February 19, 2021

ConMed Corporation
Tina Mornak
Principal Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

Re: K202303
Trade/Device Name: CORE E3 Suction/irrigator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 13, 2020
Received: August 14, 2020

Dear Tina Mornak:

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

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)*

K202303

Device Name
CORE E3 Suction/Irrigator

Indications for Use *(Describe)*

The CORE E3 Suction/Irrigator is designed to be used in conjunction with the CORE Trumpet Handpiece and probes to provide controlled powered irrigation/aspiration during laparoscopic surgical procedures (e.g., laparoscopic cholecystectomy and laparoscopic gynecological procedures). It may also be used for resection of filmy adhesions (i.e., hydrodissection) and peritoneal lavage.

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

CORE E3™ Suction/Irrigator

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number K202303.

I. SUBMITTER

ConMed Corporation
525 French Road
Utica, NY 13502

Company Contact: Tina Mornak
Principal Regulatory Affairs Specialist
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christinamornak@conmed.com

Date Prepared: January 21, 2021

II. DEVICE NAME

Proprietary Name:	CORE E3™ Suction/Irrigator
Model Numbers:	CD8185-B – CORE E3 Suction/Irrigator, 5mm x 32cm Probe CD81300-B – CORE E3 Suction/Irrigator, Handpiece Only
Common Name:	Laparoscope, General & Plastic Surgery
Panel:	Gastroenterology/Urology
Product Code:	GCJ
Device Class:	II
Regulation Number:	876.1500

III. PREDICATE/LEGALLY MARKETED DEVICE

Primary Device Name:	Hydro-Surg® Laparoscopic Irrigator
Company Name:	Davol Inc.
510(k):	K961492
Reference Device Name:	StrykeFlow
Company Name:	Stryker
510(k):	K963646

IV. DEVICE DESCRIPTION

The CORE E3™ Suction/Irrigator consists of a suction/irrigation handpiece and dual tubing that connects to a battery-powered mechanical pumping system to generate fluid output and can include a suction/irrigation probe. The device connects to a standard suction apparatus to deliver suction. Control of the flow (suction/irrigation) is generated by depressing the color-coded buttons on the handpiece. The handpiece can also be attached to separate compatible electrodes or probes, including reusable probes. The mechanical pumping system is powered with six (6) standard AAA alkaline batteries.

V. INTENDED USE / INDICATIONS FOR USE

The CORE E3™ Suction/Irrigator is designed to be used in conjunction with the CORE Trumpet Handpiece and probes to provide controlled powered irrigation/aspiration during laparoscopic surgical procedures (e.g., laparoscopic cholecystectomy and laparoscopic gynecological procedures). It may also be used for resection of filmy adhesions (i.e., hydrodissection) and peritoneal lavage.

VI. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The CORE E3™ Suction/Irrigator is similar to the predicate device in that the design of both include a battery-powered pump, dual tubing, trumpet handpiece, and optional probe. As with the predicate, the CORE E3™ Suction/Irrigator continues to function as a single use suction/irrigation device to provide controlled powered irrigation/aspiration during laparoscopic surgical procedures. The main difference in the subject device from the predicate device is the number and size of batteries that powers the device, and the average delivered irrigation flow rates. The CORE E3™ Suction/Irrigator is safe and effective and substantially equivalent to the predicate as demonstrated by non-clinical performance testing.

	Subject Device **CORE E3™ Suction/Irrigator**	**Predicate Device** **Hydro-Surg® Laparoscopic Irrigator**
Indications for Use	The CORE E3 Suction/Irrigator is designed to be used in conjunction with the CORE Trumpet Handpiece and probes to provide controlled powered irrigation/aspiration during laparoscopic surgical procedures (e.g., laparoscopic cholecystectomy and laparoscopic gynecological procedures). It may also be used for resection of filmy adhesions (i.e., hydrodissection) and peritoneal lavage.	The Hydro-Surg Irrigator is designed to be used in conjunction with a laparoscopic probe handle and tip to provide controlled powered irrigation/aspiration during laparoscopic surgical procedures (e.g., laparoscopic cholecystectomy and laparoscopic gynecological procedures). It may also be used for resection of filmy adhesions (i.e., hydrodissection) and peritoneal lavage.
Design	Battery-powered pump, dual tubing, trumpet handpiece, and optional probe.	Battery-powered pump, dual tubing, trumpet handpiece, and optional probe.
Materials	304 Stainless Steel, Polycarbonate, 420 Stainless Steel, EPDM Rubber, ABS, and PVC. Six (6) AAA alkaline batteries.	Plastic and metal components, material composition unknown. Eight (8) AA alkaline batteries.
Performance Testing	• Device performance was tested through bench testing methodologies to demonstrate functionality and that the device met the minimum flow rate of 1.2 L/min. • Flow Rate range approx..1.52-2.08 L/min • Electrical safety per IEC 60601-1 • Electromagnetic Compatibility (EMC) per IEC 60601-1-2	• Device performance was tested through bench testing methodologies to demonstrate the device met the minimum flow rate of 1.2 L/min. • Flow Rate range approx..1.42-1.5 L/min • Electromagnetic Compatibility (EMC) per IEC 60601-1-2
Single Use / Reusable	Single Use	Single Use

Sterilization	Ethylene Oxide Sterility Assurance Level (SAL) of 10^{-6}	Ethylene Oxide Sterility Assurance Level (SAL) of 10^{-6}
Environment Use	Healthcare facility/hospital	Healthcare facility/hospital
Principle of Operation	Battery powered mechanical pumping system	Battery powered mechanical pumping system

VII. PERFORMANCE DATA

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

Bench Testing
Bench testing was conducted on the CORE E3 device, including:

- Simulated use testing
- Functionality verification testing, including flow rate testing and accessory testing

Electrical safety and electromagnetic compatibility
Electrical safety and EMC testing were conducted on the CORE E3 device. The system complies with the IEC 60601-1 standard for electrical safety and IEC 60601-1-2 standard for EMC.

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

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Material-Mediated Pyrogenicity
- Acute Systemic Toxicity
- Hemocompatibility

The CORE E3 device is categorized as external communicating with a body contact of tissue/bone/dentin. The duration of body contact is limited (<24 hours).

Packaging and Sterilization
Packaging and sterilization validation were conducted on the CORE E3 device, including:

- Ethylene Oxide Sterilization Validation per ISO 11135
- Packaging Validation per ISO 11607-1

VIII. CONCLUSION

The subject CORE E3 device is substantially equivalent in design, materials, indications for use, principles of operation and technological characteristics to the predicate Hydro-Surg® Laparoscopic Irrigator by Davol Incorporated. Based upon the findings of non-clinical testing, the differences present no issues of safety and efficacy and the subject CORE E3 device is substantially equivalent to the Hydro-Surg® Laparoscopic Irrigator (K961492).