August 6, 2025

Hangzhou Viction Medical Technology Co.,Ltd
Zhicong Luo
General Manager
First Floor ,No.1 Building, No.95 Binwen Road,
Binjiang District
Hangzhou, Zhejiang 310051
China

Re: K250130
Trade/Device Name: Viction Disposable Irrigation and suction System (VC-FLA0514; VC-FLA0523; VC-FLA0532; VC-FLB0514; VC-FLB0523; VC-FLB0532; VC-FLC0514; VC-FLC0523; VC-FLC0532; VC-FLD0514; VC-FLD0523; VC-FLD0532)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: July 7, 2025
Received: July 7, 2025

Dear Zhicong Luo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Julie A. Morabito -S

Julie Morabito, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250130-S001

Device Name

Viction Disposable Irrigation and suction System (VC-FLA0514;VC-FLA0523;VC-FLA0532;VC-FLB0514;VC-FLB0523;VC-FLB0532;VC-FLC0514;VC-FLC0523;VC-FLC0532;VC-FLD0514;VC-FLD0523;VC-FLD0532)

Indications for Use *(Describe)*

The Viction Disposable Irrigation and Suction system is intended to provide irrigation and suction functions during general surgery and laparoscopic surgery.It is designed to deliver irrigation fluids to surgical sites and to remove fluid waste and tissue debris.

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510（K） Summary

K250130

This summary of 510(K)safety and effectiveness information is being submitted inaccordance with the requirements of 21 CFR §807.92.
Type of submission :Traditional
The date the summary was prepared: July 4, 2025

I.SUBMITTER

Hangzhou Viction Medical Technology Co.,Ltd
First floor, No.1 Building,
No.95 Binwen Road, Binjiang District,
Hangzhou City, Zhejiang Province, China.MD310051

Contact Person: Yu Gu
Phone:+86-057188305089
Email:guyu@victionmed.com
Date Prepared: February 11, 2025

II.Device

Name of Device : Viction Disposable Irrigation and Suction system,(model VC-FLA0514; VC-FLA0523; VC-FLA0532; VC-FLB0514; VC-FLB0523; VC-FLB0532; VC-FLC0514; VC-FLC0523; VC-FLC0532; VC-FLD0514; VC-FLD0523; VC-FLD0532)
Common or Usual Name: Suction Irrigation
Classification Name:Endoscope And Accessories(21 CFR876.1500)
Regulatory Class: 2
Product Code: GCJ

III.PREDICATE DEVICE

Single Use Surgical Suction Irrigator（K161421）, manufactured by Jiangsu Haize Medical Scientifie Development Co..Ltd. Located in WiXi city, JiangSu Province,china.
This predicate has not been subjected to a design-related recall.
No reference devices were used in this submission.

IV.DEVICE DESCRIPTION

The Viction disposable Irrigation and suction system are constitutes with Irrigation & suction device and a double tubes(optional accessories).The Irrigation & suction device including an inner/outer stainless steel tubes,On-off Control Button,Conical connectors and Hand-piece. Double tubes constitutes with Irrigation

tube、suction tube, and it connects with Yankee joint、Insert needle and Robe rt Clip.The Viction Disposable Suction Irrigation system is used to deliver steri le irrigation fluids to surgical sites during laparoscopic and endoscopic procedur es.

The Irrigation & suction device including an inner/outer stainless steel tubes,On -off Control Button,Conical connectors and Hand-piece. On-off control button o n handle-piece can control fluid circuit on and off. It is designed to deliver-ste rile irrigation fluids to surgical sites during surgery procedures.

Double tubes constitutes with Irrigation tube,suction tube, and it connects with Yankee joint,Insert needle and Robert Clip.The suction tube is connected to the negative pressure device of the hospital through the Yankee joint, The waste l iquid is discharged through a suction tube under the negative pressure environ ment.Which to improve the surgeon's visibility.

There are 12 models of the product, models VC-FLA0514;VC-FLA0523;VC-FL A0532;VC-FLB0514;VC-FLB0523;VC-FLB0532;VC-FLC0514;VC-FLC0523;VC-F LC0532;VC-FLD0514;VC-FLD0523;VC-FLD0532. All product's Structure are th e same, the length of the irrigation suction tubes is the main difference. It is a single use, disposable device and is sold sterile.

V.INDICATION FOR USE

The Viction Disposable Irrigation and Suction system is intended to provide irr igation and suction functions during general surgery and laparoscopic surgery.I t is designed to deliver irrigation fluids to surgical sites and to remove fluid waste and tissue debris.

Technological characteristics summary

The irrigation function of the disposable irrigation and suction system is achieved through the gravity of the liquid itself. The flushing fluid flows downward under its own gravity through the irrigation suction probe, forming a flushing water flow with a certain pressure.

The suction tube is connected to the negative pressure device of the hospital through the Yankee joint, The waste liquid is discharged through a suction tube under the negative pressure environment.Which to improve the surgeon's visibility.

All components should be securely connected: the irrigation flow rate should be no less than 160 ml/min; the suction tube flow rate should be no less than 600 ml/min;

the product is sterilized with ethylene oxide and should be sterile, with ethylene oxide residue ≤10μg/g; the maximum negative pressure the product can withstand is 60 kPa. This product is not a therapeutic or diagnostic medical device, the product has no diagnostic, therapeutic, preventive, mitigation or cure of disease, no monitoring function.

VI.COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATED DEVICE

The Viction Disposable Suction Irrigation system is compared with the followin g Predicate Devices in terms of intended use, design, material, specifications, a nd performance.

Predicate device name:Single Use Surgical Suction Irrigator
510(K) number:K161421
Common Name:Suction Irrigation
Manufacturer:JiangSu Medical Scientific Development CO.,LTD.

The following table shows similarities and differences of indications for use be tween our device and the predicate devices. Differences between the devices c ited in this section do not raise any new issues of safety or effectiveness.

Item	Predicate device	Proposed device	Compari son
Trade Name	Single Use Surgical Suction Irrigator	Viction Disposable Ir rigation and suction system	/
510(K)Number	K161421	K250130	/
Classification regulation	21 CFR 876.1500	21 CFR 876.1500	Equivale nce
Classification and Code	ClassII, GCJ	ClassII, GCJ	Equivale nce
Device Classification Name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery	Equivale nce

Indications for Use	The Single Use Surgical Suction lrrigator is indi cated to provide suction and irrigation functions in general surgery and laparoscopic surgery to help remove dropsy, he matocele and tissue debr is by vacuum aspiration and deliver irrigation flu ids to surgical site.	The Viction Disposable Irrigation and Suction system is intended to provide irr igation and suction functions during general surgery and laparoscopic surgery.I t is designed to deliver irrigation fluids to surgical sites and to remove fluid waste and tissue debris.	Similar
Suction Irrigat ion probe spe cification (Dia meter×Length）	JM- CX1A JM-CX4, JM-CX4B（45cm×5mm）	5mm×32cm; 5mm×23cm; 5mm×14cm;	Similar
Patient Contacting Material	Stainless steel ABS PVC Silicone	Stainless steel with PTEF coating. ABS PVC Silicone	Similar
Biocompatibili ty	Cytotoxicity Test； Intracutaneous Reactivity Test;| Acutesystemic Toxicity Test; pyrogen testing;	Cytotoxicity Test； Intracutaneous Reactivity Test;| Acutesystemic Toxicity Test; pyrogen testing;	Similar
Sterilization	EO Sterilized/ISO 11135	EO Sterilized/ISO 11135	Equivale nce
Disposable	Yes	Yes	Equivale nce
Additional accessories	Yes	Yes	Equivale nce

Conclusion

Based on the comparison of indications of use and other product performances. The Viction Disposable Suction Irrigation system manufactured by “Hangzhou Viction Medical Technology Co., Ltd.” is substantial equivalent to its predicate devices.

VII.PERFORMANCE DATA

Non-clinical tests were conducted to verify that the subject device met all design specifications to be considered substantially equivalent to the predicate device.

Electrical safety and electromagnetic compatibility

Not applicable to this submission

Biocompatibility testing

The biocompatibility evaluation for the Viction disposable Irrigation and suction system device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard IS0-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,"" May 1, 1995, and International Standard ISO10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. More details of biocompatibility tests are summarized in section 15. which include the following tests:

- Acute Systemic Toxicity
- Skin Sensitization Test
- Intracutaneous Reactivity Test
- Pyrogen Test
- In Vitro Cytotoxicity Test

Bench testing

The tests listed below evaluated the performance of the subject device.

- Fluid flow rate of Irrigation tubes and suction tubes. The test was conducted to ensure the flow rate of the irrigation tubes and suction tubes met the predefined acceptance criteria.
- Negative pressure resistance of suction.
- Sealing of irrigation tube.
- coating adhesion. The test was conducted to ensure the test results complied with standard 3B Per ASTM D3359-23.
- Particulate contamination index.

Packaging and Sterilization

- Ethylene Oxide Sterilization Validation
- Packaging Validation

Clinical Testing

Not applicable to this submission

All the test results meets the predefined acceptance criteria and complied with the design specification of the subject device throughout the use life. The results of the

non-clinical testing demonstrate that the viction disposable irrigation and suction system is as safe and effective as the predicate device.

VIII.CONCLUSIONS

Based upon the intended use and known technical information provided in this pre-market notification. the Viction Disposable Irrigation and Suction system h as been shown to be substantially equivalent to currently marketed predicate de vice K161421.