September 3, 2020

ANEST IWATA SPARMAX CO., LTD.
℅ Robert Dean
President
Compliance Systems International, LLC
1083 Delaware Ave.
Buffalo, New York 14223

Re: K201203
Trade/Device Name: Cliq Aspirator
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: August 5, 2020
Received: August 21, 2020

Dear Robert Dean:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K201203

Device Name
Cliq Aspirator DV-XXX (model family)

Indications for Use *(Describe)*
The DV-XXX aspirator provides a portable, battery-powered medical vacuum source. The DV-XXX can also be powered from a standard wall outlet with the use of an AC power adapter. It is intended for use in the home care or hospital environment.

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

Cliq Aspirator DV-XXX (Model Family)

February 20, 2020

1. Applicant Identification

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Establishment Registration: 3006789357

2. Contact Person

Robert O. Dean
Compliance Systems International, LLC
1083 Delaware Ave.
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Telephone: 716-440-7362
Email: compliancesystems@yahoo.com

3. Device Name for Which Clearance is Sought

Trade Name:	Cliq Aspirator DV-XXX (model family)
Common/Usual Name:	Suction Pump / Aspirator
Regulation Description:	Powered Suction Pump

4. Device Classification

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

5. Intended Use

The DV-XXX aspirator provides a portable, battery-powered medical vacuum source. The DV-XXX can also be powered from a standard wall outlet with the use of an AC power adapter. It is intended for use in the homecare or hospital environment.

6. Device Description

The DV-XXX is a portable AC/DC high vacuum / high flow suction pump. The DV-XXX can be powered from a standard wall outlet or from a rechargeable battery pack. The DV-XXX creates a negative pressure (vacuum) that draws fluids through tubing and into a collection container where the fluids are trapped for proper disposal. The device is comprised of a maintenance-free pump unit, an AC power

adapter with power cord, an on/off switch, a pressure relief valve and pressure adjustment knob, a pressure gauge, an inline filter, intermediate tubing, and a rechargeable battery pack. Optional accessories which may be included with the unit include a collection canister and suction tubing.

The DV-XXX produces a flow rate of up to 20 liters per minute, and has a maximum vacuum pressure of 620 mmHg. Housed in ABS plastic, the DV-XXX 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-XXX must only be used on the order of a physician.

7. Performance and Safety Testing

Non-clinical performance and safety tests conducted on the Cliq Aspirator DV-XXX (model family) include the following consensus standards:

- IEC 60601-1: Basic safety and essential performance
- IEC 60601-1-2: Electromagnetic compatibility
- IEC 60601-1-11: Requirements for medical electrical equipment used in the home healthcare environment
- ISO 10079: Electrically powered suction equipment safety requirements

Testing Conclusions:

The Cliq Aspirator DV-XXX (model family) met all predefined criteria, and passed all tests for performance, safety, and electromagnetic compatibility. Full test reports can be found in Section of Standard Conformance of this submission.

8. Predicate Device

Trade Name: EasyGo Aspirator
Manufacturer: Precision Medical
510(k) Number: K971749
Product Code: BTA

Reference Device

Trade Name: EasyVac Aspirator
Manufacturer: Precision Medical
510(k) Number: K932494
Product Code: BTA

9. Substantial Equivalence

The Cliq Aspirator DV-XXX (model family) suction pump design is substantially equivalent to the legally marketed EasyGo Aspirator manufactured by Precision Medical (K971749).

Intended Use: Both the DV-XXX and the predicate device are suction pumps that are intended for use as medical vacuum sources in the homecare or hospital environments.

Technology: The pump units for both the DV-XXX and the predicate device are 12 VDC positive displacement reciprocating pumps. Both units use an AC adapter for connection to mains; and both units can be powered by rechargeable battery.

Operation: Both the DV-XXX 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. Both devices use LED light(s) to indicate battery status.

Performance: Both the DV-XXX and the predicate device meet substantially equivalent testing and acceptance criteria. Both devices conform to the requirements of the following consensus standards: IEC 60601-1, IEC 60601-1-2, and ISO 10079-1. Further, in accordance with ISO 10079-1.

10. Substantial Equivalence Comparison Chart

See next page

	Cliq Aspirator DV-XXX	Precision Medical EasyGo Aspirator	Substantially Equivalent?
510(k) Number	Unknown	K971749	N/A
Manufacturer	Anest Iwata Sparmax Co., Ltd.	Precision Medical	N/A
Trade Name	Aspirator	Aspirator	N/A
Model Number	DV-XXX (model family)	EasyGo	N/A
Device Classification	878.4780 Powered Suction Pump Class II Product Code: BTA	878.4780 Powered Suction Pump Class II Product Code: BTA	Equivalent
Intended Use	The DV-XXX aspirator provides a portable, battery-powered medical vacuum source. The DV-XXX can also be powered from a standard wall outlet with the use of an AC power adapter. It is intended for use in the homecare or hospital environment.	The EasyGo Aspirator provides a portable, battery power medical vacuum source. The EasyGo Aspirator can also be powered from a standard wall outlet with the use of an AC power adapter. It is intended for use in the homecare or hospital environment.	Equivalent

Consensus Standards	IEC 60601-1:2005 IEC 60601-1-2:2015 EN ISO 10079-1:2015+ A: 2018 IEC 60601-1-11:2012	IEC 60601-1:2006 IEC 60601-1-2:2007 EN ISO 10079-1:2009	Equivalent

Technological and System Specifications			
	Cliq Aspirator DV-XXX	**Precision Medical EasyGo Aspirator**	**Substantially Equivalent?**
Electrical requirements	AC Adaptor: 100-240 VAC, 50-60Hz Pump Unit: 12 VDC	AC Adaptor: 100-240 VAC, 50-60Hz Pump Unit: 12 VDC	Equivalent
Protection against electric shock	Class II with Type BF applied part	Class I with Type BF applied part	
Battery type	NiMH rechargeable battery pack	Lead acid battery	
Battery status indicator	Colored LED lights used to indicate: - battery fully charged - battery low	Colored LED lights used to indicate: - battery fully charged - battery low	
Vacuum Pressure	Max: ~620 mmHg Vacuum adjustable Vacuum gauge	Max: 533 mmHg Vacuum adjustable Vacuum gauge	
Pump Type	Positive displacement reciprocating pump	Positive displacement reciprocating pump	
Flow	Up to ~20 l/min	Up to ~14 l/min	

Sound level	< 53 dBa	Not known	
Weight	3.5 kg / 7.7 lbs	4.4 kg / 9.6 lbs	
Dimensions	L30 x W16.5 x H19 cm	L30 x W24 x H25 cm	
Operating Environment	Temperature: 5 – 40˚C Humidity: 15 – 93% Atmospheric Pressure: 70–106 kPa	Temperature: 10 – 40˚C Humidity: not known Atmospheric Pressure: not known	
Storage Environment	Temperature: -20 – 50˚C Humidity: 15 – 93% Atmospheric Pressure: 50–106 kPa	Temperature: -20 – 40˚C Humidity: 0 – 95% Atmospheric Pressure: not known	

11. Conclusion

The Anest Iwata Sparmax Co., Ltd. Cliq Aspirator DV-XXX (model family) described in this 510(k) submission is substantially equivalent in design, technology, specifications, intended use, operation, and performance to the predicate device (K971749). Further the Cliq Aspirator DV-XXX (model family) does not raise any new safety or effectiveness issues when compared to the predicate device.