K131549

JUL 26 2013

Section 5 510(k) Summary

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name: ICU Medical, Inc.
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Preparation Date: May 28, 2013

Device (Trade Name): ChemoLock Closed System Drug Transfer Device

Common/Usual Name: Closed System Drug Transfer Device

Classification Names: 21 CFR 880.5440. Closed System Drug Transfer Device. Product Code: 80ONB and 80FPA.

Predicate Device: K123213 BD Phaseal Closed System Drug Transfer Device
K081361 ChemoClave Cytotoxic Medication Preparation and Delivery System
K082806 Spinning Spiros

Device Description: The ChemoLock is a needlefree, single-use, Closed System Drug Transfer Device (CSTD). The ChemoLock has a mechanical means to prevent the transfer of environmental contaminants into the system, and the escape of drug or vapor concentrations outside the system. The system includes closed vial and bag access devices, a closed syringe adapter and closed patient administration sets. All components of the system include passive, self-sealing mechanisms which cannot be deactivated and remain protective through disposal.

Intended Use: The ChemoLock Closed System Drug Transfer Device prevents the transfer of environmental contaminants, including bacterial and airborne contaminants into the system, and the escape of drug or vapor concentrations outside the system. The ChemoLock is needlefree and cannot be deactivated, which will passively aid in preventing needlestick injuries and the exposure to cytotoxic medications for healthcare personnel.

Technology: The ChemoLock Closed System Drug Transfer Device employs the same fundamental scientific technology as its predicate devices. Please see Table 1 for more information.

Table 1: Summary Comparison of Technological Characteristics Table

Feature	ChemoClave	Spinning Spiros	Phaseal	ChemoLock	Comparison
510K NUMBER	K081361	*K082806*	*K123213*	*K131549*	*N/A*
Equalizes Vial Pressure when Accessed	Yes	Not Applicable	Yes	Yes	Identical to K123213 and K081361

Feature	ChemoClave	Spinning Spiros	' Phaseal	ChemoLock	Comparison
Prevents Escape of Drug or Vapor Concentratio	Yes	Yes	Yes	Yes	Identical
Closed Drug Transfer Mechanism	Elastomeric single membrane (ISO)	Elastomeric double membrane (ISO)	Elastomeric double membrane (non-ISO)	Elastomeric double membrane (non-ISO)	Identical to K123213
Activation Mechanism	ISO Luer locking	ISO Luer Locking	Non-ISO push-together connection with bayonet lock	Non-ISO push-together connection with clip locks	Similar to K123213
Available Accessories and Useable Components	Vial Access, Bag Access, Syringe Adapter and Patient Administration Sets	Syringe Adapter and Patient Administration Sets	Vial Access, Bag Access, Syringe Adapter, Injection Port Adapter	Vial Access, Bag Access, Syringe Adapter and Patient Administration Sets	Identical to K081361
NeedleFree	NeedleFree	NeedleFree	No, 18G needle with safety sleeve and/or steel spike	NeedleFree	Identical to K081361 and K082806
Connection to External Equipment	Standard ISO luer connection	Standard ISO Luer connection with permanent locking feature which prevents removal and stays protective through disposal	Standard ISO Luer Connections and Vial Spikes	Standard ISO luer connection with permanent locking feature which prevents removal and stays protective through disposal	Identical to K082806
Microbial Barrier	Yes	Yes	Yes for Vial Access No for Syringe Adapter	Yes	Identical to K081361 and K082806
Sterilization	Ebeam	Ebeam	EO	Ebeam	Identical to K081361 and K082806
Materials of Construction	Biocompatible thermoplastics and silicone	Biocompatibile thermoplastics and silicone	Biocompatible thermoplastics, silicone and stainless steel	Biocompatible thermoplastics and silicone	Identical to K081361 and K082806
Single Use	Yes	Yes	Yes	Yes	Identical

Determination of Substantial Equivalence: The demonstration of substantial equivalence is based on a comparison of features to the predicate devices and an assessment of non-clinical performance data. Information is included with this 510(k) submission that supports this determination.

Non Clinical Performance Data Summary The ChemoLock Closed System Drug Transfer Device is intended to be used with closed vial and bag access devices, closed syringe adapters, and closed patient administration sets. The two piece system, comprised of two components called the ChemoLock and the ChemoLock Port (or Port), is intended to allow the user to adapt an ISO-594 luer system to a custom adapted, Closed System Drug Transfer Device. The female luer end of the ChemoLock is compatible with all male ISO connections and the other side is only compatible with the Port. The male end of the Port is compatible with all female ISO connections while the other side is only compatible with the ChemoLock.

The ChemoLock and Port will prevent leakage of fluid when in the inactivated state. When the ChemoLock is connected to the Port, the fluid path is activated and becomes an open two way conduit. When disconnected, the ChemoLock and Port will self-seal and offer a dry, leak proof disconnection.

Microbial Ingress testing as provided in this submission shows that the ChemoLock Closed System Drug Transfer Device has the ability to prevent bacterial ingress. Said testing shows that the device will prevent bacterial ingress completely if used in accordance with the directions for use. The prevention of bacterial ingress is specifically important for pediatrics and immune-compromised patients that would otherwise be at risk of infections.

The *Evaluation of Closed-system Drug Transfer Devices* as provided in this submission shows that the ChemoLock Closed System Drug Transfer Device is able to prevent the egress of chemicals both during preparation and transfer of the cytotoxic agent. Results of the study suggest that the ChemoLock system was effective in preventing detectible surface contamination during three separate trials of compounding activities with known amounts of cyclophosphamide. The prevention of environmental contamination is specifically important for the containment of cytotoxic pharmaceuticals which will passively prevent the exposure to such chemicals by healthcare workers.

The ChemoLock Closed System Drug Transfer Device has been tested in accordance with its performance specification which accommodates known functional requirements.

The ChemoLock Closed System Drug Transfer Device configurations are individually packaged and pre-sterilized in a peel type, Multivac pouch with sealed Tyvek lidding.. The device can be included as part of a closed vial or bag access device, closed syringe adapter, or closed patient administration set. This device may be included as part of a custom kit or set - as prescribed by a physician. ICU Medical performs analysis and design verification testing based on predetermined criteria, which is documented in the Performance Specification contained in this

submission. All testing meets these performance criteria as defined for the device.

ICU Medical has also performed testing that is recommended by the guidance document "Intravascular Administration Sets Premarket Notification Submissions [510(k)]" and successful testing is included as part of this submission in the *Extended Use Protocol Results* document.

Conclusion: Performance testing included within this 510(k) demonstrates that the ChemoLock Closed System Drug Transfer Device is safe, effective and performs in an equivalent manner to the predicate devices and in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 11, 2013

ICU Medical, Incorporated
Ms. Katherine Kenner
Regulatory Affairs Specialist
4455 Atherton Drive
SALT LAKE CITY UT 84123

Re: K131549
Trade/Device Name: ChemoLock Closed System Drug Transfer
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: ONB, FPA
Dated: May 28, 2013
Received: May 29, 2013

Dear Ms. Kenner:

This letter corrects our substantially equivalent letter of July 26, 2013.

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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Office of Device Evaluation
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Enclosure

Section 4 Indications For Use

510(k) Number (if known): K131549

Device Name: ChemoLock Closed System Drug Transfer Device

Indications for Use: The ChemoLock Closed System Drug Transfer Device prevents the transfer of environmental contaminants, including bacterial and airborne contaminants into the system, and the escape of drug or vapor concentrations outside the system. The ChemoLock is needlefree and cannot be deactivated, which will passively aid in preventing needlestick injuries and the exposure to cytotoxic medications for healthcare personnel.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

FDA Richard C. Chapman 2013.07.25 09:44:14 -04'00' (Optional Format 1-2-96)

Division Sign-Off)
ivision of Anesthesiology, General Hospital
fection Control, Dental Devices

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