March 26, 2019

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

Re: K182897
Trade/Device Name: Velano Vascular Q2® Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: February 19, 2019
Received: February 21, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sapana Patel -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K182897

Device Name
Velano Vascular Q2® Extension Set

Indications for Use *(Describe)*
Pressure Rated: The Q2® 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® 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.

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 K182897

Table 1: 510(k) Summary

Submitter:	Velano Vascular, Inc. 221 Pine St #200 San Francisco CA 94133
Contact Person:	Tiffini Wittwer Consulting Director Regulatory Affairs Phone: 707.799.6732 E-mail: tdiage@raechelon.com
Trade Name:	Velano Vascular Q2® Extension Set
Common Name:	Intravascular Administration Set
Classification:	Class II
Product Code:	FPA
Regulation	21 CFR 880.5440
Predicate Device(s):	The subject device is equivalent to the following devices: • K162804 – Q2® Low Pressure Power Injection Set
Device Description:	Sterile, single use non-pyrogenic intravenous administration extension set comprised of 5.75 inch tubing bonded to a male luer on one end and a T-connector on the other end with a clamp in between. The T-connector has a female luer on one side and a swabable, needle-free port on the other side. This device is not made with the plasticizer Diethylhexylphthalate (DEHP). The Velano Vascular Q2® Extension Set is compatible with PIVO™ devices.

Indication for Use:	Pressure Rated: The Q2® 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® 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.

	Predicate Device	Subject Device	Differences Rationale
510(k)	K162804	K182897	
Model #	95714	201-0001	
Brand Name	Q2 Low Pressure Power Injector Extension Set	Velano Vascular Q2 Extension Set	
Manufacturer	Quest Medical, Inc.	SAME	
FDA Regulation Number	21CFR 880.5440 Intravascular Administration Set	SAME	
FDA Class	II	SAME	
FDA Product Code	FPA	SAME	
Device Description	The device is an intravascular extension set available in one configuration that includes a needleless connector. The device is not made with the plasticizer Diethylhexylphthalate (DEHP).	Sterile, single use non-pyrogenic intravenous administration extension set comprised of 5.75 inch tubing bonded to a male luer on one end and a T-connector on the other end with a clamp in between. The T-connector has a female luer on one side and a swabable, needle-free port on the other side. This device is not made with the plasticizer Diethylhexylphthalate (DEHP). The Velano Vascular Q2® Extension Set is compatible with PIVO™ devices.	Additional testing for activation force, leak, and flow rate demonstrate that the addition of the T-connector and female luer dos not alter the safety or effectiveness of the device.

Intended Use	For administration of intravenous fluids to a patient's vascular system utilizing needlefree components. The device may be used with low pressure power injectors rated for a maximum setting of 325psi.	For administration of intravenous fluids to a patient's vascular system utilizing needlefree components. The device may be used with low pressure power injectors rated for a maximum setting of 325psi. The Q2® is compatible with PIVO™ devices.	Additional testing for activation force, leak, and flow rate demonstrate indication for use with PIVO™ devices does not affect safety or effectiveness of extension set device. Note: PIVO™ is a product tradename and not an acronym.
Indication for Use	Pressure Rated: The Q2® 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.	Pressure Rated: The Q2® 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® 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.	Same
Components	Tubing, Luer, Needle-less Connector, Male spin lock connector Non-fluid contacting: Pinch clamp, vented female luer lock cap	SAME	
Dimensions	Length: 7 inch (18cm)	Length: 5.75 inch (14.6cm)	Flow rate and kink resistance testing demonstrates no risk to safety or effectiveness
Material Comparison			
Tubing	PVC - clear, non-DEHP Alpha Gary 2235L-78, standard bore	SAME	
Luer	Co-polyester	SAME	

Needleless Connector	SwabSite Valve – Polycarbonate/silicone	SAME	
Colorant	None	SAME	
Use	Use with low pressure power injectors up to 325 psi and maximum flow rate of 10 mL/second	SAME	
Priming volume	< 1 mL	SAME	
Energy Source	User Operated	SAME	
Principle of Operation	Luer activation; direct injection, intermittent infusion, continuous infusion, aspiration	SAME	
Method	EtO	SAME	
Minimum SAL	1×10^{-6}	SAME	
Packaging	Tyvek pouch	SAME	
Disposable or Reusable	Disposable	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 • Backpressure leak under normal use and power injection • Flow rate for normal use and power injection • Simulated use • Tubing bond strength • Multiple Engagement • Continuous Engagement • Activation Force • Tubing kink resistance • Multiple clamping • Prolonged clamping • PIVO compatibility testing All patient contacting materials, sterilization, and design specifications are identical and unchanged from the predicate device. Additional sterilization assessments and testing were performed in accordance with the following: • 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
Conclusion:	Velano Vascular considers the Velano Vascular Q2® Extension Set device to be substantially equivalent to the predicate device listed above. This conclusion is based upon the intended use, design specifications, patient contacting materials, manufacturing and sterilization processes.