August 31, 2018

ICU Medical, Inc.
Catherine Kang
Manager, Global Regulatory Affairs
600 N. Field Drive
Lake Forest, Illinois 60045

Re: K173477
Trade/Device Name: ChemoCLAVE Cytotoxic Medication Preparation and Delivery System
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: July 20, 2018
Received: July 24, 2018

Dear Catherine Kang:

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.

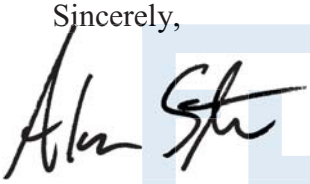
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,



for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173477

Device Name
ChemoCLAVE Cytotoxic Medication Preparation and Delivery System

Indications for Use *(Describe)*
The ChemoClave is a needle-free Closed System Transfer Device (CSTD) that mechanically prohibits the transfer of environmental contaminants, including bacterial and airborne contaminants into the system, and the escape of drug or vapor concentrations outside the system during drug preparation and administration, thereby minimizing exposure of individuals, healthcare personnel and the environment to hazardous drugs.

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.

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K173477 510(k) Summary

Submitter:	ICU Medical, Inc. 600 North Field Drive Lake Forest, IL 60045 Establishment Registration: 3013319212 (Owner/Operator #2025816)
Application Correspondent:	Catherine Kang, Ph.D Manager, Global Regulatory Affairs Phone: (224) 706-2372 Fax: (224) 706-2917 E-mail: catherine.kang@icumed.com
Preparation Date:	August 29, 2018
Trade Name:	ChemoCLAVE® Cytotoxic Medication Preparation and Delivery System
Common or Usual Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
Regulation Name:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Product Code:	ONB
Device Class:	Class II
Primary Predicate Device:	K081361 – ChemoCLAVE Cytotoxic Medication Preparation and Delivery System

Submission Purpose:
The purpose of this submission is to provide information demonstrating that the ChemoClave devices meet the design input requirements of a Closed System Transfer Device (CSTD) and to demonstrate substantial equivalence to K081361.

Device Indications For Use:
The ChemoClave is a needle-free Closed System Transfer Device (CSTD) that mechanically prohibits the transfer of environmental contaminants, including bacterial and airborne contaminants into the system, and the escape of drug or vapor concentrations outside the system

during drug preparation and administration, thereby minimizing exposure of individuals, healthcare personnel and the environment to hazardous drugs.

Device Description:

The ChemoCLAVE® Cytotoxic Medication Preparation and Delivery System devices are sterile, single use CSTDs, which prohibit the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system. The Spiros and ChemoClave components comprise the primary components of the ChemoClave CSTD System, which connect to form a closed fluid path for transfer of hazardous medications. The devices which include the ChemoClave component are vial access devices, bag access devices, adapters, and administration sets. The devices which include the mating Spiros component are syringes, adapters, and administration sets. The Spiros and the ChemoClave will each independently self-seal when they are disconnected from one another.

Technological Characteristics and Substantial Equivalence:

A technological comparison table is provided below that compares the subject device and predicate device:

Characteristic	Proposed Device	Predicate 510(k) K081361	Assessment of Differences
Indications for Use	The ChemoCLAVE is a needle-free Closed System Transfer Device (CSTD) that mechanically prohibits the transfer of environmental contaminants, including bacterial and airborne contaminants into the system, and the escape of drug or vapor concentrations outside the system during drug preparation and administration, thereby minimizing exposure of individuals, healthcare personnel and the environment to hazardous drugs.	The ChemoCLAVE Cytotoxic Medication Preparation and Delivery System consists of 6 previously cleared components (CLAVE®, Spikes, SPIROS™, GENIE™, Vial Access, and Admin Sets) that can be combined into various configurations intended for use in the preparation and patient administration of cytotoxic medications.	The Indications for Use has been updated to provide information consistent with a Closed System Transfer Device (CSTD) and devices under the ONB product code. The differences do not impact the safety or effectiveness of device.
Product Code	ONB	LHI	Updating devices as ONB.
Common name	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	Set, I.V. Fluid Transfer	Renamed to provide clarity consistent with product code.
Design and Materials of Construction	ChemoClave Adapter	ChemoClave Adapter	Same.
	Spiros Adapter	Spiros Adapter	Addition of non-fluid path cap to the proposed device.
	Genie Vial Access Device	Genie Vial Access Device	Minor change in silicone formulation in the proposed device.
	Vial Spikes	Vial Spikes	Same.

	Bag Spikes	Bag Spikes	Minor dimensional changes to improve manufacturing of the proposed device.
	Administration sets	Administration sets	Minor material modifications to connecting components in the proposed device; material is identical to materials used in other components on the set.
	Syringes with Spiros	Syringes with Spiros	Same.

Substantial Equivalence Discussion

The differences between predicate and proposed devices are identified in the table above. The proposed devices have equivalent technological characteristics as ICU Medical's current legally marketed devices cleared under 510(k) premarket notification K081316.

These minor differences, between subject device and predicate device, do not raise different questions of safety and effectiveness.

Non-Clinical Testing Summary:

Non-clinical tests were conducted to verify that the proposed device met all design specifications and is substantially equivalent (SE) to the ChemoCLAVE Cytotoxic Medication Preparation and Delivery System. The device was subjected to the following functional and performance tests to demonstrate that it performs as intended:

- Microbial Ingress Testing
- Emission Testing- Assess Vapor Leakage
- Hazardous Drug Exposure Testing – Assess Liquid/Vapor Leakage
- Urinary Catheter Compatibility Testing
- ANSI/AAMI/ISO 11137-2 2013 "Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose".
- ANSI/AAMI ST72:2011/(R)2016 Bacterial endotoxins —Test methods, routine monitoring, and alternatives to batch testing
- ISO 11607:2017 – Packaging For Terminally Sterilized Medical Devices

The materials of construction are the same as those used in the predicate device cleared under K081361. Biocompatibility testing provided in K081361 demonstrated the biocompatibility of ChemoCLAVE products.

The ChemoCLAVE products are supplied sterile for single use. The subject device is sterilized by E-beam or Gamma Radiation to achieve a sterility assurance level (SAL) of 10^{-6}. Sterility was validated in accordance with ISO 11137-2: 2013 – Dose setting using Bioburden. Packaging testing was performed per ISO 11607:2017.

A risk analysis was conducted in accordance with ISO 14971: 2007 – Medical devices — Application of risk management to medical devices.

In all testing, the pre-determined acceptance criteria were met.

Substantially Equivalence Conclusion

Differences between the intended use and technological characteristics of the subject device compared to the predicate do not raise different questions of safety and effectiveness. The performance of the device is supported by non-clinical testing and risk management activities. The ChemoCLAVE products are Substantially Equivalent (SE) to the ChemoCLAVE Cytotoxic Medication Preparation and Delivery System, cleared under K081361.