August 10, 2018

ICU Medical, Inc.
Jason Ma
Regulatory Affairs Manager
600 N. Field Drive
Lake Forest, Illinois 60045

Re: K170110
Trade/Device Name: Diana ChemoLock Transfer Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: July 10, 2018
Received: July 11, 2018

Dear Jason Ma:

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,

Alan M. Stevens -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170110

Device Name

Diana ChemoLock Transfer Set

Indications for Use *(Describe)*

The Diana ChemoLock Transfer Set is a sterile, single-use closed system transfer device used for drug preparation to transfer drug from a drug vial to an IV bag for intravenous drug administration. It prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system.

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

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92 for the Diana ChemoLock Transfer Set.

I. SUBMITTER	
Name	ICU Medical
Address	600 N. Field Drive, Lake Forest, Illinois 60045, USA
Phone number	(224)-706-2411
Fax number	(224)-706-2917
Contact Person	Jason Ma, Regulatory Affairs Manager
Date prepared	08/01/2018
II. DEVICE	
Name of Device	Diana ChemoLock Transfer Set
Regulation Name	Intravascular Administration Sets, 21 CFR 880.5440
Common Name	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System
Regulatory Class	II
Product Code:	ONB
III. PREDICATE DEVICE	
Predicate – K050339 SETS GRI-FILL Reference – K131549 ChemoLock (utilized for vapor containment characteristics/methods)	
IV. DEVICE DESCRIPTION	
Diana ChemoLock Transfer Set is intended for use with the Diana Compounding System. It is a disposable, single use ancillary device for Pharmacy Compounding Devices (PCD). The transfer set is comprised of multiple components bonded together to form a single device. These components include the following: stopcock, tubing, ChemoLock, syringe, and cassette handle. When placed in the Diana Compounding System, the Diana ChemoLock Transfer Set allows the transfer of fluids from one container to the other container for reconstitution of lyophilized drug or transfer of stock drug solution to prepare medications. The purpose of this submission is to release a new closed system transfer device (CSTD) drug transfer set to be used with Diana Pharmacy Compounding System	
V. INDICATIONS FOR USE	
The Diana ChemoLock Transfer Set is a sterile, single-use closed system transfer device used for drug preparation to transfer drug from a drug vial to an IV bag for intravenous drug administration. It prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system.	

VI. COMPARISON OF INTENDED USE WITH THE PREDICATE DEVICE		
	Subject Device	**Predicate (K050339)**
Feature	**Diana ChemoLock Transfer Set**	**SETS GRI-FILL**
Intended Use	Same	Same
Indications for Use	The Diana ChemoLock Transfer Set is a sterile, single-use closed system transfer device used for drug preparation to transfer drug from a drug vial to an IV bag for intravenous drug administration. It prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system.	SETS GRI-FILL 3.0 1 WAY and 2 WAY fluid transfer sets are ancillary devices used in conjunction with the GRI-FILL 3.0 pharmacy compounder in the hospital pharmacy to provide a fluid pathway through which one or two source substances are delivered into a final IV container or syringe. SETS GRI-FILL 3.0 MULTIPLE fluid transfer sets are ancillary devices used as fluid pathways in conjunction with the GRI-FILL 3.0 pharmacy compounder and associated I WAY or 2 WAY transfer sets through which the same substance from up to 6 source containers may be delivered into a final IV container. This device should not be used with lipids. This device is intended to be used by trained health-care personnel. It is restricted to sale by or on the order of a physician.
Classification	Class II	Class II
Product Code	ONB	LHI
Regulation No.	21 CFR 880.5440	21 CFR 880.5440
Use	Single Use	Single Use
Prescription/OTC Use	Prescription Use	Prescription Use

VI. COMPARISON OF INTENDED USE WITH THE PREDICATE DEVICE		
	Subject Device	**Predicate (K050339)**
Feature	**Diana ChemoLock Transfer Set**	**SETS GRI-FILL**
Compatible Set to a particular compounding system	Diana Automated Compounding System	GRI-FILL 3.0 Compounding System
Intended for Direct Connection to Patient During Compounding	No	No
Use Environment for Compounding	Standard Hospital Pharmacy Setting	Standard Hospital Pharmacy Setting
Target Users	Trained health-care personnel	Trained health-care personnel
Closed system (fluid not in contact with any reusable part of the compounding device)	Yes	Yes

Overall, Diana ChemoLock Transfer Set has the same intended use as the predicate. The differences in indications (e.g, inclusion of hazardous drug transfer and vapor containment) do not alter the intended use of the device when compared to the predicate, as both devices are intended for fluid transfer and preparation, and do not raise different questions of safety and effectiveness.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE		
	Subject Device	**Predicate (K050339)**
Feature	**Diana ChemoLock Transfer Set**	**SETS GRI-FILL**
System	Syringe Unit	Syringe Unit

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE		
	Subject Device	**Predicate (K050339)**
Feature	**Diana ChemoLock Transfer Set**	**SETS GRI-FILL**
Components	Connector to Source Container(Drug Vial)	Connector to Source Container(Drug Vial)
	Connector to Receiving Container (IV Bag)	Connector to Receiving Container (IV Bag)
	Connection Tubing	Connection Tubing
	Integral stopcock (distribution purpose)	Integral distributor (distribution purpose)
	Cassette Handle	Not Applicable
Principles of Operation	Multicomponent device compatible with compounding system to distribute fluid from sourcing container to receiving container	Multicomponent device compatible with compounding system to distribute fluid from sourcing container to receiving container
Fluid Transfer Mechanism	Integrated Syringe with connectors - Single Channel	Integrated Syringe with connector – Single or multiple Channel
Closed system (fluid not in contact with any reusable part of the compounding device)	Yes	Yes
Connections to Source Containers	proprietary closed connector	Male luer connector or vented bag spike
Connections to Final Containers	proprietary closed connector	Male luer connector. Also supplied with female to female luer to allow for female to male luer connection
Fluid Contact Material for tubing	PVC with Non-DEHP	PVC with DEHP Plasticizer
Pyrogenicity	Non-pyrogenic	Non-pyrogenic

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE		
	Subject Device	**Predicate (K050339)**
Feature	**Diana ChemoLock Transfer Set**	**SETS GRI-FILL**
Biocompatibility	Per FDA Guidance and ISO 10993-1 Biological Effect • Hemocompatibility • Cytotoxicity • Sensitization • Intracutaneous Irritation • Acute Systemic Toxicity • Pyrogenicity	Information Not Available
Sterilization	Radiation (E-beam)	Ethylene Oxide
SAL	10^{-6}	Information Not Available

The technological differences between the Diana ChemoLock Transfer Set and the predicate are:

- Use in an integrated system including syringe, stopcock and ChemoLock system for the proposed device as compared to an integrated syringe with luer or proprietary closed connector for the predicate
- The Diana ChemoLock Transfer Set uses Non-DEHP PVC tubing compared to DEHP PVC tubing in the predicate
- Sterilization method

These differences in technology do not raise different questions of safety or effectiveness.

VIII. PERFORMANCE DATA

Functional Testing

Functional testing was conducted to demonstrate the functionality of the Diana ChemoLock Transfer set that consists of ChemoLock, stopcock, tubing, syringe, and cassette handle. This testing follows the FDA guidance document of "Intravascular Administration Sets Premarket Notification Submissions [510(k)]".

Functional Testing included

- Fluid Flow
- Positive Pressure
- Chemical Compatibility
- Stopcock Handle Torque
- Component Bond Strength Testing
- Visual Inspection
- Accuracy Testing
- Internal Seal Integrity

Packaging Integrity and Shelf Life

Package integrity and Shelf Life was conducted according to FDA recognized consensus standards of ASTM D4169 Standard Practice For Performance Testing Of Shipping Containers And Systems, ASTM F1980 Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices, ASTM F2096 Standard Test Method For Detecting Gross Leaks In Packaging By Internal Pressurization (Bubble Test), and ASTM F88 Standard Test Method For Seal Strength Of Flexible Barrier Materials.

Biocompatibility

The biocompatibility evaluation for Diana ChemoLock Transfer Set device was conducted in accordance with the FDA Guidance for Industry and FDA Staff - "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; and ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process", as recognized by FDA. Testing included:

- Hemocompatibility
- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogencity

Microbial Ingress Testing

Microbial ingress testing was conducted to demonstrate that needless access site of Diana ChemoLock Transfer Set maintains physical integrity and mechanically prohibits the transfer of environmental contaminants into the system in use after access (the device is intended for single-use). The tests were conducted consistent with the recommendations for microbial ingress testing provided in FDA guidance titled "*Intravascular Administration Sets Premarket Notification Submissions [510(k)]"* issued on July 11, 2008.

Emission, Dry Disconnection, and CSTD Hazardous Drug Exposure Evaluation

Emission, Dry Disconnection, and CSTD Hazardous Drug Exposure Evaluation were performed to validate no escape of drug from the subject device outside the closed system.

Particulates

Particulate contamination testing was performed by following USP <788> (method 1) to demonstrate particulate levels in the subject device meet USP 788 requirements.

Sterility Testing
E-beam sterilization process validation was conducted according to ISO 11137-1 and ISO 11137-2, Sterilization of health care products – Radiation: Requirements for development, validation and routine control of a sterilization process for medical devices.
Bacterial endotoxin testing was conducted based on AAMI ST72 and USP <85>, and followed FDA Guidance for Industry – Pyrogen and Endotoxins Testing: Questions and Answers.

IX. CONCLUSION

The Diana ChemoLock Transfer Set is substantially equivalent to the predicate device.