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510(k) Summary K132899

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: May 12, 2014

Applicant

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Device Information

Trade Name:	Equashield Closed System drug Transfer Device (CSTD)
Model Numbers:	Generations 1 & 2: (VA-x, SU-x, SA-x, LL-x, MC-x, FC-x, PP-x)
Classification Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
Review Panel:	General Hospital
Product Code:	ONB
Device Class:	Class II
Regulation:	21 C.F.R. §880.5440

Predicate Device Information

K101940 Equashield Closed System, cleared November 19, 2010
K130197 PhaSeal Closed System, cleared February 27, 2013

Intended Use/Indications for Use

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 exposure to drug vapor, aerosols, and spills and also prevents microbial ingress.

Principle of Operation

Equashield (first and second generation) is a device which has been substantiated to prevent microbial ingress up to a time period of 7 days and has been substantiated for multiple reconnections of components up to 10 times. Equashield is a Closed System drug Transfer Device (CSTD) which does not require priming, does not include an Insertion Tube, and is not a "Gravity Feed" System. Equashield does contain accessories which contain tubing, one accessory uses "drip therapy" but no tubing contains plasticizer DEHP. Equashield is a single use, nontoxic, non-pyrogenic fluid path system which is provided sterile as long as the package is intact, undamaged, and protective caps are secure. 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. System contains filters and needles using a needle stick safe design.

Device Description

The Equashield system consists of a piston syringe (Syringe Unit), an adaptor to the medication vial (Vial Adaptor), an adaptor for the infusion bag for injection (Spike Adaptor I), an adaptor for the infusion bag for withdrawal (Spike Adaptor W), an adaptor for female luer lock ports (Luer Lock Adaptor), nursing pair connectors for male and female luer lock ports (Female LL Connector and Male LL Connector), and a protective plug (Protective Plug). The Equashield closed system consists of 8 components that are dedicated to each other to create a system. The components are not intended to be used individually. Vial Adaptor is 48 x 31mm, 23mm at distal end. Plug is 51 x 17mm large. Female luer lock is 50 x 23 mm with a 5.2mm ID. Male luer lock is 42 x 21mm with a 15mm depth. Spike Adaptor is 75 x 42 mm and the height is 22mm.

Accessories Description

Y-Site Tubing – this accessory consists of a Luer Lock Adaptor permanently attached to a Y-Site. Short pieces of tubing extend from each of the other two Y-Site ports, creating one tubing line. One tube is terminated with a female luer lock and the other is terminated with a male luer lock. The Y-Site Tubing Accessory is intended to be attached in series to an infusion line and the Equashield Luer Lock Adaptor enables safe connection and injection with the Equashield Syringe Unit or Female Connector. Priming volume: 1.9ml, length 25cm, Y-angle 30 degrees.

Spike Adaptor Secondary Tubing - consists of a Spike Adaptor-1 for injection with a drip chamber at its outlet. The drip chamber with the attached tubing, the roller clamp and the male luer lock at the tubing end, all constitute standard secondary infusion tubing sets. The integration of the standard infusion tubing set with the Equashield Spike Adaptor provides a closed system protection during injection of drugs into the infusion bag and during their administration. It reduces the assembly steps and the risk of exposure to drugs associated with such assembly procedures. Length is 100 cm, priming volume 7.5ml.

Performance

No performance standards or special controls have been developed under Section 514 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") for Closed System Transfer Devices (CSTD). However, the Equashield System Generation 2, its accessories, and its components follow FDA recognized consensus standards:

- Recognition Number 6-11: ISO 594-1:1998, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
- Recognition Number 6-129: ISO 594-2:1998, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
- Recognition Number 6-170: ISO 7886-1:1993, Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- Recognition Number 6-245: ISO 8536-4:2010, Infusion equipment for medical use - Part 4: Systems for single use, gravity feed
- Recognition Number 2-156: ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-4:2002, Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
- Recognition Number 2-153: ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- Recognition Number 5-40: ISO 14971:2007, Medical devices - Application of risk management to medical devices
- ISO 22413:2010, Transfer sets for pharmaceutical preparations -- Requirements and test methods
- Recognition Number 6-273: ISO 23908:2011, Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Substantial Equivalence

Equivalence was determined using a side by side tabular comparison between the predicate and proposed devices which included: Features, Intended Use, Labeling, Materials, Specifications, Performance Data, and Technological Aspects

SE Table of Attributes

	Proposed Device	Predicate Device (K101940)	Predicate Device (K130197)
Intended Use	Same	Same	Same
Indications for Use	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 exposure to drug vapor, aerosols, and spills and also prevents microbial ingress.	Contained system to be used by pharmacists or other healthcare professionals to prepare drugs, including cytotoxic drugs for intravenous infusion or injection.	System is an airtight and leak-proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor contractions outside the system thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The system also prevents microbial ingress.
Classification	Class II	Class II	Class II
Regulation Number	888.5440	888.5440	888.5440
Product Code	ONB	LHI	ONB

	Proposed Device	Predicate Device (K101940)	Predicate Device (K130197)
System components	Vial Adaptor	Vial Adaptor	Vial Adaptor (“Protector”)
	Syringe Unit	Syringe Unit	Syringe connector (“Injector” with female luer lock)
	Spike Adaptor I- for injection	Spike Adaptor I- for injection	Spike Adaptor (“Infusion Adaptor”)
	Spike Adaptor W- for withdrawal	Spike Adaptor W- for withdrawal	
	Luer Lock Adaptor	Luer Lock Adaptor	Male “Connector Luer Lock”
	Male Luer Lock Connector	Male Luer Lock Connector	Male “Connector Luer Lock”
	Female Luer Lock Connector	Female Luer Lock Connector	Female luer lock connector (“Injector”)
	Protective Plug	Protective Plug	NA
	Y-Site Tubing (Accessory)	NA	Luer Lock Adaptor with Y-site tubing (“Y-Site Connector”)
	Secondary Tubing (Accessory)	NA	Spike adaptor with secondary tubing (“Secondary Set with Drip Chamber”)
Characteristics	Closed System used for antineoplastic and hazardous drug reconstitution, transfer and administration, in order to prevent contamination of the surrounding environment and of the drug	Closed System used for antineoplastic and hazardous drug reconstitution, transfer and administration, in order to prevent contamination of the surrounding environment and of the drug	Closed System used for antineoplastic and hazardous drug reconstitution, transfer and administration, in order to prevent contamination of the surrounding environment and of the drug
	Multi-component system. Components are intended to be used as a system.	Multi-component system. Components are intended to be used as a system.	Multi-component system. Components are intended to be used as a system.
Principles of Operation	Multi-component system. Components are intended to be used as a system.	Multi-component system. Components are intended to be used as a system.	Multi-component system. Components are intended to be used as a system.

	<i>Proposed Device</i>	<i>Predicate Device (K101940)</i>	<i>Predicate Device (K130197)</i>
Technological Characteristics	<p>A leak-proof connector with a single use syringe permanently attached to it as part of the system.</p>	<p>A leak-proof connector with a single use syringe permanently attached to it as part of the system.</p>	<p>A leak-proof connector ("InjectorSM") that needs to be connected to an off the shelf single use syringe.</p>
	<p>All system components are sealed with resealing membranes (Septum). When components are joined together the two membranes are pressed together and then pierced by needles. System has integrated closed pressure equalization.</p>	<p>All system components are sealed with resealing membranes (Septum). When components are joined together the two membranes are pressed together and then pierced by needles. System has integrated closed pressure equalization.</p>	<p>All system components are sealed with resealing membranes (Septum). When components are joined together the two membranes are pressed together and then pierced by needles. System has integrated closed pressure equalization.</p>
	<p>The system syringe is closed from all sides. The syringe barrel is sealed airtight also at its rear end, thereby isolating the plunger rod and the interior of the barrel.</p>	<p>The system syringe is closed from all sides. The syringe barrel is sealed airtight also at its rear end, thereby isolating the plunger rod and the interior of the barrel.</p>	<p>NA</p>

	Proposed Device	Predicate Device (K101940)	Predicate Device (K130197)
Secondary Tubing (“Secondary Set with Drip Chamber”)	Spike Adaptor with drip chamber and secondary tubing attached.	NA	Spike Adaptor (“infusion adaptor”) with drip chamber and secondary tubing attached.
System	<p>A fully encapsulated Syringe Unit is the active transfer device of this closed system.</p> <p>The syringe barrel is sealed airtight also at its rear end, thereby isolating the plunger rod and the interior of the barrel. A leak-proof connector is permanently welded to the syringe.</p> <p>The closed pressure equalization system with a chamber containing sterile air is built-in the Syringe Unit and makes the system airtight consequently containing all aerosols, particles and vapors.</p> <p>For transfer of fluids the Syringe Unit connects to the passive Vial Adaptors, infusion bag and infusion tubing adaptors of the system, using the double membrane method to create a leak-proof and drug residual-free connection.</p>	<p>A fully encapsulated Syringe Unit is the active transfer device of this closed system.</p> <p>The syringe barrel is sealed airtight also at its rear end, thereby isolating the plunger rod and the interior of the barrel. A leak-proof connector is permanently welded to the syringe.</p> <p>The closed pressure equalization system with a chamber containing sterile air is built-in the Syringe Unit and makes the system airtight consequently containing all aerosols, particles and vapors.</p> <p>For transfer of fluids the Syringe Unit connects to the passive Vial Adaptors, infusion bag and infusion tubing adaptors of the system, using the double membrane method to create a leak-proof and drug residual-free connection.</p>	<p>The system uses a double membrane to create a leak-proof connection. The closed expansion chamber makes the system airtight consequently containing all aerosols, particles and vapors. The expansion chamber also equalizes the pressure within the system. It can handle most types of IV sets and syringes to enable a totally safe and convenient administration of drugs.</p>
Device Type	Rx/Single Use	Rx/Single Use	Rx/Single Use
Target Users	Licensed Pharmacists/Health Care Professionals	Licensed Pharmacists/Health Care Professionals	Licensed Pharmacists/Health Care Professionals
Environment	Hospitals and clinics	Hospitals and clinics	Hospitals and clinics
Sterilization	EO/SAL 10 ⁻⁶	EO/SAL 10 ⁻⁶	EO/SAL 10 ⁻⁶



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

May 13, 2014

Equashield Medical Ltd.
c/o Raymond J Kelly IV
Arazy Group
57 Lazy Brook Rd
MONROE, CT 06468

Re: K132899

Trade/Device Name: Equashield Closed System drug Transfer Device (CSTD)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: ONB
Dated: April 14, 2014
Received: April 17, 2014

Dear Mr. Kelly,

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K132899

Device Name
Equashield Closed System drug Transfer Device (CSTD)

Indications for Use (Describe)

Closed System drug 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Digitally signed by Richard C. Chapman
Date: 2014.05.13 14:21:18 -04'00'

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