July 23, 2018

Ding Hwa Co., Ltd.
% Mr. John MacMahon
CEO
V2K Medical, Inc.
1221 Innsbruck Drive
Sunnyvale, California 94089

Re: K181398
Trade/Device Name: Cliq Aspirator DV-300
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: JCX
Dated: March 16, 2018
Received: May 29, 2018

Dear Mr. MacMahon:

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 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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

K181398

Device Name

Cliq Aspirator DV-300

Indications for Use *(Describe)*

The DV-300 is intended for general suction use in hospitals or clinics.

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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DING HWA CO., LTD.
漢 弓 股 份 有 限 公 司

510(k) Summary

Cliq Aspirator DV-300

Date Prepared: April 27, 2018

1. Applicant Identification

Ding Hwa Co., Ltd.
No. 121, Sec 3, Zhongshan Rd.
Dacun, Taiwan 51542

Telephone: +886-2-2345-1868
Fax: +886-2-2345-3162
Establishment Registration: 3006789357

2. Contact Person

John MacMahon, CEO
V2K Medical, Inc.
1221 Innsbruck Drive
Sunnyvale, CA 94089
Phone: 408-940-5587
Email: JMacMahon@V2KMedical.com

DING HWA CO., LTD.
漢 弓 股 份 有 限 公 司

3. Device Name for Which Clearance is Sought

Trade Name:	Cliq Aspirator DV-300
Common/Usual Name:	Suction Pump / Aspirator
Regulation Description:	Powered Suction Pump

4. Device Classification

Product Code:	JCX
Device:	Pump, Portable, Aspiration (Manual or Powered)
Reg. Number:	878.4780
Class:	II
Review Panel:	General and Plastic Surgery

5. Intended Use

The DV-300 is intended for general suction use in hospitals or clinics.

6. Device Description

The DV-300 is a portable AC suction pump capable of delivering 24.4 inHg of negative pressure (vacuum) to draw fluids and small particles through tubing and into a disposable collection canister, where the suctioned fluids and particles are trapped for proper disposal. The device is comprised of a maintenance-free pump unit, a power cord, an on/off switch, a pressure relief valve and pressure adjustment knob, an analog pressure gauge, a microbial filter, intermediate tubing, and a disposable collection canister (≥ 800 ml) with overflow protection.

HEADQUARTERS Rm. 4B-02/03, Taipei World Trade Center,
4 FL, No. 5, HsinYi Road, Section 5, Taipei, Taiwan 11011
TEL : +886-2-2345-1868 FAX : +886-2-2345-3162

FACTORY No. 121, Sec. 3, Zhongshan Road,
Dacun, Chang- Hwa, Taiwan 51542
TEL : +886-4-852-5755

EMAIL : info@cliqmedical.com Website : www.cliqmedical.com

The DV-300 requires an AC input voltage of 110-120V 60Hz. Housed in ABS plastic, the DV-300 has an IP22 ingress protection rating; and, as a Class II (double-insulated) electrical appliance, the unit affords Type BF applied part protection against electric shock.

The DV-300 must only be used on the order of a physician.

7. Predicate Device

Trade Name:	Penumbra Pump MAX™
Manufacturer:	Penumbra Inc. (Alameda, CA)
510(k) Number:	K122756
Product Code:	JCX

8. Substantial Equivalence

The Cliq Aspirator DV-300 suction pump design is substantially equivalent to the legally marketed Penumbra Pump MAX™ manufactured by Penumbra Inc. (K122756).

Intended Use:	Both the DV-300 and the predicate device are suction pumps that are intended for general suction use in hospitals or clinics.

Technology:	The pump units for both the DV-300 and the predicate device are positive displacement pumps that generate negative pressure using the same operating principles. Both units are AC units powered by a connection to mains.
Operation:	Both the DV-300 and the predicate device require connection to a hydrophobic filter, which, in turn, connects, via tubing, to a collection container. Both devices have a knob for adjustment of vacuum pressure; and both devices have an analog gauge that displays current pressure.
Performance:	Both the DV-300 and the predicate device meet substantially equivalent testing and acceptance criteria, as outlined below, in subsection 9 of this 510k Summary.

Further details on substantial equivalence are provided in the table below:

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Substantial Equivalence Comparison Chart

	Cliq Aspirator DV-300	**Penumbra Pump MAX™**	**Substantially Equivalent?**
510(k) Number	Unknown	K122756	N/A
Manufacturer	Ding Hwa Co., Ltd.	Penumbra Inc.	N/A
Trade Name	Aspirator	Aspiration Pump	Equivalent
Model Number	DV-300	Pump MAX™	N/A
Device Classification	878.4780 Powered Suction Pump Class II Product Code: JCX	878.4780 Powered Suction Pump Class II Product Code: JCX	Equivalent
Intended Use	The DV-300 is intended for general suction use in hospitals or clinics.	The Penumbra Pump MAX™ is intended for general suction use in hospitals or clinics.	Equivalent

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Substantial Equivalence Comparison Chart (cont.)

Technological and System Specifications			
	Cliq Aspirator DV-300	**Penumbra Pump MAX™**	**Substantially Equivalent?**
Electrical requirements	110-120 VAC 60 Hz	110-115 VAC 50 Hz or 60 Hz	Equivalent
Protection against electric shock	Class II with Type BF applied part	Class I with Type CF applied part	Equivalent Both the subject and predicate device have been verified to provide appropriate protective measures to prevent the user or patient from being electrically shocked.
Vacuum Pressure	Max: 24.4 inHg Vacuum adjustable Vacuum gauge	Max: 29 inHg Vacuum adjustable Vacuum gauge	Equivalent
Pump Type	Positive displacement pump	Positive displacement pump	Equivalent
Flow	Up to ~18 l/min	Up to ~21 l/min	Equivalent
Sound level	< 53 dBa	< 60 dBa	DV-300 Quieter
Weight	3.5 kg / 7.7 lbs	10.1 kg / 22.3 lbs	DV-300 lighter
Dimensions	L30 x W16.5 x H19 cm	L40 x W28 x H34 cm	DV-300 smaller

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Operating Environment	Temp: 0 – 40˚C Humidity: 0 – 90% Atmospheric Pressure: 70–106 kPa	Temp: 18 – 24˚C Humidity: 0 – 75% Atmospheric Pressure: not known	DV-300 can operate in wider temp range.
Storage Environment	Temp: -20 – 50˚C Humidity: 0 – 95% Atmospheric Pressure: 50–106 kPa	Temp: -29 – 49˚C Humidity: 0 – 95% Atmospheric Pressure: not known	Equivalent

Accessories			
	Cliq Aspirator DV-300	**Penumbra Pump MAX™**	**Substantially Equivalent?**
Filter	inline, hydrophobic	inline, hydrophobic	Equivalent
Collection Container	≥ 800 ml	1000 ml	

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9. Performance and Safety Testing (Non-Clinical)

The safety and performance testing of the Cliq DV-300 further demonstrates that this device is substantially equivalent to the predicate device.

Attribute	Acceptance Criteria	Results
The pump shall be compliant with IEC 60601-1 requirements.	100% Pass	Pass: 100%
The pump shall be compliant with IEC 60601-1-2 requirements.	100% Pass	Pass: 100%
The pump shall be compliant with ISO 10079-1 requirements.	100% Pass	Pass: 100%
The pump controls shall be easily identifiable by the User.	100% Pass	Pass: 100%
The pump controls shall be validated for Usability	100% Pass	Pass: 100%
The DV-300 should supply uniform vacuum level for an entire case	100% Pass	Pass: 100%
The DV-300 will be a durable piece of capital equipment	100% Pass	Pass: 100%
The DV-300 should be quiet	100% Pass	Pass: 100%

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Attribute	Acceptance Criteria	Results
After use, any blood or clot collected in the canister should be able to be removed for analysis	100% Pass	Pass: 100%
The canister should have volume reference markings	100% Pass	Pass: 100%
The canister should be able to withstand the maximum pressure delivered by the pump	100% Pass	Pass: 100%
The canister lid should include a feature to prevent excess fluid from entering the pump.	100% Pass	Pass: 100%

Testing Conclusions:
The Cliq Aspirator DV-300 met all predefined criteria, and passed all tests for performance, safety, and electromagnetic compatibility. Full test reports can be found in Section 16 of this submission.

10. Conclusion

The Ding Hwa Co., Ltd. Cliq Aspirator DV-300 described in this 510(k) submission is substantially equivalent in design, technology, specifications, intended use, operation, and performance to the predicate device (K122756). Further the Cliq Aspirator DV-300 does not raise any new safety or effectiveness issues when compared to the predicate.