June 12, 2024

Perfect Medical Industry (VN) Co., Ltd.
℅ Thomas Huang
Lead Consultant, Quality and Regulatory Affairs
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K232950
Trade/Device Name: Sterile Disposable Syringe, Sterile Disposable Syringe with Needle, Sterile Disposable Syringe with Safety Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI, MEG
Dated: May 9, 2024
Received: May 9, 2024

Dear Thomas Huang:

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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
Division of Drug Delivery and General
Hospital Devices, and Human Factors
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232950

Device Name
Sterile Disposable Syringe, Sterile Disposable Syringe with Needle, Sterile Disposable Syringe with Safety Needle

Indications for Use *(Describe)*
Sterile Disposable Syringe is intended to be used to withdraw solutions and insert solutions into patient's body. Sterile Disposable Syringe with needle are intended to be used with a luer slip or luer lock syringe to withdraw solutions and insert solutions into patient's body. Sterile Disposable Syringe with safety needle is intended to be used with a luer slip or luer lock syringe to withdraw solutions and insert solutions into patient's body. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

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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510(k) Summary

510(k) Submitter
[K232950]

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Date Prepared May 03, 2024

I Device

Trade Name of Device:	Sterile Disposable Syringe, Sterile Disposable Syringe with Needle, Sterile Disposable Syringe with Safety Needle
Regulation Number:	21 CFR 880.5860, 21 CFR 880.5570
Classification Name:	Piston syringe
Product Code:	FMF, FMI, MEG
Regulation Name:	Piston Syringe
Common name	Syringes with Needle
Regulatory Class	II
Review Panel	Injection

II Predicate Devices

510k Number	K211329
Trade Name of Device:	Sterile Disposable Syringe with Safety Needle, Sterile Disposable Syringe with Needle, Sterile Disposable Syringe, Sterile Disposable Safety Needle, Sterile Disposable Needle
Regulation Number:	21 CFR 880.5860, 880.5570
Regulation Name:	Piston Syringe
Regulatory Class	II
Product Code:	MEG, FMF, FMI

III Device Descriptions

The Sterile Disposable Syringe consists of barrel, plunger and piston. The proposed device is available in luer slip or luer lock connector types which are intended to be connected with a hypodermic needle. The Sterile Disposable Syringe with Needle is available in 18-19, 21-26 gauge and 3/8 – 2 inch lengths. The proposed device is also available with fixed needle 25-26 gauge and 1/2 – 1 inch length. The Sterile Disposable Syringe with Safety Needle is available in 18-19, 21-26 gauge and 3/8 – 2 inch lengths. The safety cap will be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks. All subject device are operated manually.

IV Indications for use

Sterile Disposable Syringe are intended to be used to withdraw solutions and insert solutions into patient's body. Sterile Disposable Syringe with needle are intended to be used with a luer slip or luer lock syringe to withdraw solutions and insert solutions into patient's body. Sterile Disposable Syringe with safety needle are intended to be used with a luer slip or luer lock syringe to withdraw solutions and insert solutions into patient's body. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

V Technological Characteristics Comparison

VI-1: Comparison of Piston Syringe

Attribute	Subject Device	Predicate Device, K211329	Comparison
Syringe Type:	FMF, FMI, MEG	FMF, FMI, MEG	Same
Indications for Use:	1. Sterile Disposable Syringe are intended to be used to withdraw solutions and insert solutions into patient's body. 2. Sterile Disposable Syringe with needle are intended to be used with a luer slip or luer lock syringe to withdraw solutions and insert solutions into patient's body. 3. Sterile Disposable Syringe with safety needle are intended to be used with a luer slip or luer lock syringe to withdraw solutions and insert	1. The Sterile Disposable Syringe is a sterile luer slip or luer lock syringe which is intended to be used with a hypodermic needle for the aspiration and injection of fluids for medical purpose. 2. The Sterile Disposable Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose. 3. The Sterile Disposable Syringe with Safety Needle is intended for use in the aspiration	Same

	solutions into patient's body. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.	and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks. 4. The Sterile Disposable Needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose. 5. The Sterile Disposable Safety Needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk	

		of accidental needle sticks.	
Principle of Operation	For manual use only	For manual use only	Same
Specific Drug Use	N/A	N/A	Same
Length	Complied with ISO 7886-1:2017	Complied with ISO 7886-1:2017	Same
Diameter	Complied with ISO 7886-1:2017	Complied with ISO 7886-1:2017	Same
Tip Type	Luer lock, luer slip, fixed	Luer lock, luer slip	Different, see analysis below
Volume	1mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50mL	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30m l, 50ml, 60ml	Different, see discuss below
Needle Length	3/8", 1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2", 2"	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"	Different, see discuss below
Needle Gauge	18G, 19G, 21G, 22G, 23G, 24G, 25G, 26G	23G	Different, see discuss below
Needle Tip Configuration	Bevel tip Complied with ISO 7864:2016	Complied with ISO 7864:2016	Same, see analysis below
Nozzle Type	Luer lock, luer slip	Luer lock, luer slip	Same
Barrel Marking Spec	Graduated scale: 1cc: 0.01 mL; 3cc:0.1 mL; 5cc, 10cc:0.2 mL; 20cc, 30cc, 50cc:1mL. Length of scale (Min): 1cc: 57mm, 3cc: 27mm, 5cc: 36mm, 10cc: 44mm, 20cc: 52mm, 30cc:67mm, 50cc: 75mm Complied with ISO 7886-1:2017	Complied with ISO 7886-1:2017	Same, see analysis below
Gradations Legibility	Complied with ISO 7886-1:2017	Complied with ISO 7886-1:2017	Same

Needle Cover Dimensions	ID : min 5.9mm; OD: min 7.2mm; Length: 42mm~70mm Complied with ISO 7864:2016	Complied with ISO 7864:2016	Same, see analysis below
Needle Cover Color	unpigmented Complied with ISO 7864:2016	Complied with ISO 7864:2016	Same, see analysis below
Lubricant Composition	Silicone oil	Silicone oil	Same
Lubricant Amount/cm2	Complied with ISO 7886-1:2017	Complied with ISO 7886-1:2017	Same
Barrel Transparency	Transparent Complied with ISO 7886-1:2017	Complied with ISO 7886-1:2017	Same, see analysis below
Delivery Accuracy	1cc and 3cc: ±5% of expelled volume when it filled equal to or greater than half nominal capacity; ±(1.5% of volume + 2% of expelled volume when it filled less than half nominal capacity 5cc, 10cc, 20cc, 30cc, 50cc: ±4% of expelled volume when it filled equal to or greater than half nominal capacity; ±(1.5% of volume + 1% of expelled volume when it filled less than half nominal capacity,	Complied with ISO 7886-1:2017	Same, see analysis below

	Complied with ISO 7886-1:2017		
Reuse Durability	Single use	Single use	Same
Needle Cover Strength	0.4-1.8kgf Complied with ISO 7864:2016	Complied with ISO 7864:2016	Same, see analysis below
Hub/Needle Bond Strength	Min. 22-69N Complied with ISO 7864:2016	Complied with ISO 7864:2016	Same, see analysis below
Biocompatibility	Cytotoxicity, Irritation, Sensitization, Systemic Toxicity, Hemolysis, Pyrogen	Cytotoxicity, Irritation, Sensitization, Systemic Toxicity, Hemolysis, Pyrogen	Same
Materials	Gasket: Polyisoprene Rubber; Barrel: Polypropylene (PP); Plunger: Polypropylene (PP); Needle: Stainless Steel 304; Needle cap: Polypropylene (PP)	Gasket: Polyisoprene Rubber; Barrel: Polypropylene (PP); Plunger: Polypropylene (PP); Needle: Stainless Steel SUS 304; Needle cap: Polypropylene (PP)	Same
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Sterilization method	EO Sterilized	EO Sterilized	Same
Environment of use	Hospital	Hospital	Same
Shelf life	3 years. Complied with ASTM F1980-07	5 years. Complied with ASTM F1980-07	Different, see analysis below
Transport conditions	Complied with ISTA 2A:2011	Not public	Different, see analysis

Difference Analysis:

Tip Type: The tip configuration of the proposed device is similar to the predicate device. However, this difference is in a fixed connector. The difference in technological characteristics does not raise new questions of safety and effectiveness. Connectivity to the needle is

assessed with performance data.

Volume: The Syringe volume for the subject device is different from the predicate device. However, this difference is in dimension. Different volume devices will be selected by the physician per the patient's condition. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Needle Length: The needle length for the subject device is different from the predicate device. This difference is in dimension. Different length devices will be selected by the physician per the patient's condition. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Needle Gauge: The needle size for the subject device is different from the predicate device. This difference is in dimension. Different size devices will be selected by the physician per the patient's condition. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Needle Tip Configuration: The needle tip for the subject device is different in needle point geometry from the predicate device. This difference will not raise new questions of safety and effectiveness of the subject device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Barrel Marking Spec: The Syringe Barrel Marking Spec for the subject device is different from the predicate device. However, different Marking Specs will be dependent on the Syringe volume. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Needle Cover Dimensions: The Needle Cover Dimensions for the subject device is different from the predicate device. However, this difference is in dimension. Different Needle Cover Dimensions will be dependent on the Needle Length. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Needle Cover Color: The Needle Cover Color for the subject device is different from the predicate device. However, this difference is in Color. Different colors will be dependent on either pigmented or unpigmented material. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Barrel transparency: The Barrel transparency for the subject device is different from the predicate device. However, this difference is in color. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Delivery accuracy: The Delivery accuracy for the subject device is different from the predicate device. However, this accuracy is dependent on the Syringe volume. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Needle cover strength: The needle cover strength for the subject device is different from the predicate device. However, differences are assessed via performance data and conformance to the same ISO standards as the predicate device. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device.

Hub/needle bond strength: The hub/needle bond strength for the subject device is different from the predicate device. However, differences are assessed via performance data and conformance to the same ISO standards as the predicate device. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device.

Shelf life: The Shelf life for subject device is different from the predicate device. However, differences are assessed via performance data and conformance to the same ISO standards as the predicate device. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device.

Transport conditions: The Transport conditions for the subject device is different from the predicate device. However, differences are assessed via performance data and conformance to the same ISO standards as the predicate device. Therefore, this difference will not raise new questions of safety and effectiveness of the subject device.

VI Summary of Non-clinical Testing (Bench)

Nonclinical tests were conducted to verify that the proposed device met all design specifications to establish Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and skin sensitization
- ISO 10993-23:20212021 Biological evaluation of medical devices- Part 23: Test for irritation
- ISO 10993-11:2017 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- ISO 10993-4:2017 Biological evaluation of medical devices--Part 4: Selection of Tests for Interactions with Blood
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for

Flexible Packaging by Visual Inspection

- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials. (Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- 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 6009:2016 Hypodermic needles for single use – Colour coding for identification
- 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
- ISO 10993-7:2008 Biological Evaluation of Medical Device-Part 7: Ethylene Oxide Sterilization Residuals
- ISO 23908:2011 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- USP<85> Bacterial Endotoxins Test
- USP<151> Pyrogen Test
- USP<788> Particulate Matter in Injections
- Guidance on the Content of Premarket Notification [510(K)] Submissions for Hypodermic Single Lumen Needles
- Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes
- Medical Devices with Sharps Injury Prevention Features - Guidance for Industry and FDA Staff

VII Conclusion

The subject device has the same indications for use as the predicate device. Any minor differences in the technological characteristics of the subject device when compared to the predicate device have been successfully evaluated through appropriate safety and performance testing which demonstrates that the subject device, when compared to the predicate device does not raise any new questions of safety and effectiveness. Therefore, the subject device has been determined to be substantially equivalent to the predicate device.