November 23, 2022

Shinva Ande Healthcare Apparatus Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K201460
Trade/Device Name: Closed System Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: October 28, 2022
Received: October 28, 2022

Dear Ray Wang:

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,

David Wolloscheck, Ph.D.
For Joyce M. Whang, Ph.D.
Acting 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)*
K201460

Device Name
Closed System Transfer Device

Indications for Use *(Describe)*
The Closed System Transfer Device (CSTD) for preparation, reconstitution, compounding and administration of drugs, including antineoplastic and hazardous drugs. This closed system mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills and also prevents microbial ingress.

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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K201460 510(k) Summary

1. Date of Preparation

   11/27/2022

2. Sponsor

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3. Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Closed System Transfer Device
Common Name: Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
Classification Name: Intravascular Administration Set
Classification: II;
Product Code: ONB;
Regulation Number: 21 CFR 880.5440；
Review Panel: General Hospital;

5. Identification of Proposed Device
K170706 - Equashield Closed System Drug Transfer Device (CSTD)

6. Device Description

The Closed System Transfer Device is a sterile, single use, Closed System drug Transfer Device (CSTD) for preparation, reconstitution, compounding and administration of antineoplastic and hazardous drugs. The Closed System Transfer Device consists of a piston syringe set (Dispensing Connector), an adaptor to the medication vial (Vial Adaptor), an adaptor for the IV bag for injection (Spike Adaptor), and Infusion Set.
The model of each component listed in Table 1.

Table 1 Models listing

Components Name	Models
Vial Adapter	CSTD-A13，CSTD-A28，CSTD-A20
Spike Adapter	CSTD-B1，CSTD-B2，CSTD-B3，CSTD-B4
Dispensing Connector	CSTD-C5，CSTD-C10，CSTD-C30
Closed Infusion Set	MSQ-W1-P1, MSQ-W3-P1, MSQ-W4-P1

7. Operation Principle

Connection of Vial adaptor, Spike adaptor and dispensing connector

Vial and infusion bag are respectively connected with Vial adaptor and spike adaptor, then in order to realize the connection between Vial and infusion bag, the Vial adaptor and spike adaptor are correspondingly connected with each matching end of the dispensing connector. All system components are sealed with resealing membranes, and elastomeric double membrane technology is used to ensure that there is no drug leakage at the connecting parts during the dispensing process. As a

power device, the double sealed syringe provides positive and negative pressure for the CSTD to realize the closed transfer of liquid medicine from the Vial to the infusion bag in the system.

Closed Infusion Set

The working principle of the infusion set is gravity infusion, which is connected with the indwelling needle or other connector. Under the action of gravity, the medicine is infused into human blood vessels through the infusion tube.

Drug Vapor Seal

Vial adaptor contains spike end and assembly end, there is an inverted structure at the puncture end, and there is a sealing element at the assembly end. After the Vial adaptor is matched with the vial, it can ensure that there is no leakage, and it is not easy to separate.

Table 2 Final Combinations List

No.	Final Combination Model	Components Included in the Final Combinations			
		Closed Infusion Set Model	Spike Adapter Model	Dispensing Connector Model	Vial Adapter Model
001	W1-P1/B1/C5/A13	MSQ-W1-P1	CSTD-B1	CSTD-C5	CSTD-A13
002	W1-P1/B1/C5/A20	MSQ-W1-P1	CSTD-B1	CSTD-C5	CSTD-A20
003	W1-P1/B1/C5/A28	MSQ-W1-P1	CSTD-B1	CSTD-C5	CSTD-A28
004	W1-P1/B1/C10/A13	MSQ-W1-P1	CSTD-B1	CSTD-C10	CSTD-A13
005	W1-P1/B1/C10/A20	MSQ-W1-P1	CSTD-B1	CSTD-C10	CSTD-A20
006	W1-P1/B1/C10/A28	MSQ-W1-P1	CSTD-B1	CSTD-C10	CSTD-A28
007	W1-P1/B1/C30/A13	MSQ-W1-P1	CSTD-B1	CSTD-C30	CSTD-A13
008	W1-P1/B1/C30/A20	MSQ-W1-P1	CSTD-B1	CSTD-C30	CSTD-A20
009	W1-P1/B1/C30/A28	MSQ-W1-P1	CSTD-B1	CSTD-C30	CSTD-A28
010	W1-P1/B2/C5/A13	MSQ-W1-P1	CSTD-B2	CSTD-C5	CSTD-A13
011	W1-P1/B2/C5/A20	MSQ-W1-P1	CSTD-B2	CSTD-C5	CSTD-A20
012	W1-P1/B2/C5/A28	MSQ-W1-P1	CSTD-B2	CSTD-C5	CSTD-A28
013	W1-P1/B2/C10/A13	MSQ-W1-P1	CSTD-B2	CSTD-C10	CSTD-A13
014	W1-P1/B2/C10/A20	MSQ-W1-P1	CSTD-B2	CSTD-C10	CSTD-A20
015	W1-P1/B2/C10/A28	MSQ-W1-P1	CSTD-B2	CSTD-C10	CSTD-A28
016	W1-P1/B2/C30/A13	MSQ-W1-P1	CSTD-B2	CSTD-C30	CSTD-A13
017	W1-P1/B2/C30/A20	MSQ-W1-P1	CSTD-B2	CSTD-C30	CSTD-A20
018	W1-P1/B2/C30/A28	MSQ-W1-P1	CSTD-B2	CSTD-C30	CSTD-A28
019	W3-P1/C5/A13	MSQ-W3-P1	/	CSTD-C5	CSTD-A13
020	W3-P1/C5/A20	MSQ-W3-P1	/	CSTD-C5	CSTD-A20
021	W3-P1/C5/A28	MSQ-W3-P1	/	CSTD-C5	CSTD-A28
022	W3-P1/C10/A13	MSQ-W3-P1	/	CSTD-C10	CSTD-A13

023	W3-P1/C10/A20	MSQ-W3-P1	/	CSTD-C10	CSTD-A20
024	W3-P1/C10/A28	MSQ-W3-P1	/	CSTD-C10	CSTD-A28
025	W3-P1/C30/A13	MSQ-W3-P1	/	CSTD-C30	CSTD-A13
026	W3-P1/C30/A20	MSQ-W3-P1	/	CSTD-C30	CSTD-A20
027	W3-P1/C30/A28	MSQ-W3-P1	/	CSTD-C30	CSTD-A28
028	W4-P1/B3/C5/A13	MSQ-W4-P1	CSTD-B3	CSTD-C5	CSTD-A13
029	W4-P1/B3/C5/A20	MSQ-W4-P1	CSTD-B3	CSTD-C5	CSTD-A20
030	W4-P1/B3/C5/A28	MSQ-W4-P1	CSTD-B3	CSTD-C5	CSTD-A28
031	W4-P1/B3/C10/A13	MSQ-W4-P1	CSTD-B3	CSTD-C10	CSTD-A13
032	W4-P1/B3/C10/A20	MSQ-W4-P1	CSTD-B3	CSTD-C10	CSTD-A20
033	W4-P1/B3/C10/A28	MSQ-W4-P1	CSTD-B3	CSTD-C10	CSTD-A28
034	W4-P1/B3/C30/A13	MSQ-W4-P1	CSTD-B3	CSTD-C30	CSTD-A13
035	W4-P1/B3/C30/A20	MSQ-W4-P1	CSTD-B3	CSTD-C30	CSTD-A20
036	W4-P1/B3/C30/A28	MSQ-W4-P1	CSTD-B3	CSTD-C30	CSTD-A28
037	W4-P1/B4/C5/A13	MSQ-W4-P1	CSTD-B4	CSTD-C5	CSTD-A13
038	W4-P1/B4/C5/A20	MSQ-W4-P1	CSTD-B4	CSTD-C5	CSTD-A20
039	W4-P1/B4/C5/A28	MSQ-W4-P1	CSTD-B4	CSTD-C5	CSTD-A28
040	W4-P1/B4/C10/A13	MSQ-W4-P1	CSTD-B4	CSTD-C10	CSTD-A13
041	W4-P1/B4/C10/A20	MSQ-W4-P1	CSTD-B4	CSTD-C10	CSTD-A20
042	W4-P1/B4/C10/A28	MSQ-W4-P1	CSTD-B4	CSTD-C10	CSTD-A28
043	W4-P1/B4/C30/A13	MSQ-W4-P1	CSTD-B4	CSTD-C30	CSTD-A13
044	W4-P1/B4/C30/A20	MSQ-W4-P1	CSTD-B4	CSTD-C30	CSTD-A20
045	W4-P1/B4/C30/A28	MSQ-W4-P1	CSTD-B4	CSTD-C30	CSTD-A28

8. Indication for Use:

Table 3 Indication For Use

Characteristic	**Proposed Device** Closed System Transfer Device (CSTD) K201460	**Predicate Device** Equashield Closed System Drug Transfer Device (CSTD) K170706
Indication For Use	The Closed System Transfer Device (CSTD) for preparation, reconstitution, compounding and administration of drugs, including antineoplastic and hazardous drugs. This closed system mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor,	Closed System drug Transfer Device (CSTD) for safe preparation, reconstitution, compounding and administration of drugs, including antineoplastic and hazardous drugs. This closed system mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental

	aerosols, and spills and also prevents microbial ingress.	exposure to drug vapor, aerosols, and spills and also prevents microbial ingress up to 7 days.
Prescription Only or Over the Counter	Prescription Only	Prescription Only

Discussions of differences in Indications for Use statement

There are only editorial differences to the indications for use statement between the predicate and the subject device which do not change the indications.

9. Technological Characteristics

Table 4 Technological Characteristics Comparison

ITEM	Proposed Device	Predicate Device K170706	Remark
Biocompatibility	Externally communicating medical device, blood path, indirect	Externally communicating medical device, blood path, indirect	Same
Device Type	Rx/Single Use	Rx/Single Use	Same
Target Users	Licensed Pharmacists/Health Care Professionals	Licensed Pharmacists/Health Care Professionals	Same
Environment	Hospitals Clinics	Hospitals Clinics	Same
Sterilization	EO SAL 10-6	EO and Gamma SAL 10-6	Same
System Components	Vial Adaptor Dispensing Connector Spike Adaptor Infusion Set	Vial Adaptor Syringe Unit Spike Adaptor Luer Lock Connectors IV Tubing set Protective Plug	Difference - See Comments #1
Type of vials the device is compatible with	13 mm vial neck size; 28 mm vial neck size; 20 mm vial neck size;	13 mm vial neck size; 28 mm vial neck size; 20 mm vial neck size; 20 mm vial neck size, and extra thick vial rubber stoppers (Concave stoppers);	Same
Mechanism of connection	Vial Adaptor will connection with Vial	Vial Adaptor will connection with Vial	Same
	Dispensing Connector will connect with Vial Adaptor and Spike Adaptor at same time	Syringe Unit will connect with Vial Adaptor and Spike Adaptor separately	Difference - See Comments #2
	IV infusion will connect with the IV bag	IV tubing set will connect with the IV bag	Same
Safety features to prevent contamination	Leak proof connector with Membranes (Septum) seal	Leak proof connector with Membranes (Septum) seal	Same
Activation Mechanism	The barrel of syringe unit of Dispensing	The barrel of syringe unit (pull the	Same

		Connector (pull the plunger) will provide the power for drug transfer.	plunger) will provide the power for drug transfer.	
Drug Path		Vial – Vial Adaptor - Dispensing Connector (connector and tube) – Spike Adaptor – IV bag	Vial – Vial Adaptor – Syringe Unit (Connector and Barrel of Syringe) - Spike Adaptor – IV bag	Difference - See Comments #3
Materials	**Vial Adaptor**	Synthetic Rubber (Sealing element); PP (Body);	Polypropylene (Protective Cap) Polyisoprene (Septum) POM (External guiding ring) Silicon (Lubricant) ABS (Body) Hydrophobic Membrane (Membrane)	Difference - See Comments #4
	Dispensing Connector	PP (Single channel needle seat, Double channel needle seat, barrel, plunger); ABS (Guide sleeve, Rubber plug holder); Stainless Steel SUS304 (Needle, Stainless steel heads); Synthetic Rubber (Piston, Sealing Ring); TPE (Tube);	Polypropylene (Syringe body, connector and housing); Stainless Steel (Plunger rod, screw, cannulas); Polyisoprene (Piston, septum); POM (Syringe lid, lid disc, needle compartment); Silicon (Seal ring, seal tube, lubricant); EPDM (O-ring); ABS (Handle);	
	Spike Adaptor	PE (Protection Cap); PVC/PP (Air inlet with air filter and closure); ABS (Spike adaptor) Synthetic Rubber (Sealing element, Rubber plug);	Polypropylene (Clamp, Luer Cap, Protective cap (Spike)); Polyisoprene (Septum); Silicon (Valve); ABS (Male luer lock, Female luer lock, Y-site, regulator, body (Spike Adaptor), Body (Luer lock adaptor)); PVC (Tubing, drip chamber); Hydrophobic membrane (Membrane);	
	IV Infusion	PE (Protective cap); ABS (Closure-piecing device, fluid filter shell, Male conical fitting); PVC (Air inlet, drip chamber); PP(Air inlet); PA/PES (fluid filter shell); ABS/synthetic rubber (Injection site); POM (Robert clamp); ABS/Silicon rubber (Closed Male luer, Needle-free Y connector, Check Valve);	Polypropylene (Clamp, luercap, protective cap (spike)); Polyisoprene (Septum); Silicon (Valve); ABS (Male luer lock, female luer lock, Y-site, Regulating clamp, body (spike adaptor), body (luer lock adaptor)); PVC (Tubing, Drip chamber); Hydrophobic Membrane (Membrane)	
Specification	**Vial Adaptor**	CSTD-A13 is for 13 mm vial neck size; CSTD-A28 is for 28 mm vial neck size;	VA-13/2 is for 13 mm vial neck size; VA-28/2 is for 28 mm vial neck size;	Same

		CSTD-A20 is for 20 mm vial neck size;	VA-20/2 is for 20 mm vial neck size; VA-20C/2 is for 20 mm vial neck size, and extra thick vial rubber stoppers (Concave stoppers);	
	Dispensing Connector	CSTD-C5 is for 5 ml volumes; CSTD-C10 is for 10 ml volumes; CSTD-C30 is for 30 ml volumes;	SU-1/2 is for 1 ml volumes; SU-3/2 is for 3 ml volumes; SU-5/2 is for 5 ml volumes; SU-10/2 is for 10 ml volumes; SU-20/2 is for 20 ml volumes; SU-35/2 is for 35 ml volumes; SU-60/2 is for 60 ml volumes;	Similar-See Comments #5
	IV Infusion	Length: 2.38 m/2.555 m/2.535 m ID: 3.0±0.05mm OD: 4.0±0.05mm	Length: 1.15 m/ 0.48 m/ 0.23 m ID: 3.0±0.05mm OD: 4.0±0.05mm	Similar-See Comments #5

Difference Analysis:

Comments #1:
The proposed device does not include exactly same system components with the predicate device, there two main differences about component,

1) The Dispensing Connector of proposed device has different design feature with the Syringe Unit of predicate device. We have conducted detailed analysis about this difference in Analysis 5 below.
2) The predicate device includes two more components than proposed device, Luer Lock Connectors and Protective Plug.
   - The Luer Lock Connectors (Male and Female) provide closed system and contamination-free protection to any standard luer lock ports, by converting them into a membrane sealed port, such as required when connecting two IV tubing segments (Secondary to Primary) or for safe injection of medication using the Syringe Unit (IV Push/Bolus). The two pieces lock together and can be released by simply pushing the lever.

   As the function description for the Luer Lock Connector above, this component is used to administer an IV push, but the proposed device does not have this function, and it would not affect the Indication for Use of proposed device.

   - The protective plug is an accessory providing additional protection for Female Luer Connector or Syringe Unit port, such as for safe transportation with disabled movement of the syringe plunger.

   As the function description for the Protective Plug above, this component is used to seal the port of syringe unit to provide protective for prepared compounding or drugs in the syringe unit from microbial ingress up to 7 days as the Indication For Use claimed by predicate device. But the proposed device does not have the function, and it would not affect the Indication for Use of proposed device.

Comments #2

The Mechanism of connection of proposed device is different with the Syringe Unit of predicate device. Both components are syringe-like design, but the “Dispensing Connector” is designed as two connectors (adapter ends) used to connect with Vial Adaptor and Spike Adaptor and prevents leaks & drug residuals on its surfaces, one connector (the one used to connect with Vial Adaptor) is factory welded to the syringe, another connector is used to connect with Spike Adaptor, two connectors are connected by a factory welded TPE tube. The dispensing connector will connect the vial and IV bag via vial adaptor and spike adaptor at same time, the drug will be transferred from vial to IV bag without passing through syringe.

But the “Syringe Unit” of predicate is designed as single motion connector used to connect with Vial Adaptor and prevents leaks & drug residuals on its surfaces and is factory welded to the syringe.

The syringe unit will connect vial via vial adaptor and transfer the drug into syringe first, and then inject the drug in the syringe into infusion bag via spike adaptor.

The main difference between these two components is the design of connector, two connectors VS. one connector.

The Dispensing Adaptor use two connectors could be connected with vial adaptor and spike adaptor at same time, in this way, the drug in vial can be transferred directly from the vial to the infusion bag through the two connectors and the connecting tube in between under the power provided by pulling syringe barrel, without separating the Dispensing Adaptor from the vial and the drug does not need to be withdraw into the syringe during the transfer process. This way can always keep the drug in a closed environment in the process of drug transfer, thus reducing the probability and risk of contaminants entering the drug.

The Syringe Unit use one connector, the syringe unit need to connect with vial adaptor first for withdrawal of drug from vial to syringe, and then the syringe unit need to separating from vial adaptor and to connect with spike adaptor for injection of drug in syringe to infusion bag.

As the discussion above, the design difference of two components causes the different operation process. But they share same operation principle, they both withdraw the drug form vial and transfer the drug to infusion bag to complete their claimed Indication for Use, which is preparation, reconstitution, compounding and administration of drugs. Because the design feature of dispensing adaptor, the transferred drug in this way has more effectiveness in reducing chance of exposure to contaminants, then we believe that this method can more effectively prevent the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system during the process, thereby to accomplish clamed Indication for Use, which is minimizing individual and environmental exposure to drug vapor, aerosols, and spills and also prevents microbial ingress.

We have conducted the performance testing for the proposed device, the results shown that the proposed device could accomplish the drug transfer without drug leakage or exposure to contaminants, so we believe the proposed device has same effectiveness and safety with predicate device.

Comments #3

The drug path of proposed device is different with the predicate device, which because the different Mechanism of connection, as described in analysis 3, we believe the proposed device has same effectiveness and safety with predicate device.

Comments #4

The materials used in each components of proposed device are not exactly same with the materials used in predicate device, for these difference, we have conducted biological evaluation as the guidance of ***Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"***, as the endpoints of contact level and duration, we have conducted tests of Acute Systemic Toxicity, Skin Sensitization, Intracutaneous Reactivity, Hemolysis, In Vitro Cytotoxicity, Pyrogen and Chemical Characterization Study. The tests results shown that the materials used in proposed device would not raise safety concerns.

Comments #5

The specification of Dispensing Connector and IV Infusion are similar with the predicate device, for this difference we have conducted the performance testing to Vial Adaptor and Dispensing Connector as ISO 22413, ISO 7886-1 and ISO 8536-4, the test results shown that the proposed device could meet the requirements of claimed.

So, this difference would not raise safety or effectiveness concerns.

10. Non-Clinical Test Conclusion

Nonclinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

The test results demonstrated that the proposed device complies with the following standards:

- ISO 594-1:1986 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements;
- ISO 594-2:1998 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings;
- ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use;
- ISO 8536-2:2010 Infusion equipment for medical use – Part 2: Closures for infusion bottles;
- ISO 8536-4:2010 Infusion equipment for medical use - Part 4: Systems for single use, gravity feed;
- ISO 8536-12:2007 Infusion equipment for medical use – Part 12: Check valves;
- ISO 10555-5:2013 Intravascular catheters --Sterile and single-use Catheters---Part5：Over-needle peripheral catheter
- ISO 22413:2010 Transfer sets for pharmaceutical preparations - Requirements and test methods;
- ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices

11. Biocompatibility

In accordance with ISO 10993-1, the Closed System Transfer Device is classified as: Externally Communicating Device, Blood Path Indirect, Prolonged Contact (>24hrs to 30days). The following testing was conducted:

- Acute Systemic Toxicity Test
- Cytotoxicity Test Report
- Hemolysis Test (Indirect contact)
- Hemolysis Test (Direct Contact
- Intracutaneous Reactivity Test
- Platelet Activation Test
- Material Mediated Pyrogen Test
- Skin Sensitization (Guinea Pig Maximization Test)
- Subacute Systemic Toxicity Test

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

12. Sterility, Shipping and Shelf-Life

- Simulated Transportation Testing was conducted in accordance with ASTM D4169-16 DC13
- Sterile Barrier Packaging Testing performed on the proposed device:
  - Seal strength testing was conducted in accordance with ASTM F88/F88M-15
  - Dye Penetration testing was conducted in accordance with ASTM F1929-15
- Shelf-life life of 3 years is validated using the FDA recognized standard ASTM F1980-21 for Accelerated Aging of Sterile Barrier System for Medical Devices

13. Clinical Test Conclusion

No clinical study is included in this submission.

14. Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device (K170706 - Equashield Closed System Drug Transfer Device (CSTD)) with respect to the indications for use, target population, treatment methods and technological characteristics.