Vault Paragon Group, Inc.
Sari Luciano
Managing Partner
189 3rd Street A101
Oakland, California 94607

Re: K220114
Trade/Device Name: PowerPAK™ Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: December 21, 2022
Received: December 22, 2022

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 (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,

Courtney Evans -S
Digitally signed by Courtney Evans -S
Date: 2023.01.25 18:00:01 -05'00'

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)* K220114

Device Name
PowerPAK Syringe

Indications for Use *(Describe)*

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.

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.

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K220114 510(K) SUMMARY

Submitter Information:

Company Name:	Vault Paragon Group, Inc. on behalf of L.O.M Laboratories
Company Address:	189 3rd Street, A101 Oakland, CA 94607
Company Phone:	858-945-3651
Contact Person:	Sari Luciano Owner sluciano@vpgmed.com
Date:	January 23, 2023

Device Information Information:

Device Trade Name:	PowerPAK™ Syringe
Common Name:	Syringe, Antistick
Classification Name(s):	Piston Syringe, Antistick Syringe, Hypodermic Single Lumen Needle
Regulation:	880.5860, 880.5570
Device Class:	Class II
Product Code:	FMF, MEG, FMI
Advisory Panel:	General Hospital

Predicate Device:

The Subject Device is substantially equivalent to the following device:

Device Name	Classification Regulation	Product Code	510(K) Number	Clearance Date
BD Integra Syringe	880.5860	FMF, MEG	K023752	2/7/2003

Device Description

The PowerPAK™ syringe is single-use, non-reusable, sterile safety syringe containing a 22GA needle with a usable needle length of 1.80 inches and a syringe capacity of 3mL. The PowerPAK™ Syringe is indicated for general medical use by healthcare providers in the aspiration and injection of fluids via subcutaneous, intradermal, and intramuscular routes of administration. Phlebotomy and intravenous use are not an intended use of this device.

The PowerPAK™ syringe is a 3mL safety syringe with a permanently attached needle system containing an internal mechanism that retracts the needle inside the plunger rod of the syringe to prevent reuse of the syringe and accidental needle sticks during normal handling and disposal. Activation of the syringe occurs when the forward plunger movement punctures the propellant gas cell inside the needle assembly and initiates needle retraction. Propellant is the same medical grade propellant currently used in legally marketed dose inhalers.

The subject device is a single use, non-reusable, sterile safety syringe comprised of three main components including a Plunger, Syringe body, and Needle System.

Indications for Use

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.

Comparison of Technological Characteristics:

Table 5.1: Comparison of Subject Device and Predicate Device			
Comparison Feature	**Subject Device**	**Predicate Device**	**Same / Similar / Different**
Device Name	**PowerPAK™ Syringe**	**BD Integra™ Syringe**	
Regulation Number	**21 CFR 880.5860 / 21 CFR 880.5570**	**21 CFR 880.5860**	Similar (Comment 1)
Device Classification	**Class II**	**Class II**	Same
Product Code	**FMF, MEG, FMI**	**FMF, MEG**	Similar (Comment 2)
Indications for Use	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.	The BD Integra Syringe is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin. It is not intended to be used for phlebotomy. The Insulin syringe has scale lines in insulin units and is used for insulin injections. The tuberculin syringe can be used for any of the 3 types of common injections (intra-dermal, intra-muscular, subcutaneous). The BD Integra ™ 1ml Syringe has a permanently attached needle. The BD Integra™ contains a tool used to cut through the hub and stopper allowing the needle to become retracted inside the plunger rod of the syringe after use. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.	Similar (Comment 3)
Syringe Type	Plunger, anti-Stick with Hypodermic Needle	Plunger, anti-Stick with Hypodermic Needle	Same
Safety Features	Active Safety Feature, manually activated by user	Active Safety Feature, manually activated by user	Same
Tip Type	Tri-Beveled Tip	Tri-Beveled Tip	Same
Volume	3 mL	1mL and 3mL	Similar (Comment 4)

Comparison Feature	Subject Device	Predicate Device	Same / Similar / Different
Needle Length	1.80 inches (usable length)	22G: 1.5 inches (usable length)	Similar (Comment 5)
Needle Gauge	22 G	3mL (G): 21, 22, 23, 25G 1mL (G): 30-25	Similar (Comment 6)
Needle Tip Configuration	15 oC regular point	15 oC regular point	Same
Nozzle Type	Needle Assembly & syringe not separable	Needle hub Locking-fit; Needle & syringe not separable	Similar (Comment 7)
Barrel Marking Specs	Scales as required by ISO 7886-1	Scales as required by ISO 7886-1	Same
Gradations Legibility	Legible according to ISO 7886-1	Legible according to ISO 7886-1	Same
Needle Cover Color	Traditional Cover comply to ISO 7864	Traditional Cover comply to ISO 7864	Same
Lubricant Amount	Comply to ISO 7864 & ISO 7886-1	Comply to ISO 7864 & ISO 7886-1	Same
Barrel Transparency	Clear as required by ISO 7886-1	Clear as required by ISO 7886-1	Same
Delivery Accuracy/Capacity Tolerance	Comply to ISO 7886-1	Comply to ISO 7886-1	Same
Hub/Needle Bond Strength	Conform to ISO 7864	Conform to ISO 7864	Same
Re-use Prevention Features	Conform to ISO 7886-4 ; and FDA Guidance, Submission for Medical Devicewith Sharps Injury Prevention Features	Conform to ISO 7886-4	Similar (Comment 8)
Re-use Durability	Can't be re-used as required by ISO 7886-4	Can't be re-used as required by ISO 7886-4	Same
Primary Package Barrier	Sterile Barrier of primary package according to ISO 11607-1/2	Sterile Barrier of primary package according to ISO 11607-1/2	Same
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993	Same
Performance	Conforms to ISO 7864, ISO 7886-1& ISO 7886-4	Conforms to ISO 7864, ISO 7886-1& ISO 7886-4	Same
Labeling	Conforms to ISO 7886, ISO 7886-1& ISO 7886-4, and 21 CFR Part 801	Conforms to ISO 7886, ISO 7886-1& ISO 7886-4, and 21 CFR Part 801	Same
Sterilization Level and Method	Ethylene Oxide (SAL 10^{-6})	Ethylene Oxide (SAL 10^{-6}); Gamma sterilization	Similar (Comment 9)
Shelf Life	1Year	5 Years	Different (Comment 10)
Retraction (Safety) Mechanism	Manual activation	Manual activation	Same
Venting Path for Retraction Mechanism	Venting	No Venting	Different (Comment 11)

Comment 1: Performance standards for both regulation numbers are are met by the subject device. Additional regulation number listed for subject device does not raise additional questions in safety and efficacy.

Comment 2: Standards for predicate product codes (FMF, MEG) and additional product code (FMI) listed for subject device have been met and do not raise additional questions in safety and efficacy as evidenced by performance testing.

Comment 3: Intended Use of the subject device falls within the intended use of the predicate and does not raise additional questions of safety and efficacy.

Comment 4: The additional device configurations for the predicate does not raise additional questions of safety and efficacy for the subject device as evidenced by performance testing.

Comment 5: Variance in device specification does not raise additional questions of safety and efficacy as evidenced by performance testing.

Comment 6: Variance in the predicate device specification for the 1mL and a 3mL, does not raise additional questions of safety and efficacy for the 3mL subject device as evidenced by performance testing.

Comment 7: Variance in device specification does not raise additional questions of safety and efficacy as evidenced by performance testing.

Comment 8: Predicate 510(k) submission does not indicate utility of FDA Guidance document, Submission for Medical Device with Sharps Injury Prevention Features (Aug 9, 2005). Guidance was published after predicate device clearance on Feb 7, 2003. Conformance with the previously used ISO standards for the predicate device, in addition to FDA guidance documentation does not raise additional questions of safety or efficacy for the subject device.

Commnet 9: The predicate and subject device both use EO (SAL 10^{-6}) for sterilization. The alternate method of sterilization used by the predicate does not raise additional questions of safety and efficacy for the subject device.

Comment 10: Variance in shelf life of the subject device does not raise additional questions of safety or efficacy as evidenced by aging and performance testing.

Comment 11: The predicate device operates on a spring mechanism for the energy source of retraction. The subject device uses propellant as the energy source for retraction. Both devices have the same performance requirements.

Propellant used for the retraction mechanism in the subject device is legally marketed in the United States and is used for dose inhalers (asthma sprays). The propellant does not raise additional questions of safety and efficacy.

Venting for the subject device is completed through multiple vents located on the back (posterior) end of the PowerPAK syringe. The septum located at the tip (anterior) of the needle system prevents propellant venting through the anterior of the syringe. Venting in the subject device does not raise additional questions of safety and efficacy.

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 - Biological evaluation of medical devices - part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2010 / ISO 10993-23: 2021 - Biological evaluation of medical devices - part 10: Tests for irritation and skin sensitization

ISO 10993-4:2010 - Biological evaluation of medical devices - part 4: Tests for ASTM Hemolysis

ISO 10993-11:2010 / USP 151 - Biological evaluation of medical devices - part 11: Tests for pyrogenicity

ISO 10993-11:2017 - Biological evaluation of medical devices - part 11: Tests for Toxicity

- Performance:

ISO 7886-1:2017- Leakage during aspiration

ISO 7886-1:2017 - Determination of Dead Space

ISO 7886-1:2017 - Leakage during compression

ISO 7886-1:2017 - Piston operating force

ISO 7886-1:2017(en) - Silicone quantity (lubricant)

ISO 7886-1:2017(en) - Limits for Extractable Metals

ISO 7864:2016 (en) - Needle fragmentation

ISO 7864:2016 (en) - Needle flow rate

ISO 7864:2016 (en) - Needle penetration & drag force

ISO 7864:2016 (en) - Needle bonding strength

ISO 23908:2011 - Needle Safety Mechanism

ISO 9626:2016 - Needle Stiffness

ISO 9626:2016 - Needle Resistance to breakage

ISO 9626:2016 - Needle Resistance to corrosion

ISO 7886-4:2018 - Re-use prevention feature

ISO 7886-1:2017(en) - Limits for Alkalinity/Acidity

ISO 7864: 2016 (en) - Limits for Extractable Metals

ISO 7864-1:2016(en) - Limits for Alkalinity/Acidity

ISO 7864:2016 (en) - Needle Silicone quantity (lubricant)

ISO 7886-1:2017(en) - Graduated Tolerance Testing

USP 788 - Particulate Testing
FDA Guidance for Industry & FDA Staff Medical Devices with Sharps Injury Prevention Features (August 9, 2005): The rate of fluid flow simulating extremes of pressure (e.g., the maximum force applied to the piston).

- Transportation:

ASTM D4169-16:2016 - Standard Practice for Performance Testing of Shipping Containers and Systems

- Packaging:

ASTM F1886: 2016 - Visual Inspection

ASTM F2096:2011 - Bubble Emission

ASTM F88/F88M: 2015 - Seal Peel Strength

- Sterilization: ANSI/AAMISO

ANSI/AAM ISO 11135-1:2014 Sterilization of healthcare products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.

ISO 10993-7:2008 - Biological evaluation of medical devices - Part 7L Ethylene oxide residuals

ANSI/AAMISO 11737-1:2006 Sterilization of medical devices - microbial methods - Part 1: Determination of a population of microorganisms on products
ANSI/AAMISO 11737-2:2009 Sterilization of medical devices - microbial methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterility process

- Biosafety (Endotoxin):

ANSI / AAMI ST72

- 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)

Results of the evaluations demonstrate that the Subject Device met the safety and performance requirements as it relates to its indication for use.

Conclusions Drawn from Nonclinical Evaluation:
The results of the evaluation demonstrate that the PowerPak™ Syringe is Substantially Equivalent to the predicate device as it pertains to the indications for use and device performance.