January 25, 2018

ClearLine MD
% Sheila Hemeon-Heyer
Founder and President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K171954
Trade/Device Name: ClearLine IV™
Regulation Number: 21 CFR 880.5445
Regulation Name: Intravascular Administration Set, Automated Air Removal System
Regulatory Class: Class II
Product Code: OKL
Dated: December 22, 2017
Received: December 26, 2017

Dear Ms. Sheila Hemeon-Heyer:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K171954

Device Name

ClearLine IV™

Indications for Use *(Describe)*

ClearLine IV™ is intended for detection and automatic removal of air in intravenous (IV) lines during administration of IV solutions, blood, and blood products. It is indicated for use in critical care areas such as the operating room (OR), post-anesthesia care unit (PACU), and intensive care unit (ICU). ClearLine IV™ is placed between the patient and the IV source and can be used with or without fluid warmers.

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

This summary of 510(k) safety and effectiveness information is being submitted per the requirements of 21 CFR 807.92.

A. Submitter:

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B. Manufacturer/ 510(k) Applicant:

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C. Date Prepared: January 16, 2018

D. Device Name and Classification Information:

Trade Name:	ClearLine IV™
Classification Name:	Intravascular Administration Set, Automated Air Removal System
Regulation:	21 CFR 880.5445
Product Code:	OKL
Review Panel:	General Hospital
Class:	II

E. Predicate Device(s): DEN080009, AirPurge™ System

F. Summary Device Description:

The ClearLine IV™ is a modification to the predecessor device, the AirPurge™ System. Both devices consist of two main components, the control unit and the sterile, single-use disposable cartridge. The control unit is mounted to the I.V. pole using a pole clamp attached to the back of the control unit. The disposable cartridge is loaded onto the control unit and connected to the infusion line between the infusion source and the patient. During infusion, air entering the cartridge will be detected by an ultrasonic sensor in the control unit, which will automatically close the patient line and divert the fluid flow containing the air to the waste collection bag. A second ultrasonic sensor in the control unit monitors the line to the waste collection bag. When both sensors detect liquid again, flow to the patient is resumed.

Both the ClearLine IV™ and AirPurge™ have the same air detection and removal response time of less than 60 msec. Both devices can detect air bubbles as small as 25 µL with fluid volume loss per purge of 0.1 mL at a typical flow rate of 300 mL/hr.

The modifications resulting in the ClearLine™ IV are:

- Redesign of the cartridge for improved fluid flow
- Redesign of the user interface to provide more comprehensive information to the user

G. Indications for Use Statement:

ClearLine IV™ is intended for detection and automatic removal of air in intravenous (IV) lines during administration of IV solutions, blood, and blood products. It is indicated for use in critical care areas such as the operating room (OR), post-anesthesia care unit (PACU), and intensive care unit (ICU). ClearLine IV is placed between the patient and the IV source and can be used with or without fluid warmers.

H. Technical Comparison with Predicate Device

The table below provides a side-by-side comparison of the modified to legally marketed device.

	Cleared Device AirPurge™ System (DEN080009)	**Modified Device ClearLine IV™**	**Same or Discussion of Differences**
Indications for Use	The AirPurge™ is intended for detection and automatic removal of air in intravenous (IV) lines during administration of intravenous solutions, blood and blood products. It is indicated for use in the Operating Room and post anesthesia care areas. The AirPurge™ System is placed distal to I.V. bags using gravity feed or pressure, and may be used with or without fluid warmers.	ClearLine IV™ is intended for detection and automatic removal of air in intravenous (IV) lines during administration of IV solutions, blood, and blood products. It is indicated for use in critical care areas such as the operating room (OR), post-anesthesia care unit (PACU), and intensive care unit (ICU). ClearLine IV is placed between the patient and the IV source and can be used with or without fluid warmers.	Clarification added that device is used in critical care areas, including the ICU. Clarification added to assure that the device is placed between the patient and IV source
System Components	Control unit Sterile, single-use disposable cartridge Waste outlet line Waste collection bag	Control unit Sterile, single-use disposable cartridge Waste outlet line Waste collection bag	Same

	Cleared Device AirPurge™ System (DEN080009)	Modified Device ClearLine IV™	Same or Discussion of Differences
Air detection and removal response time	Less than 60 msec	Less than 60 msec	Same
Minimal detectable air volume	25 µL	25 µL	Same
Flow rates for reliable detection and air removal	1 mL/min to 600 mL/min	1 mL/min to 600 mL/min	Same
Fluid loss during air removal as a function of flow rate	600 mL/min: ~10 mL 300 mL/hr: ~0.1 mL	600 mL/min: ~10 mL 300 mL/hr: ~0.1 mL	Same
Software controlled	Yes	Yes	Same
Indicators and alarms	Discrete LEDs with limited characters	Status displayed on LCD and longer text messages provide more descriptive information to user	Redesigned I/O enables more informative messaging regarding device status
Method of detecting air	Ultrasonic sensors	Ultrasonic sensors	Same
Patient contacting materials (cartridge)	Medical grade polymers: PVC SAN ABSD	Medical grade polymers: PVC Polycarbonate MBS	Biocompatibility of all fluid path materials confirmed by testing conducted in conformance with applicable ISO 10993 standards.
Cartridge Sterilization	EtO	EtO	Same
Power	AC line and rechargeable battery operation. Adapter rated at 15 watts. AC Source: 100-240V, 50-60 Hz, 400 mA. 5 hours typical battery life on fully charged battery.	AC line and rechargeable battery operation. Adapter rated at 15 watts. AC Source: 100-240V, 50-60 Hz, 400 mA. 5 hours typical battery life on fully charged battery.	Same
Control Unit Dimensions	H 5.5 in (14 cm) W 5 in (13 cm) D 5 in (13 cm)	H 5.5 in (14 cm) W 5 in (13 cm) D 5 in (13 cm)	Same
Control Unit Weight (with battery)	2.3 lbs (1.05 kg)	2.3 lbs (1.05 kg)	Same

I. Non-Clinical Testing

The following non-clinical testing was conducted for verification and validation of the system requirements and to support substantial equivalence under this 510(k). All testing met the pre-defined acceptance criteria and were considered to have passed.

a. Performance testing to verify the following functional requirements
    i. System start-up upon inserting the cartridge and closing the controller door
    ii. Cartridge priming
    iii. Cartridge leak testing
    iv. Air sensor response time (ultrasound sensors) at low and high flow rates
    v. Air detection to solenoid reaction time at low and high flow rates
    vi. Detection and removal of air bubbles ≥ 25 µl at low and high flow rates when infusing water and blood, with and without a fluid warmer
    vii. Detection and removal of air bubbles ≥ 25 µl at low and high flow rates when infusing lipids
    viii. System operation when the unit is tilted in any of four directions (forward, backward, left, right)
    ix. System operation when used with in-line filters and small diameter extension tubing
    x. System operation when used with infusion and syringe pumps
    xi. System power and battery requirements
    xii. Solenoid life expectancy testing
b. Software verification and validation testing of all software requirements including:
    i. Controller start-up self-test
    ii. Software monitoring of system operation
    iii. Controller interface operations, including alarm situations (high and medium priorities)
c. Electrical safety testing in conformance with IEC/EN 60601-1:2006 + A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
d. Electromagnetic compatibility testing in conformance with IEC 60601-1-2:2007 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests and IEC 60601-1-2:2014 for Special Environments (immunity to low frequency equipment found in the OR such as electrosurgery and RFID)
e. Sterilization validation for the sterile cartridge
    i. Validation of the EtO sterilization cycle according to ISO 11135 to an SAL of 10^{-6}
    ii. EtO residuals testing according to ISO 10993-7:2008
    iii. LAL testing according to USP <85>

f. Biocompatibility testing on the finished, sterilized cartridge (fluid contacting pathway) in compliance with ISO 10993 and FDA's 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. Device is categorized as externally communicating, prolonged contact, indirect blood contacting.
    i. ISO 10993-5:2009: Cytotoxicity MEM elution test
    ii. ISO 10993-10:2010: Sensitization: guinea pig maximization
    iii. ISO 10993-10:2010: Intracutaneous reactivity in rabbits
    iv. ISO 10993-11:2006: Acute systemic toxicity in mice
    v. ISO 10993-11:2006 and USP <151> Pyrogen Test: Material-mediated pyrogenicity test in rabbits
    i. ISO 10993-4:2002 and ASTM F756-13: Direct contact and indirect contact hemolysis testing
    ii. ISO 10993-4:2002: Complement activation testing
    iii. ISO 10993-18:2005: Chemical characterization and toxicological risk assessment
g. Package validation testing of cartridge pouches after 2X EtO sterilization was conducted at time 0, after environmental conditioning per ISTA 2A and distribution conditioning per ASTM D4169-16, and after accelerated aging per ASTM F1980-16. Tests conducted included:
    i. Seal strength test according to ASTM F88/F88M-15
    ii. Bubble leak test according to ASTM F2096-11
h. Cartridge integrity and functionality testing was also conducted on samples that had been subjected to the 2X sterilization, environmental, distribution, and aging conditions. Tests conducted included:
    i. Cartridge leak test
    ii. Verification of bubble detection and removal at low and high flow rates

i. A summative human factors study and Human Factors Engineering Report per FDA's guidance on "Applying Human Factors and Usability Engineering to Medical Devices," February 3, 2016.

J. Clinical Testing

Clinical testing was not required to support this 510(k).

K. Conclusion

The information and testing presented in this 510(k) demonstrate that the ClearLine IV™ is substantially equivalent to the predicate device, the AirPurge™ System.