DING HWA CO., LTD.
漢弓股份有限公司

510(k) Summary

Cliq Aspirator Model DV-300

March 31, 2014

1. **Applicant Identification**

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

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Establishment Registration: 3006789357

2. **Contact Person**

Janna Babson
Regulatory Affairs Associate
Telephone: 1-678-708-4773
Fax: 1-678-567-8218
Email: Janna.Babson@EndoChoice.com

3. **Device Name for Which Clearance is Sought**

Trade Name:	Cliq Aspirator, model DV-300
Common/Usual Name:	Aspirator
Classification Name:	Powered Suction Pump

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4. Device Classification

Product Code:	JCX
Regulation Number:	878.4780
Class:	II
Review Panel:	General and Plastic Surgery

5. Intended Use:

The device is intended to be used for aspiration during flexible endoscopy.

6. Device Description

The Cliq Aspirator model DV-300 is an AC-powered high-vacuum / low-flow suction unit used for endoscopic aspiration. The DV-300 creates a negative pressure (vacuum) that draws fluids through disposable tubing, and into a collection container. The fluids are trapped within the collection container for proper disposal. The device is comprised of a maintenance-free pump unit, power cord, on/off switch, pressure relief valve, pressure adjustment knob, pressure gauge, microbial filter, and intermediate tubing.

The Cliq Aspirator model DV-300 requires 110-120 V and 60 Hz. It has Class II with Type BF applied part protection against electric shock. The DV-300 suction pump operates via a piston pump type, and has a maximum vacuum pressure of 620 mm Hg. The pump produces a flow rate of up to 18 Liters per minute.

7. Substantial Equivalence

The Cliq Aspirator model DV-300 is substantially equivalent to the legally marketed suction pump model KV-5 (K011725) manufactured by Olympus. Both the Cliq Aspirator model DV-300 and the Olympus Suction Pump model KV-5 are intended to be used for aspiration during flexible endoscopy.

Substantial Equivalence Conclusion:

- The devices are equivalent in terms of intended use, operating principle, technology, energy used, packaging, and materials. A table comparing specifications for the Cliq Aspirator model DV-300 and Olympus Suction Pump model KV-5 is provided below.

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Substantial Equivalence Comparison Table:

Comparison Table			
	Cliq Aspirator Model DV-300	**Olympus Suction Pump Model KV-5**	**Substantially Equivalent?**
510k Number	Unknown	K011725	NA
Trade Name	Cliq Aspirator	Suction Pump	NA
Model Number	DV-300	KV-5	NA
Manufacturer	Ding Hwa Co., Ltd.	Olympus	NA
Device Classification	878.4780 Powered Suction Pump Class II, Product Code JCX	878.4780 Powered Suction Pump Class II, Product Code JCX	Equivalent
Indications	The device is intended to be used for aspiration during flexible endoscopy.	For aspiration during flexible endoscopy and general or surgical suction in a healthcare establishment. It is not intended for thoracic, domiciliary, field or transport use.	Equivalent

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Comparison Table			
	Cliq Aspirator Model DV-300	**Olympus Suction Pump Model KV-5**	**Substantially Equivalent?**
Performance Standards	EN IEC 60601---1 EN IEC 60601---1---2 EN ISO10079---1	EN IEC 60601---1 (220---240V model) EN IEC 60601---1---2 EN ISO10079---1 UL 2601---1 CAN/CSA Std. No. C22.2 No.601.1---M90	Equivalent
Packaging	The device is packaged in a foam-secured carton.	The device is packaged in a foam-secured carton.	Equivalent
Technological and System Specifications			
Electrical requirements	110---120 V, 60 Hz	100---120 V, 50/60 Hz	Equivalent
Protection against electric shock	Class II with Type BF Applied part	Class I with Type BF applied part	
Maximum Vacuum pressure	620 mm Hg	638 mm Hg	
Vacuum Pump Type	Piston	Piston	

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Comparison Table			
	Cliq Aspirator Model DV-300	**Olympus Suction Pump Model KV-5**	**Substantially Equivalent?**
Flow	Up to 18 L/min	Up to 20 L/min	
Sound level	53 dbA	Not known	
Weight	3.5 kg	12.7 kg	
Dimensions	30 x 16.5 x 19 cm	31 x 25.5 x 22 cm	
Operating Environment	Temperature: 0 – 40 °C Humidity: 0 – 90 % Atm. Pressure: 70 – 106 kPa	Temperature: 10 – 40 °C Humidity: 0 – 95 % Atm. Pressure: 70 – 106 kPa	
Storage Environment	Temperature: -20 – 50 °C Humidity: 0 – 95 % Atm. Pressure: 50 – 106 kPa	Temperature: -40 – 70 °C Humidity: 0 – 95 % Atm. Pressure: 23.5 – 106 kPa	
Accessories			
Filter	Microbial, hydrophobic	Microbial, hydrophobic	Equivalent
Suction Tube length	1.8 m	2 m	
Filter Tube length	250 mm	900 mm	
Power Cable	yes	yes	
Suction Jar volume	1.5 L or 2.4 L	2 liter (one liter optional)	

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8. Performance Data

Testing includes:

- Electrically powered suction equipment safety requirements per EN ISO 10079-1:2009 (See Section 16 for detailed report)
- Electromagnetic Compatibility per IEC/EN 60601-1-2:2007 (3rd Ed.) (See Section 16 for detailed report)
- General basic safety and essential performance per IEC 60601-1 (See Section 16 for detailed report)
- Performance verification testing (See Section 18 for detailed protocol and report)

Tests Conclusion:

- The Cliq Aspirator model DV-300 met all predefined criteria, and passed all tests for performance, electrical safety, and electromagnetic compatibility. The tests verified substantial equivalence to the Olympus Suction Pump model KV-5, and verified that the Cliq Aspirator Model DV-300 performs similarly to the predicate device as indicated in the Substantial Equivalence Comparison Table.

9. Conclusion:

The Ding Hwa Cliq Aspirator Model DV-300 is substantially equivalent to the predicate device listed above.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 23, 2014

Ding Hwa Company, Ltd.
% Ms. Janna Babson
EndoChoice Incorporated
11810 Wills Road
Alpharetta, Georgia 30549

Re: K140809
Trade/Device Name: Cliq Aspirator Model DV-300
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: April 2, 2014
Received: April 3, 2014

Dear Ms. Babson:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140809

Device Name
Cliq Aspirator model DV-300

Indications for Use *(Describe)*
The device is intended to be used for aspiration during flexible endoscopy.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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