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: K250124
Trade/Device Name: Viction Disposable Irrigation and suction catheter (VC-IRA0532, VC-IRA0523, VC-IRB0532, VC-IRB0523, VC-IRC0532, VC-IRC0523, VC-IRD0532, VC-IRD0532)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 17, 2025
Received: January 17, 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,

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)*

k250124

Device Name

Viction Disposable Irrigation and suction catheter (VC-IRA0532、VC-IRA0523、VC-IRB0532、VC-IRB0523VC-IRC0532、VC-IRC0523、VC-IRD0532、VC-IRD0532)

Indications for Use *(Describe)*

The Viction disposable Irrigation and suction Catheter is indicated for use in conjunction with the handpiece , dual tubing, and probes to provide controlled powered irrigation during Laparoscopic surgery.

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.

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510（K） Summary

K250124

This summary of 510(K)safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.
Type of submission :Traditional
The date the summary was prepared: June8, 2025

I.SUBMITTER

Hangzhou Viction Medical Technology Co.,Ltd
First floor, No.1 Building,
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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 Suction Irrigation Catheter, (VC-IRA0532, VC-IRA0523, VC-IRB0532, VC-IRB0523, VC-IRC0532,VC-IRC0523,VC-IRD0532, VC-IRD0532)
Common or Usual Name: Suction Irrigation Catheter
Classification Name:Endoscope And Accessories(21 CFR876.1500)
Regulatory Class: 2
Product Code: GCJ

III.PREDICATE DEVICE

CORE E3 Suction/Irrigator （K202303）, manufactured by ConMed Corporation. Located in 525 French Road Utica.
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 Catheter is constitutes with Suction/irrigation handpiece , dual tubing, Irrigation device that is a battery-powered mechanical pumping system connect with dual tubing(suction tubing and irrigation tubing) to deliver sterile fluids to surgical sites. Control of the irrigation flow is generated by depressing the on-off Control Button on the handpiece. The mechanical pumping system is powered with nine(9) standard AAlkaline Battery.

Hand piece equipped with pistol style attach to Suction irrigation probes and suction tubing . And it should be used with negative pressure device of the hospital.

There are 8 models of the product, models VC-IRA0532, VC-IRA0523, VC-IR B0532, VC-IRB0523, VC-IRC0532,VC-IRC0523,VC-IRD0532, VC-IRD0532. All product's Structure are the 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 Catheter is indicated for use in conjunction with the handpiece , dual tubing, and probes to provide controlled powered irrigation during Laparoscopic surgery.

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:CORE E3 Suction/Irrigator
510(K) number:K202303
Common Name:Suction Irrigation
Manufacturer:ConMed Corporation.

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	Subject device	Comparison
Trade Name	CORE E3 Suction/Irrigator	Viction Disposable Irrigation and suction catheter	Similar product, different name
510(K) Number	K202303	K250124	/
Classificatio n regulation	21 CFR 876.1500	21 CFR 876.1500	same
Classificatio n and Code	ClassII, GCJ	ClassII, GCJ	same

Device Classification Name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery	same
Design	Battery-powered pump, dual tubing, trumpet handpiece, and optional probe.	Battery-powered pump, dual tubing, handpiece, and four types of probe.	Different; subject device's probe has different shapes, but it can't change, do not have optional Probes.
materials	304 Stainless Steel, Polycarbonate, 420 Stainless Steel, EPDM Rubber, ABS, and PVC. Six (6) AAA alkaline batteries.	304 Stainless Steel, ABS, and PVC. Nine (9) AA alkaline batteries.	Similar
Sterilization	Ethylene Oxide Sterility Assurance Level (SAL) of 10^{-6}	Ethylene Oxide Sterility Assurance Level (SAL) of 10^{-6}	
Single Use / Reusable	Single Use	Single Use	same
Principle of Operation	Battery powered mechanical pumping system	Battery powered mechanical pumping system	same
Environment Use	Healthcare facility/hospital	Healthcare facility/hospital	same

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

The following performance data were provided in support of the substantial eq uivalence determination.

Electrical safety and electromagnetic compatibility

Electrical safety and EMC testing were conducted on the device.

Electromagnetic compatibility is evaluated following IEC 60601-1-2:2014+AMD

1:2020,IEC 60601-2-18:2009.
Electrical safety is evaluated following IEC 60601-1: 2005: Medical electrical e quipment – Part 1: General requirements for basic safety and essential perform ance. Apply with standard IEC606011:2005+AMD1:2012+AMD2:2020

Biocompatibility testing
The Biocompatibility evaluation for the CORE E3 device was conducted in acc ordance with ISO 10993- 1:2018 Biological evaluation of medical devices – Pa rt-1: Evaluation and testing within a risk management process and application of applicable principles detailed in FDA Guidance Use of International Standar d ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and Testing within a Risk Management Process" (June 16, 2016). The followi ng tests were completed:

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

Bench Testing
- Fluid flow rate of Irrigation tube
- Negative pressure resistance of suction
- Sealing of irrigation tube

Sterilization
Performance qualification for ethylene oxide sterilization

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 catheter 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 Catheter has been shown to be substantially equivalent to currently marketed predicate device K202303.