April 24, 2022

Omnicell, Inc.
David Vanella
VP Quality and Product Regulatory Affairs
500 Cranberry Woods Drive
Cranberry, Pennsylvania 16066

Re: K212530
Trade/Device Name: IVX Fluid Transfer Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI, NEP
Dated: March 24, 2022
Received: March 25, 2022

Dear David Vanella:

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,

Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212530

Device Name
IVX Fluid Transfer Set

Indications for Use *(Describe)*
The IVX Fluid Transfer Set is a single use device indicated for use with the IVX Station Pharmacy Compounding System.

The IVX Fluid Transfer device contains three separate tubing configurations and is indicated for the following applications:
• Aseptic withdraw of fluid from I.V. bag(s) in preparation for compounding,
• aseptic reconstitution of lyophilized drug in vial(s) from an I.V. bag source and
• aseptic transfer of fluid from an I.V. bag of compounded drug into a final container(s)
for use in the preparation of final compounded drugs for patient infusion administration.

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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K212530 - 510(k) SUMMARY

1. Submitter Information

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Contact Person:	David J. Vanella Vice President, Quality and Product Regulatory Affairs
Telephone Number:	(724) 741-8115
E-mail:	david.vanella@omnicell.com
Date Prepared:	March 23, 2022

2. Device Name and Classification

Device Trade Name:	IVX Fluid Transfer Set
Common Name:	Set, I.V. Fluid Transfer
Classification Name:	21 CFR 880.5440
Regulatory Class:	II
Product Code:	LHI
Secondary Product Code:	NEP

3. Predicate Device

Device Trade Name:	KIRO Set
Common Name:	IV Fluid Transfer Set
Classification Name:	21 CFR 880.5440 Set, I.V. Fluid Transfer
Regulatory Class:	II
Product Code:	LHI
Secondary Product Code:	NEP
510(k) Number:	K152441

4. Device Description

The IVX Fluid Transfer Set is a sterile, single-use fluid transfer tubing set that contain three separate tubing configurations, Withdraw Transfer Set, Reconstitution Transfer Set and Stock Solution Transfer Set.

- The Withdraw Transfer Set is used to remove excess fluid from an I.V. bag and place the fluid in a waste container for disposal.
- The Reconstitution Transfer Set is used to withdraw fluid from an I.V. bag and transfer the fluid to a vial that contains powdered drug so that the drug can be reconstituted.
- The Stock Solution Transfer Set is used to transfer fluid from an I.V. bag of a compounded drug into a final container, which is a syringe.

Each process is performed using aseptic technique within the ISO 5 environment using the IVX Pharmacy Compounding Station.

The IVX Fluid Transfer Set is intended to be used by trained healthcare personnel and is not intended to be used for direct patient contact.

5. Indication for Use/ Intended Use

Indication for Use:

The IVX Fluid Transfer Set is a single use device indicated for use with the IVX Station Pharmacy Compounding System. The IVX Fluid Transfer device contains three separate tubing configurations and is indicated for the following applications:

• Aseptic withdraw of fluid from I.V. bag(s) in preparation for compounding,

• aseptic reconstitution of lyophilized drug in vial(s) from an I.V. bag source and

• aseptic transfer of fluid from an I.V. bag of compounded drug into a final container(s)

for use in the preparation of final compounded drugs for patient infusion administration.

Intended Use:
The IVX Fluid Transfer Set is used for fluid transfer in the preparation of final medication containers and the reconstitution of drug vials in hospital pharmacies when used with the IVX Pharmacy Compounding Station.

6. Comparison of the Technological Characteristics with the Predicate Device

The technological characteristics of the subject device, IVX Fluid Transfer Set, are substantially equivalent to those of the predicate device, KIRO Set, in regard to the following technological characteristics:

- Principle of operation and conditions of use of the subject device are similar to those of the predicate device.
- Material composition of the subject device is equivalent to that of the predicate device in that both devices are made from plastics used in medical devices of this type. Material composition of the proposed device does not raise new questions of safety and effectiveness, as demonstrated by performance testing and biocompatibility evaluation.
- Physical specifications of the subject device are equivalent to those of the predicate device. The IVX Fluid Transfer Set does not raise new questions of safety and effectiveness, as demonstrated by performance testing.
- Design features and interfaces are equivalent in that both devices are used to provide a pathway through which fluid is transferred from one source container into another suitable container within in a pharmacy compounding station. The subject and predicate devices are limited to use within their respective pharmacy compounding stations. Performance verification of the subject device does not raise new questions of safety and effectiveness.
- Sterilization method and SAL level are identical between the subject and predicate device.

A comparison between the predicate device and the subject device is provided in Table 1:

Table 1: Comparison of Technological Characteristics with the Predicate Device

Areas for Comparison	Subject Device IVX Fluid Transfer Set	Predicate Device KIRO Set	Comparison
Product Code and Regulation	LHI 21 CFR 880.5440 Secondary: NEP 21 CFR 880.5440	LHI 21 CFR 880.5440 Secondary: NEP 21 CFR 880.5440	Identical
510(k) Number	K212530	K152441	---
Classification	LHI: Class II (non-exempt) NEP: Class II (exempt)	LHI: Class II (non-exempt) NEP: Class II (exempt)	Identical

Areas for Comparison	Subject Device IVX Fluid Transfer Set	Predicate Device KIRO Set	Comparison
Intended Use	This product is used for fluid transfer in the preparation of final medication containers and the reconstitution of drug vials in hospital pharmacies when used with the IVX pharmacy compoundingdevice.	This product is used for fluid transfer in the preparation of final medication containers and the reconstitution of drug vials in hospital pharmacies when used with the KIRO Oncology pharmacy compounding device.	Both devices are intended for fluid transfer and reconstitution of drug vials within their respective pharmacy compounding station.
Indication for Use	The IVX Fluid Transfer Set is a single use device indicated for use with the IVX Station Pharmacy Compounding System. The IVX Fluid Transfer device contains three separate tubing configurations and is indicated for the following applications: • Aseptic withdraw of fluid from I.V. bag(s) in preparation for compounding, • aseptic reconstitution of lyophilized drug in vial(s) from an I.V. bag source and • aseptic transfer of fluid from an I.V. bag of compounded drug into a final container(s) for use in the preparation of final compounded drugs for patient infusion administration.	The KIRO Set is a sterile, single-use disposable ancillary device used with the peristaltic pump in the KIRO Oncology pharmacy compounding device for the transfer of fluids into sterile powder drug vials or into sterile medication containers for intravenous drug administration. The device is for prescription use only.	The differences are minimal and do not impact the risk to patient or user. Both devices are sterile, single use devices indicated for the transfer of fluids into drug vials or other containers and reconstitution of drugs within their respective pharmacy compounding stations.
Type of Use	Prescription use only	Prescription use only	Identical
Conditions of Use	Single use only	Single use only	Identical

Areas for Comparison	Subject Device IVX Fluid Transfer Set	Predicate Device KIRO Set	Comparison
Sterilization Method	Gamma radiation	Gamma radiation	Identical
Intended for Direct Connection to Patient	No	No	Identical
Use Environment	Hospital pharmacy inside the IVX Station ISO 5 environment	Hospital pharmacy inside the KIRO Oncology PCD ISO 5 environment	Both are used in their respective pharmacy compounding stations in an ISO 5 environment
Target Users	Trained health-care personnel	Trained health-care personnel	Identical
Primary Fluid Contact Material—Tubing	Polycarbonate, Polyvinylchloride, Acrylonitrile Butadiene Styrene, Medical Grade Silicone, Polypropylene	Medical Grade Silicone	The differences are minimal and do not impact the risk to patient or user. Both devices are made of plastics commonly used in I.V. sets.
Fluid Transfer Mechanism	External Peristaltic Pump – Single Channel for the Withdraw Transfer Set Reconstitution Transfer Set and Stock Solution Transfer Set utilize a syringe for the pump	External Peristaltic Pump – Double Channel	The Withdraw Transfer Set is used with a peristaltic pump, which is identical to the KIRO Set. The Reconstitution and Stock Solution Transfer Sets utilize a syringe. The differences are minimal and do not impact the risk to patient or user.
Final Containers	Reconstitution Transfer Set: Vial Stock Solution Transfer Set: Syringe	Vials, Infusion Bags, Cassettes, Elastomeric pumps	The subject device includes two of the four final containers used with the predicate device.

7. Performance Testing

Performance Testing—Bench

Performance bench testing was conducted to demonstrate that the IVX Fluid Transfer Set performs as intended. No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

The following performance testing was conducted to support the substantial equivalence determination:

Biocompatibility Test	Standard Number	Standard Description
Hemolysis	ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
Cytotoxicity	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
Irritation and Sensitization	ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
Acute Systemic Toxicity	ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
Material Mediated Pyrogen Testing	USP <151>	Rabbit Pyrogen Test
Bench Test	**Standard Number**	**Standard Description**
Performance Testing	ISO 22413:2021	Transfer sets for pharmaceutical preparations — Requirements and test methods
	ISO 8536-4:2019	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
	ISO 80369-7:2021	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
	ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications
	USP<788>	Particulate Matter in Injections
	---	Microbial Ingress Testing
	IEC 62366-1:2015	Usability Testing

Sterilization and Packaging	Standard Number	Standard Description
Sterilization	ISO 11137-1: 2018	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
	ISO 11137-2: 2013	"Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
	ISO 11137-3: 2017	"Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control"
	ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population
	ISO 11737-2: 2019,	"Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
Bacterial Endotoxins/Packaging	USP <161>	Transfusion and Infusion Assemblies and Similar Medical Devices
	USP<85>,	Bacterial endotoxins test
	ANSI/AAMI ST72: 2019	Bacterial endotoxins - Test methods, routine monitoring
	F88/F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
	F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
	F2096-11 (Reapproved 2019)	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

In addition, compatibility of the IVX Fluid Transfer Set with the IVX Pharmacy Compounding Station was evaluated for dose accuracy with representative fluids.

Conclusion:
The IVX Fluid Transfer Set has met all established acceptance criteria for performance testing and design verification testing. Results of performance and biocompatibility testing conducted with the IVX Fluid Transfer Set demonstrate that the subject device supports a substantial equivalence determination to the predicate device, KIRO Set.