6}	10^{-6}	Same
Materials	Barrel: PP Plunger: PP Piston: Silicone Rubber Needle: Stainless 304 Needle hub: PP	Barrel: PP Plunger: PP Piston: Isoprene Rubber Needle: Stainless 304 Needle hub: PP	Difference 2
Pyrogen	Non-pyrogenic	Non-pyrogenic	Same
Biocompatibility	The biocompatibility evaluation for the subject device was conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical 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	The biocompatibility evaluation for the subject device was conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical 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	Same
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Same

Discussion:

Difference 1

The syringe volume and length of subject devices are different from the predicate device. However, this difference is just in dimension. Different needle specification will be

selected by physician per patient's condition. This difference does not affect intended use. In addition, differences were addressed through ISO 7886-1, ISO 7864, ISO 9626 and ISO 80369-7. Therefore, the differences on syringe volume, needle gauge and length do not raise different question of safety and effectiveness.

Difference 2
The material of subject device is similar as predicted device. However, the subject devices were tested and comply with ISO 10993 series standards. The differences on material do not affect substantial equivalence.

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

Biocompatibility testing
Biocompatibility of the Sterile syringes for single use with/without needle 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; Skin sensitization; Hemolysis; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity. All evaluation acceptance criteria were met.

Sterilization and shelf life testing
The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters.

The testing is performed according to the following standards:

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008

Package integrity testing was conducted on the final, packaged, and sterile devices after environmental conditioning and simulated transportation. All packaging was deemed acceptable for protection of product and sterility maintenance.

The shelf life of 5 year is determined based on stability studies which include ageing test according to FDA recognized standard ASTM F1980-16.

The testing is performed according to the following standards:

Seal strength	ASTM F88/F88M-15
Dye penetration	ASTM F 1929-2015

Performance testing
Performance testing is performed according to the following standards:

- 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
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use.
- USP <788> Particulate Matter in Injections

VIII Conclusion

The predicate device submission was cleared with Sterile Hypodermic Syringe for Single use with/without Needle, Sterile Insulin Syringe for single use, with needle and Sterile Hypodermic Needle for single use. The subject device is being compared to only the predicate Sterile Hypodermic Syringe for Single use with/without Needle. The subject device, Sterile Syringes for Single Use with/without Needle, is substantially equivalent to its predicate devices (Sterile Hypodermic Syringe for Single use with/without Needle). The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.