January 26, 2018

V2K Medical Inc.
Jake Wolenberg
Quality and Regulatory Consultant
1221 Innsbruck Drive
Sunnyvale, California 94089

Re: K172716
Trade/Device Name: V2K Rinspiration System, P7 Catheter - 9mm Rinse x 135cm Working Length,
V2K Rinspiration System, P7 Catheter - 20mm Rinse x 135cm Working Length,
V2K Rinspiration System, Filter Line - 108" Length
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE, KRA
Dated: December 13, 2017
Received: December 18, 2017

Dear Jake Wolenberg:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K172716

Device Name
V2K Rinspiration System

Indications for Use *(Describe)*
The V2K Rinspiration System is intended to infuse physician specified fluids and remove/aspirate fluid, fresh, soft emboli and thrombi from the peripheral vasculature.

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
V2K Rinspiration System

A. Submitter Information

Submitter's Name:	V2K Medical Inc.
Address:	1221 Innsbruck Drive Sunnyvale, CA 94089
Telephone:	408-940-5587
Fax:	408-726-2977
Email:	jwolenbergV2K@gmail.com
Contact Person:	Jake Wolenberg
Date of Preparation:	January 25, 2018

B. Subject Device

Proprietary Name:	V2K Rinspiration System
510(k) #:	K172716
Common/Usual Name:	Embolectomy Catheter and Infusion Catheter
Classification Name:	Catheter, Embolectomy and; Catheter, Continuous Flush
Product Code:	DXE per 21 C.F.R. 870.5150 and; KRA per 21 C.F.C 870.1210

C. Predicate Device

Proprietary Name:	Kerberos Proximal Solutions Rinspiration System
510(k) #'s:	K062275
Common/Usual Name:	Embolectomy Catheter
Classification Name:	Catheter, Embolectomy
Product Code:	DXE per 21 C.F.R. 870.5150

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D. Device Description:

The V2K Rinspiration System is comprised of the V2K Rinspiration Catheter and two accessory components; an Infusion Syringe and a Filter Line.

The V2K Rinspiration Catheter is a multi-lumen catheter that has infusion holes located near the distal end of the catheter to dispense an infusible fluid. The central lumen of the catheter is used for aspiration. Simultaneous infusion and aspiration can be performed through these lumens to perform fluid mechanical thrombectomy to remove fluid, fresh, soft emboli and thrombi from peripheral vasculature. The Rinspiration Catheter will be placed in the target vasculature of a patient over an 0.014" guide wire. The V2K Rinspiration Catheter uses a rapid exchange (a.k.a. rail) configuration for the guidewire lumen. The Rinspiration catheter distal tip will be positioned at the intended treatment site. Infusion occurs approximately 1 to 2cm proximal to the distal tip. The catheter includes a smaller radiopaque marker band at the distal tip and two larger radiopaque marker bands designating the infusion portion of the catheter. The catheter has a V-hub on the proximal end that allows access to the infusion and aspiration lumens.

Included in the same packaging as the V2K Rinspiration Catheter is a 12cc Infusion Syringe with an attached check valve. The Infusion Syringe is intended to be used for infusing physician specified fluids through the V2K Rinspiration Catheter.

The V2K Rinspiration Catheter will also be supplied with an accessory Filter Line which is intended to be used to connect the catheter to a continuous vacuum source such as an aspiration pump or hospital vacuum line. The Filter Line has two connections, one male Luer and one slip-fit connector. The male Luer is connected to the aspiration lumen of the V2K Rinspiration Catheter. The slip-fit connector is connected to the continuous vacuum source.

The Filter Line also has an in-line flow control switch and an in-line filter. The in-line flow control switch is used to open/close the connection between the continuous vacuum source and the aspiration lumen of the catheter. This allows the user a simple method to manage the aspiration flow. The in-line filter is used to collect any debris that is aspirated through the catheter and allows the user to clearly visualize what has been aspirated. This also allows for temporary storage, inspection, analysis, transport and / or disposal of the aspirated materials.

E. Intended Use:

The V2K Rinspiration System is intended to infuse physician specified fluid and remove/aspirate fluid, fresh, soft emboli and thrombi from the peripheral vasculature.

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F. Predicate Comparison:

The subject V2K Rinspiration Catheter has the same basic catheter design, intended use, and operating principles as the predicate Kerberos Rinspiration System.

The primary update made was to replace the handheld pump (Rinspirator) that was used as part of the Kerberos Rinspiration System to simultaneously operate both an infusion syringe and an aspiration syringe. In the V2K Rinspiration System, the Rinspirator was replaced with the 12cc Infusion Syringe and the Rinspiration Filter Line. These accessories still allow for simultaneous infusion and aspiration.

The catheter hub design was also updated to help make it easier to identify how to connect the catheter to the accessory devices.

Additional updates can be found in the table below which compares the subject device models included in the 510(k) to the most similar predicate device models.

	Predicate Device	**Subject Device**
	Kerberos Proximal Solutions Rinspiration System	**V2K Rinspiration System**
Product Code	DXE per 21 C.F.R. 870.5150	DXE per 21 C.F.R. 870.5150 KRA per 21 C.F.C 870.1210
Class	Class II	Same
Name	Embolectomy Catheter Infusion Catheter	Same
Indications for Use	The Kerberos Proximal Solutions Rinspiration Catheter System is intended to infuse physician specified fluid and remove/aspirate fresh, soft emboli and thrombi from the coronary and peripheral vasculature.	The V2K Rinspiration System is intended to infuse physician specified fluid and remove/aspirate fluid, fresh, soft emboli and thrombi from the peripheral vasculature.
Catheter & Accessory Materials	Commonly used medical grade plastics & stainless steel.	Same
Lubricious Coating	Silicone Oil Solution	Same
Catheter Visibility	Radiopaque Tip and Infusion Markers	Same
Outer Diameter	7.0 French (<0.093")	Same
Aspiration Lumen ID	ID ≥ 0.050"	ID ≥ 0.048"
Infusion Hole Spacing	9mm	9mm & 20mm
Effective Length	135cm	Same

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	Predicate Device	Subject Device
	Kerberos Proximal Solutions Rinspiration System	**V2K Rinspiration System**
Guidewire Compatibility	0.014”	Same
Maximum Infusion Pressure	3.1 psi	Same
Catheter Accessories	3cc Infusion syringe Infusion Supply Line Rinspirator Handle 5cc aspiration syringe In-Line Filter Aspiration bag	12cc Infusion Syringe with Check Valve Filter Line
Sterile Barrier	Tyvek with polymer backing	Same
Sterilization	EtO, SAL 10^{-6}	E-Beam, SAL 10^{-6}
Condition Supplied	Sterile, Single Use, Disposable	Same

G. Performance Data Supporting Substantial Equivalence:

Bench and Lab testing was conducted in order to evaluate the differences between the proposed V2K Rinspiration System and the predicate Kerberos Rinspiration System. As V2K has access to the original design verification and validation documentation for the predicate Kerberos Rinspiration System, the data from this testing was leveraged, where possible, for comparison to the proposed V2K Rinspiration System.

The test results were reviewed and found to demonstrate that the differences between the proposed and predicate device do not significantly impact any catheter performance parameters that would affect the safety or efficacy of the proposed V2K Rinspiration Catheter.

A summary of the tests and performance specifications that were evaluated is presented on the following pages. These tests were performed per V2K approved methods based on prior Kerberos test methods and catheter performance standard ISO 10555-1.

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Test Performed	Specification Summary
Visual Inspection	The product and packaging shall be free of significant defects or assembly issues.
Dimensional Verification	All product dimensions critical to device performance shall meet the product specifications with the required tolerances.
Catheter Bond Strength	All bonds/joints made throughout the catheter and accessories shall be strong enough to prevent separation during normal use.
Fatigue Testing – Infusion	The catheter and accessories shall be able to function and maintain integrity following infusion of a worst-case fluid volume through the infusion lumen.
Fatigue Testing – Filter Line	The Filter Line shall function and maintain integrity following continuous aspiration for a clinically relevant time.
Fatigue Testing – Flow Control Switch	The flow control switch shall be able to function and maintain integrity following a clinically relevant number of on/off cycles and following continuous aspiration for a clinically relevant time.
Freedom from Leakage	The catheter and accessories shall remain free of leaks or damage following exposure to clinically relevant positive pressure and vacuum.
Simulated Use	The catheter shall be able to be delivered through a simulated use model and successfully used to infuse fluids, aspirate and be retracted per the IFU without incurring any damage.
Infusion Flow Rate & Height	The user shall be able to inject physician specified fluids at a rate of 1.5cc/sec without generating excessive pressure/fluid velocity at the distal tip of the catheter.
Aspiration Flow Rate	When connected to an aspiration pump, the user should be able to aspirate at an average flow rate >= 1.5cc/sec.
Flexibility and Kink Resistance	The catheter shall not kink when passed through clinically relevant bend radii.
Strain Relief Flexibility	The strain relief shall protect the catheter shaft when deflected with a force of 1 lbf.

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Test Performed	Specification Summary
Guide Sheath Compatibility / Coating Durability	After a clinically relevant number of insertions and removals through a 7 French guide sheath, the catheter shall be intact with no deformation or kinks and no detectable change in resistance.
Guidewire Compatibility	The user shall be able to advance the catheter with little resistance over a 0.014" diameter wire while infusing at a rate of 1.5cc/sec.
Radiopacity	The radiopaque markers on the distal and infusion site of catheter shall be visible under typical fluoroscopic methods.
Corrosion Test	The metallic components of the catheter shall show no signs of corrosion following worst case exposure conditions to a heated saline solution.

H. Biocompatibility

Biocompatibility testing was performed on all direct and indirect patient contacting components of the V2K Rinspiration System. This testing was conducted to ensure that the components and raw materials used in the proposed V2K Rinspiration System, as well as the manufacturing processes and sterilization processes result in a biocompatible product. All biocompatibility tests were conducted pursuant to 21 CFR Part 58, Good Laboratory Practices, ISO 10993-1, and per the recommendations in FDA guidance document titled: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

A summary of the selected biocompatibility tests performed for the direct and indirect patient contacting components of the V2K Rinspiration System is presented for reference on the following pages. All test results passed, indicating that the V2K Rinspiration is biocompatible for its intended use.

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Test	Test Method	Extraction Methods/Conditions	Acceptance Criteria	Results
Cytotoxicity: ISO MEM Elution Method	ISO 10993-5	Test device extracted in MEM with 5% serum at 37+/- 1°C for 24-25 hours.	Sample extracts must yield cell lysis grade 2 or lower.	**Pass, Non-cytotoxic**
Sensitization: Magnusson-Kligman Method	ISO 10993-10	Guinea pigs exposed to test device extracts. Challenged sites observed for skin sensitization 24 +/- 2 and 48 +/- 2 hours after removal of extracts. Extracts were prepared at 37+/- 1°C for 72 +/- 2 hours.	Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided control Grade < 1).	**Pass, Non-Sensitizing**
Irritation: ISO Intracutaneous Toxicity	ISO 10993-10	Rabbits are injected with extracts of test device. Injection sites examined/scored at 24 +/- 2, 48 +/- 2 and 72 +/- 2 hours after injections. Extracts were prepared at 37+/- 1°C for 72 +/- 2 hours.	The difference in the mean test article and mean control score must be grade 1.0 or lower.	**Pass, Non-Irritant**
Systemic Toxicity				
Systemic Toxicity: ISO Systemic Injection	ISO 10993-11	Mice are injected with extracts of test device. Animals are observed for signs of toxicity immediately after injection, 4+/- 0.75, 24 +/- 2, 48 +/- 2 and 72 +/- 2 hours after injections. Body weights are measured prior to injection and on all 3 days. Extracts were prepared at 37+/- 1°C for 72 +/- 2 hours.	Sample extracts must not cause the following: • > 10% weight loss in 3 or more test animals • Mortality of 2 or more test animals • Abnormal behavior in 2 or more test animals	**Pass, Non-Toxic**

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Test	Test Method	Extraction Methods/Conditions	Acceptance Criteria	Results
Systemic Toxicity: ISO Material Mediated Pyrogen	ISO 10993-11	Test device extracted in 0.9% saline solution and injected in the marginal ear vein. Rectal temperatures recorded prior to injection and every 30 min until 1-3 hours post injection. Extracts were prepared at 37+/- 1°C for 72 +/- 2 hours.	Sample Extracts must not cause a total rise in body temperature of ≥0.5°C.	**Pass, Non-pyrogenic**
Hemocompatibility				
Hemocompatibility: ASTM Hemolysis, indirect (human blood)	ISO 10993-4 ASTM F756	Extract exposed to blood cell suspension. Hemoglobin releases is measured.	Sample extracts must be nonhemolytic (≤ 2% hemolytic index).	**Pass, Non-hemolytic**
Hemocompatibility: ASTM Hemolysis, direct contact (human blood)	ISO 10993-4 ASTM F756	Test device exposed to blood cell suspension. Hemoglobin releases is measured.	Sample extracts must be nonhemolytic (≤ 2% hemolytic index).	**Pass, Non-hemolytic**
Hemocompatibility: Partial Thromboplastin Time (PTT)	ISO 10993-4 ASTM F2382	Test device and controls are directly exposed to human blood plasma with anticoagulants at 37+/- 2°C for 60 +/- 5 minutes. Following exposure, the anticoagulant is neutralized and the time for the serum to start clotting is recorded.	The clotting time for the test device should be similar to or less than either a predicate device, a negative control, or the plasma control.	**Pass, Minimal Activator**
Hemocompatibility: Complement Activation Test	ISO 10993-4 ASTM F756	Preformed in vitro using a prepared Enzyme Immunoassay (EIA) kit. This kit will detect the presence of specific complement enzymes. Test device extracted in Normal Human Serum (NHS) at 37+/- 2°C for 0.5, 1, and 1.5 hours.	The concentrations of C3a and SC5b-9 in the test samples are statistically similar to the predicate (Exposure Control & Ref Material) control and statistically lower than the positive control for all exposure times.	**No Significant Differences**
In Vivo Thrombogenicity (Dog)	ISO 10993-4 ASTM F756	Performed in duplicate. Placed in one side of the jugular vein. Vasculature closed up and remains in place for 4 hours.	The device must be nonthrombogenic after 4 hours in vivo when compared to a control device (Merit Fountain Infusion Catheter).	**Pass, Minimal Thrombus Formation**

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I. Sterilization

The V2K Rinspiration Catheter and Rinspiration Filter Line are both sterilized using an electron beam process with a sterility assurance level of $1x10^{-6}$. The sterilization process was validated per the VDmax 25 method described in ANSI/AAMI/ISO 11137-1, "Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices". A summary of the completed testing is presented below.

Test Group	Catheter Results	Filter Line Results
Sterilization Dose Map	**Pass**	**Pass**
Bioburden Recovery Correction Factor	**Pass**	**Pass**
Device Bioburden Assessment	**Pass**	**Pass**
Sterile Verification Dose	**Pass**	**Pass**
Bacteriostasis/ Fungistasis (B/F) Testing	**Pass**	**Pass**

J. Shelf Life and Packaging

Accelerated aging testing based on ASTM F1980 was conducted to verify device, accessory, and packaging performance. A real time aging equivalent of 25 months was used for this testing and will allow for labeling of product with a 2-year shelf life.

Device and accessory performance was verified by repeating the functional tests previously discussed in Section G.

Packaging and sterile barrier integrity through transportation and aging testing was verified per the testing summarized below.

Test	Test Method	Time Points	Catheter Results	Filter Line Results
Packaging Visual Inspection	ASTM F1886 / V2K TM00294	25 months	Pass	Pass
Pouch Integrity Test – Gross Leak Detection	ASTM F2096	25 months	Pass	Pass
Pouch Seal Strength – Peel Strength	ASTM F88	25 months	Pass	Pass
Label Integrity	V2K TM00294	25 months	Pass	Pass

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K. Conclusions

Where differences were identified between the subject V2K Rinspiration Catheter and the predicate Kerberos Rinspiration Catheter, an assessment was conducted to determine if the difference would result in new safety or efficacy concerns regarding the use of the device. As appropriate, bench and lab testing was conducted to support this assessment.

Based on the results of the conducted assessments and testing, it is concluded that V2K Rinspiration System is substantially equivalent to the predicate Kerberos Rinspiration System and that there are no new safety or efficacy concerns associated with the identified differences. This conclusion is based on both devices sharing the same intended use, basic technology characteristics, and performance characteristics, as demonstrated through well-designed bench and lab testing.