Velano Vascular
Tiffini Wittwer
Consulting Director Regulatory Affairs
221 Pine St #200
San Francisco, California 94104

Re: K200439
Trade/Device Name: Velano ExT™ Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: February 9, 2021
Received: February 22, 2021

Dear Tiffini Wittwer:

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 Payal Patel
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200439

Device Name
Velano ExT™ Extension Set

Indications for Use *(Describe)*
The Velano ExT™ Extension Set with needle-free connector is for single use only. Each port of the Velano ExT™ Extension Set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. The pressure rated port of the Velano ExT™ Extension Set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10 ml per second.

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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510(k) Summary K200439

February 23, 2021

Submitter:	Velano Vascular
Contact Person:	Tiffini Wittwer Regulatory Affairs Consultant Phone: (707) 799-6732 Email: twittwer@mededge.io
Trade Name:	Velano ExT™ Extension Set
Common Name:	Intravascular Administration Set
Classification:	Class II
Product Code:	FPA
Regulation:	880.5440
Predicate Device(s):	The subject device is equivalent to the following devices: • Velano Vascular Q2® Low Power Injector Extension Set (K182897)
Device Description:	The Velano ExT™ Extension Set is a sterile, single use, non-pyrogenic intravenous administration extension set comprised of an approximate 5" inch tube bonded to a T-connection port on one end and a female luer on the other end with a clamp in between. The T-connection port has a swabable, needle-free port on one side and a locking male luer on the other side. The device contains and integrated stabilizer under the swabable needle-free port. This component (along with IV tape / adhesive) is intended to help anchor the extension set to the patient. This device is not made with the plasticizer Diethylhexylphthalate (DEHP). The Velano ExT™ Extension Set is compatible with Velano Vascular PIVO™ devices.
Indication for Use:	The Velano ExT™ Extension Set with needle-free connector is for single use only. Each port of the Velano ExT™ Extension Set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. The pressure rated port of the Velano ExT™ Extension Set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10ml per second.

	Subject Device: Velano ExT™ Extension Set (K20439)	**Velano Vascular Q2® Low Pressure Power Injector Extension Set (K182897)**	**Comment**
Manufacturer	Velano Vascular	Velano Vascular	
Product Code	FPA	Same	
Regulation	880.5440	Same	
Classification	II	Same	

	Subject Device: Velano ExT™ Extension Set (K20439)	**Velano Vascular Q2® Low Pressure Power Injector Extension Set (K182897)**	**Comment**
Indications for Use	The Velano ExT™ Extension Set with needle-free connector is for single use only. Each port of the Velano ExT™ Extension Set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. The pressure rated port of the Velano ExT™ Extension Set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10ml per second.	Pressure Rated: The Q2® Low Pressure Power Injector Extension Set with needleless connector is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10ml per second. Non Pressure Rated: The Q2® Low Pressure Power Injector Extension Set with needleless connector is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration.	Wording changes for clarity and does not change the indication for use.
Intended Use	For administration of intravenous fluids to a patient's vascular system utilizing needle-free components and provide short-term intravascular or subcutaneous access using a variety of infusates (i.e. anesthesia drugs, chemotherapeutics, drugs, antibiotics, blood products, commonly used prep solutions). The device may also be used with low pressure power injectors rated for a maximum setting of 325 psi. The ExT™ Extension Set is compatible with Velano Vascular PIVO™ devices.	For administration of intravenous fluids to a patient's vascular system utilizing needle-free components and provide short-term intravascular or subcutaneous access using a variety of infusates (i.e. anesthesia drugs, chemotherapeutics, drugs, antibiotics, blood products, commonly used prep solutions). The device may also be used with low pressure power injectors rated for a maximum setting of 325 psi. The Q2® Extension Set is compatible with Velano Vascular PIVO™ devices.	Same

	Subject Device: Velano ExT™ Extension Set (K20439)	**Velano Vascular Q2® Low Pressure Power Injector Extension Set (K182897)**	**Comment**
Components	Tubing, Luer, Needle-less Connector, Male spin lock connector Non-fluid contacting: Stabilizer, pinch clamp, vented female luer lock cap	Tubing, Luer, Needle-less Connector, Male spin lock connector Non-fluid contacting: Pinch clamp, vented female luer lock cap	Flow rate, spin collar height and spin collar angle demonstrate that the difference does not alter the safety or effectiveness of the device
Dimensions	Overall Length: 5.0 inch (12.7cm)	Overall Length: 5.75 inch (14.6cm)	Flow rate, torque, and kink resistance testing demonstrate that the difference does not alter the safety or effectiveness of the device
Tubing	PVC	PVC	Same
Luer	Polycarbonate	Co-polyester	Biocompatibility testing demonstrate that the difference does not alter safety or effectiveness of the device
Needle-free Connector	NP Medical Proprietary Design Polycarbonate / silicone	Quest SwabSite Valve – Proprietary Design Polycarbonate / silicone	Microbial ingress, flow rate, pressure, and multiple activation testing demonstrate that the difference does not alter safety or effectiveness of the device
Stabilizing component	Yes	No	Flow rate, spin collar height and spin collar angle demonstrate that the difference does not alter the safety or effectiveness of the device
Principle of Operation	Swabable luer activation; direct injection, intermittent infusion, continuous infusion, aspiration	Swabable luer activation; direct injection, intermittent infusion, continuous infusion, aspiration	Same

	Subject Device: Velano ExT™ Extension Set (K20439)	Velano Vascular Q2® Low Pressure Power Injector Extension Set (K182897)	Comment
Use	Use with low pressure power injectors up to 325 psi and maximum flow rate of 10 mL/second.	Use with low pressure power injectors up to 325 psi and maximum flow rate of 10 mL/second.	Same
Priming volume	< 1 mL	< 1 mL	Same
Energy Source	User Operated	User Operated	Same
Disposable or Reusable	Disposable	Disposable	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Minimum SAL	1 x 10-6	1 x 10-6	Same
Packaging	Reinforced paper / nylon	Reinforced paper / nylon	Same

Functional and Safety Testing:

To verify that the device design meets its functional and performance requirements, representative samples of the device underwent mechanical testing. As a result of verification and validation activities and risk assessment, testing ensured the device design meets its functional and performance requirements. The following tests were performed:

- Visual inspection
- Simulated shipping
- Priming volume
- Microbial ingress
- Particulate
- Backpressure leak under normal use and power injection
- Flow rate for normal use and power injection
- Spin collar height and spin collar angle
- Simulated use
- Tubing bond strength

	• Multiple Engagement • Continuous Engagement • Activation Force • Tubing kink resistance ISO 11135:2014, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices ISO 10993-1, 2018 Biological Evaluation of Medical Devices USP <788> Particulate Matter in Injections ASTM D4169:2016 Standard practice for performance testing of shipping containers and systems ASTM F1980:2016 Standard guide for accelerated aging of sterile medical device packages. AAMI TIR28: 2016 Product Adoption and Process Equivalence for Ethylene Oxide Sterilization
Conclusion:	Velano Vascular considers the Velano ExT™ Extension Set device to be equivalent to the predicate devices, K182897, listed above. This conclusion is based upon the identical intended use, Indication for use, principles of operation, patient contacting materials, and sterilization processes.