December 12, 2025

Vault Paragon Group, Inc
Sari Luciano
Managing Partner
199 E 52nd Street Ste. 240
Garden City, Idaho 83714

Re: K250847
Trade/Device Name: VaporShield
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG, FMI, ONB
Dated: November 11, 2025
Received: November 12, 2025

Dear Sari Luciano:

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.

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

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)*
K250847

Device Name
VaporShield

Indications for Use *(Describe)*
The VaporShield™ is a sterile, single-use, closed system transfer device (CSTD), incorporating a preassembled Drug Vial holder (DVH) and Syringe (1mL, 22GA). The preassembled device is intended for medication draw from a drug vial only. After medication draw, the DVH is removed from the syringe, and the syringe is used for direct injection of hazardous and non-hazardous medication via subcutaneous or intramuscular administration. The syringe incorporates a safety mechanism which automatically retracts the needle inside the device for drug containment, and prevention of accidental needlesticks and device reuse. The VaporShield mechanically prevents drug transfer external to the device to minimize individual and environmental drug exposure. The VaporShield is intended for use by medical professionals who prepare/administer injection(s) to adults and adolescents in healthcare facilities. The device is not intended for neonates (<28 days old), infants (< 2 yrs old), or children (> 2 yrs. old – 12 yrs. old). The VaporShield Device is not intended for Compounding, Reconstitution, Phlebotomy, Intravenous injection, Intraperitoneal injection, or Intrathecal injection.

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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K250847 - 510K Summary

Submitter Information

Company Name:	Vault Paragon Group Inc.
Company Address:	199 E 52nd Street, Ste. 240 Garden City, ID 83714
Company Phone:	(858) 945 -3651
Contact Person:	Sari Luciano Managing Partner sluciano@vpgmed.com
Date:	December 12, 2025

Device Identification

Device Trade Name:	VaporShield
Common Name:	Syringe, Antistick, Closed System Transfer Device
Classification Name(s):	Piston Syringe, Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System
Regulation(s):	880.5860; 880.5570; 880.5440
Device Class:	Class II
Product Code(s):	FMF, MEG, FMI, ONB
Advisory Panel:	General Hospital

Identification of Predicate Devices

The Subject Device is substantially equivalent to the following device:

Device Name	Classification Regulation	Product Code	510(K) Number	Clearance Date
PowerPAK Syringe	880.5860; 880.5570	MEG, FMF, FMI	K220114	1/25/2023

Device Description

The VaporShield closed system transfer device (CSTD) is sterile, for single use, and is intended for direct injection of hazardous or non-hazardous drugs. A single configuration includes a 1 mL syringe, 22G cannula, and is pre-assembled with a Drug Vial Holder (DVH). Preassembly of the syringe and drug vial holder components are interlocked via a flex tab snap-fit connection. During drug draw, the DVH ensures a stable connection between the drug vial and syringe. The VaporShield has three (3) settings, two for needle length, and one (1) for safety. The DVH can be removed from the syringe when the syringe is placed in locked setting.

The VaporShield includes a safety mechanism that is manually activated by full plunger depression. When activated, the safety mechanism retracts the needle inside the plunger rod for containment, preventing accidental needlestick, and disallowing device reuse.

Syringe is intended for parenteral injection (subcutaneous / intramuscular).

Indications for Use

The VaporShield™ is a sterile, single-use, closed system transfer device (CSTD), incorporating a preassembled Drug Vial holder (DVH) and Syringe (1mL, 22GA). The preassembled device is intended for medication draw from a drug vial only. After medication draw, the DVH is removed from the syringe, and the syringe is used for direct injection of hazardous and non-hazardous medication via subcutaneous or intramuscular administration. The syringe incorporates a safety mechanism which automatically retracts the needle inside the device for drug containment, and prevention of accidental needlesticks and device reuse. The VaporShield mechanically prevents drug transfer external to the device to minimize individual and environmental drug exposure. The VaporShield is intended for use by medical professionals who prepare/administer injection(s) to adults and adolescents in healthcare facilities. The device is not intended for neonates (<28 days old), infants (< 2 yrs old), or children (> 2 yrs. old – 12 yrs. old). The VaporShield Device is not intended for Compounding, Reconstitution, Phlebotomy, Intravenous injection, Intraperitoneal injection, or Intrathecal injection.

Comparison of Technological Characteristics:

Table: Comparison of Subject Device and Predicate Device

Comparison Feature	Subject Device	Predicate Device	Same / Similar / Different
Device Name	**VaporShield**	**PowerPAK™ Syringe**	
Regulation Number	**21 CFR 880.5860 / 21 CFR 880.5570**	**21 CFR 880.5860 / 21 CFR 880.5570**	Same
Device Classification	**Class II**	**Class II**	Same
Product Code	**FMF, MEG, FMI, ONB**	**FMF, MEG, FMI**	Different (Comment 1)
Indications for Use	The VaporShield™ is a sterile, single-use, closed system transfer device (CSTD), incorporating a preassembled Drug Vial holder (DVH) and Syringe (1mL, 22GA). The preassembled device is intended for medication draw from a drug vial only. After medication draw, the DVH is removed from the syringe, and the syringe is used for direct injection of hazardous and non-hazardous medication via subcutaneous or intramuscular administration. The syringe incorporates a safety mechanism which automatically retracts the needle inside the device for drug containment, and prevention of accidental needlesticks and device reuse. The VaporShield mechanically prevents drug transfer external to the device to minimize individual and environmental drug exposure. The VaporShield is intended for use by medical professionals who prepare/administer injection(s) to adults and adolescents in healthcare facilities. The device is not intended for neonates (<28 days old), infants (< 2 yrs old), or children (> 2 yrs. old – 12 yrs. old). The VaporShield Device is not intended for Compounding, Reconstitution, Phlebotomy, Intravenous injection, Intraperitoneal injection, or Intrathecal injection.	The PowerPAK™ Syringe is indicated for general medical use in healthcare facilities by medical professionals for pediatric and adult population patients for aspiration and injection of fluids. Phlebotomy is not an intended use of this device.The PowerPAK™ Syringe is a 3mL syringe with a permanently attached needle system. Routes of Administration include subcutaneous, intradermal and intramuscular. Intravenous and Intraperitoneal are not intended uses of this device.The needle system contains an internal mechanism that retracts the needle inside the syringe after activation. Upon retraction, the needle is fully contained inside the syringe preventing reuse of the needle and accidental needlesticks during normal handling and disposal.	Different (Comment 1)
Drug Vial Holder	Yes	None	Different (Comment 2)
Syringe Type: Plunger, anti-Stick with Hypodermic Needle	No Change	ISO 7886-1:2017- Leakage during aspiration	Same
	No Change	ISO 7886-1:2017 - Determination of Dead Space	
	No Change	ISO 7886-1:2017 - Leakage during compression	
	No Change	ISO 7886-1:2017 - Piston operating force	
	No Change	Medical Devices with Sharps Injury Prevention features: Guidance for Industry & FDA Staff: Rate of flow simulating extreme pressure	

	No Change	ISO 7886-1:2017(en) - Limits for Extractable Metals	
	No Change	ISO 7886-1:2017(en) - Limits for Alkalinity/Acidity (Annex A) / ISO 7864-1:2016(en) - Limits for Alkalinity/Acidity	
Delivery Accuracy/Capacity Tolerance	No Change	ISO 7886-1:2017(en) - Graduated Tolerance Testing	Same
Hub/Needle Bond Strength	No Change	ISO 7864:2016 (en) - Needle bonding strength	Same
	No Change	USP 788 - Particulate Testing	
Retraction (Safety) Mechanism	No Change	ISO 23908:2011 - Needle Safety Mechanism - Activation force	Same
Re-use Prevention Features	No Change	ISO 7886-4:2018 - Re-use prevention feature	Same
Syringe Volume	1 mL	3 mL	Different (Comment 3)
Needle Length	59 mm (full needle length) .5 and .75 inches (usable length)	1.80 inches (usable length)	Different (Comment 4)
Needle Gauge: 22 GA	No Change	ISO 7864:2016 (en) - Needle fragmentation	Same
	No Change	ISO 7864:2016 (en) - Needle flow rate	
	No Change	ISO 7864:2016 (en) - Needle penetration & drag force	
	No Change	ISO 7864: 2016 (en) - Limits for Extractable Metals	
	No Change	ISO 7886-1:2017(en) - Limits for Alkalinity/Acidity (Annex A) / ISO 7864-1:2016(en) - Limits for Alkalinity/Acidity	
	No Change	ISO 9626:2016 - Needle Stiffness	
	No Change	ISO 9626:2016 - Needle Resistance to breakage	
	No Change	ISO 9626:2016 - Needle Resistance to corrosion	
Lubricant/Silicone	No Change	ISO 7864:2016 (en) - Needle Silicone quantity (lubricant)	Same
	No Change	ISO 7886-1:2017(en) - Silicone quantity (lubricant)	
Primary Package Barrier	No Change	ASTM D4169-16:2022 - Standard Practice for Performance Testing of Shipping Containers and Systems	Same
		ASTM F1886: 2016 - Visual Inspection	
		ASTM F2096:2011 - Bubble Emission	
		ASTM F88/F88M: 2015 - Seal Peel Strength	
Biocompatibility	No Change	ISO 10993-23: 2021 - Biological evaluation of medical devices - Intracutaneous (irritation)	Same
	No Change	ISO 10993-5:2009 - Biological evaluation of medical devices - part 5: Tests for in vitro cytotoxicity	Same

	No Change	ISO 10993-10:2010 / ISO 10993-23: 2021 - Biological evaluation of medical devices - part 10: Tests for irritation and skin sensitization	Same
	No Change	ISO 10993-4:2010 - Biological evaluation of medical devices - part 4: Tests for ASTM Hemolysis	Same
	No Change	ISO 10993-11:2010 / USP 151 - Biological evaluation of medical devices - part 11: Tests for pyrogenicity	Same
	No Change	ISO 10993-11:2017 - Biological evaluation of medical devices - part 11: Tests for Toxicity	Same
Sterilization Level and Method	Sterilization Ethylene Oxide (SAL 10^{-6})	Ethylene Oxide (SAL 10^{-6})	Same
Shelf Life	1 Year	1 Year	Same
Venting Path for Retraction Mechanism	Non-Venting: "ASTM F1140/F1140M -13 (Reapproved 2020) – Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages"	Venting	Different (Comment 5)
Vapor Containment Feature	"Vapor containment testing per the draft NIOSH Vapor Containment Performance Protocol, “Performance Test Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs”, Chemical characterization and toxicological risk assessment per ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management.	None	Different (Comment 6)
Human Factor Testing	No Change	Applying Human Factors & Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff (Feb 3, 2016)	Same
Chemical Characterization	ISO 10993-18: 2020 / AMD 1: 2022	None	Different (Comment 7)
Clinical Testing	None	None	Same

Comment 1	The product code ONB under the regulation 880.5440 was added as a secondary product code for the closed system transfer indication. Performance standards for regulation numbers are met by both devices. Vapor containment testing per the draft NIOSH Vapor Containment Performance Protocol was completed for the subject device in relation to product code ONB - specific for closed system transfer devices. Based on performance testing results, the added Closed System Transfer Device functionality and drug vial holder does not raise additional questions of safety and effectiveness when compared to the predicate device.
Comment 2	Performance Testing for device use with DVH during leakage tests evidences the Drug Vial Holder functions as designed, is securely attached to the syringe, and does not allow leakage when filling from a drug vial. The DVH does not raise additional questions of Safety and effectiveness when compared to the predicate device.
Comment 3	Performance testing per ISO 7886-1: 2017 Sterile hypodermic syringes for single use – Part 1: Syringes for manual use demonstrated that the difference in syringe volume between the predicate and the subject device does not raise additional question of safety and effectiveness.
Comment 4	The Vaporshield includes a 1 ml syringe with a single 22 GA needle; however, the usable (exposed) needle length of either 0.5 or 0.75 inches is controlled by sliding the shield up or down a single fixed needle, exposing less or more of the same needle length. Variance of device specification of usable needle length between the predicate and the subject device does not raise additional questions of safety and effectiveness. Performance testing per ISO 7864: 2016 Sterile hypodermic needles for single use – Requirements and test methods demonstrated that the difference in needle length between the predicate and the subject device does not raise additional question of safety and effectiveness.
Comment 5	Both the predicate and subject device are based on the same technology using a gas cell as the energy for the manually activated safety mechanism. The predicate device allowed propellant to vent out of the device into the exterior environment post activation of the safety mechanism. The subject device includes a sheath for containment. Non-clinical burst testing exposed components (gas cell/sheath) to elevated temperature and pressure until containment failure. Results evidence components can contain more than the maximum volume of propellant within the device. Based on performance testing and risk analysis, the materials used in the device performed as designed in form and function for the shelf life of the device. Labeling for proper storage to mitigate possible risks associated with risk to temperature are outlined on packaging. Leakage testing conducted evidences successful containment and the design variance in specification of subject device does not raise additional questions of safety and effectiveness when compared to the predicate device.
Comment 6	The Predicate device was not designed to function as a Closed System Transfer Device. The subject device testing results evidence equivalent or better performance to comparative device. The performance of the closed system transfer component was verified by vapor containment testing per the draft NIOSH Vapor Containment Performance Protocol. Chemical characterization and toxicological risk assessment per ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management, which was used to ensure that the device is appropriate for use with hazardous drugs. This additional functionality does not raise additional questions of safety and effectiveness for the subject device.
Comment 7	A Chemical Characterization was completed of the subject device. The report was also reviewed under a Toxicological Risk Assessment with a conclusion of a tolerable toxicological risk of systemic toxicity, genotoxicity, carcinogenicity, and developmental and reproductive toxicity associated with exposure to extractables from the ZEPH-2 Syringe device. Additional testing of device materials does not raise additional questions of safety and effectiveness for the subject device.

Non-Clinical Performance Testing:

Biocompatibility:

ISO 10993-1:2018 - Biological evaluation of medical devices - part 1: evaluation and testing within risk management

ISO 10993-5:2009 (2014) - 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 10993-4:2017 - Biological evaluation of medical devices - part 4: Selection of tests for interactions with blood

USP - NF 151 - Pyrogen Test (2017)

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

ASTM F 619 - 20: Standard Practice for Extraction of Medical Plastics (2020)

ASTM F 756 - 17: Standard Practice for Assessment of Hemolytic Properties of Materials (2017)

Performance:

ISO 7886-1:2017(en) - Sterile Hypodermic Syringes for single use - Part 1: Syringes for Manual Use (May 2017)
ISO 7864:2016 (en) - Sterile Hypodermic Needles for Syringe use - Requirements and Test Methods (Aug 01, 2016)
ISO 9626:2016 - Stainless Steel needle tubing for the manufacture of medical devices - Requirements and Test Methods (Aug 01, 2016)
ISO 7886-4:2018 - Sterile Hypodermic syringes for single use - Part 4: Syringes with re0use prevention feature (Nov 2018)
ISO 23908:2011 - Sharps Injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used or blood sampling (June 2011)
USP 788 - Particulate Matter in injections (July 2012)
FDA Guidance for Industry & FDA Staff Medical Devices with Sharps Injury Prevention Features (August 9, 2005)
ISO 10993-18: 2020 / AMD 1: 2022 - Biological Evaluation of Medical Devices - Part 18: Chemical Characterization of medical device materials within a risk management process Amendment 1: Determination of the uncertainty factor
ASTM: F1140/F1140M - 13 (Reapproved 2020) - Standard Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

Transportation:

ASTM D4169:2022 - Standard Practice for Performance Testing of Shipping Containers and Systems

Packaging:

ASTM F1886-16: 2016 - Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F2096-11: Reapproved 2019 - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F88/F88M: 2023 - Standard Test Method for Seal Strength of Flexible Barrier Materials

Sterilization:

ANSI/AAM ISO 11135-1:2014 (2015.04.15) - Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
ISO 10993-7:2008 (2008.10.15) - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009) AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)
ANSI/AAMISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product [Including Amendment 1 (2021)
AAMI: TIR28:2016/(R)2020: Product adoption and process equivalence for ethylene oxide sterilization

Biosafety (Endotoxin):

ANSI AAMI ST72: 2019 - Bacterial endotoxins - Test methods routine monitoring and alternatives to batch testing

Human Factor - Usability Study:

FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices (Dated: 2/3/2016)
FDA Guidance: Medical Devices with Sharps Injury Prevention Features (Dated: 8/9/2005)

Clinical Testing:

No clinical testing was conducted.

Conclusion: Non-clinical performance testing conducted on the predicate device, was also completed on the subject device to compare performance. To address additional functionality, containment testing (see above for specifics) was performed for the subject device and compared against currently US marketed device, indicated for drug/drug vapor containment. Results of the evaluations demonstrate the VaporShield CSTD 1mL is substantially equivalent to the predicate device.