DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 3, 2017

Equashield Medical Ltd.
% Mr. Raymond Kelly
Consultant
Licensale Inc.
68 Southwoods Terrace
Southbury, Connecticut 06488

Re: K170706
Trade/Device Name: Equashield Closed System drug Transfer Device (CSTD)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: ONB
Dated: May 28, 2017
Received: May 31, 2017

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 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,

Lori A. Wiggins -S6

Lori A. Wiggins, MPT, CLT
Acting Director
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General Hospital, Respiratory,
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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)*

K170706

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 up to 7 days.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: July 3, 2017

510k Number: K170706

Applicant
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Contact Person
Raymond Kelly
68 Southwoods Terrace
Southbury, CT 06488 USA
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Device Information

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

Predicate Device Information
K132899 Equashield Closed System drug Transfer Device (CSTD)
K150219 Equashield Closed System drug Transfer Device (CSTD)

Indications for Use
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 up to 7 days.

Device Description

Equashield is a sterile, single use, Closed System drug Transfer Device (CSTD) for preparation, reconstitution, compounding and administration of antineoplastic and hazardous drugs. The Equashield closed system consists of a piston syringe (Syringe Unit), an adaptor to the medication vial (Vial Adaptor), an adaptor for the IV bag for injection (Spike Adaptor), an adaptor for the IV bag for withdrawal (Spike Adaptor-W), adaptors for injection into IV lines, syringes, or catheters (Luer Lock Adaptors), Nursing Pair connectors for standard IV tubing set ports (Female Luer Lock Connector and Male Luer Lock Connector), a Protective Plug, an adaptor for injection into an IV line with a Y-Site Tubing Set, or Secondary Tubing Accessory, and a Reconstitution Tubing Set for reconstituting powder drugs. The variable sterile air chamber integrated into the encapsulated syringe provides self-contained pressure equalization. The connector unit is welded to the syringe and uses the double-membrane method as high efficiency microbial barrier and for leak-proof and drug residual-free connections to the adaptors of the system. The double membrane seals off the transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, spills and also prevents microbial ingress up to 7 days.

The purpose of this submission is to add new components to the system including a thin size for components, introduce different material to the components and make labeling changes.

Summary of Technological Characteristics Including Modifications to the Device:

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. The proposed modified device is SE to the predicate device and does not raise different questions of safety or effectiveness.

	Proposed Device	Predicate Device (K132899)	Predicate Device (K150219)
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 up to 7 days.	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.	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 up to 7 days.
Classification	Class II	Class II	Class II
Regulation Number	888.5440	888.5440	888.5440
Product Code	ONB	ONB	ONB

No differences in regulatory classification, risk, or indications for use except for the addition of 7 days for microbial ingress prevention claim.

	Proposed Device	Predicate Device (K132899)	Predicate Device (K150219)
System components	Vial Adaptor (VA)	Vial Adaptor	Vial Adaptor
	Syringe Unit (SU)	Syringe Unit	Syringe Unit
	Spike Adaptor for injection (SA-Regular and Thin Size)	Spike Adaptor for injection	Spike Adaptor for injection
	Spike Adaptor W- for withdrawal (SA-W)	Spike Adaptor W- for withdrawal	Spike Adaptor W- for withdrawal
	Luer Lock Adaptor (LL-1)	Luer Lock Adaptor	Luer Lock Adaptor
	Male Luer Lock Connector (MC-1)	Male Luer Lock Connector	Male Luer Lock Connector
	Female Luer Lock Connector (FC-1)	Female Luer Lock Connector	Female Luer Lock Connector
	Protective Plug (PP-1)	Protective Plug	Protective Plug
	Y-Site Tubing (Accessory) (LL-1Y)	Y-Site Tubing (Accessory)	Y-Site Tubing (Accessory)
	Secondary Tubing (Accessory) (SA-1S) (Regular and Thin Size)	Secondary Tubing (Accessory)	Secondary Tubing (Accessory)
	Reconstitution Tubing(Accessory) (LL-1R)	NA	Reconstitution Tubing(Accessory)
	Catheter Luer Lock Adaptor (LL-1C)	NA	NA
	Syringe-Syringe Luer Lock Adaptor (LL-1DC)	NA	NA
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
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.

	Proposed Device	Predicate Device (K132899)	Predicate Device (K150219)
Technological Characteristics	A leak-proof connector with a single use syringe permanently attached to it as part of the system.	A leak-proof connector with a single use syringe permanently attached to it as part of the system.	A leak-proof connector with a single use syringe permanently attached to it as part of the system.
	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.	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.	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.
	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.	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.	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.

No differences in technological characteristics

	Proposed Device	Predicate Device (K132899)	Predicate Device (K150219)
Secondary Tubing Sets	Spike Adaptor with drip chamber and secondary tubing attached, Y Tubing set with Y-Connector attached.	Spike Adaptor with drip chamber and secondary tubing attached, Y Tubing set with Y-Connector	Spike Adaptor with drip chamber and secondary tubing attached, Y Tubing set with Y-Connector attached.
System	A fully encapsulated Syringe Unit is the active transfer device of this closed system. 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. 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. 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.	A fully encapsulated Syringe Unit is the active transfer device of this closed system. 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. 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. 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.	A fully encapsulated Syringe Unit is the active transfer device of this closed system. 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. 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. 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.
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 and Gamma SAL 10^{-6}	EO and Gamma SAL 10^{-6}	EO and Gamma SAL 10^{-6}

No differences in system function, sharps protection, use environment, user populations, or sterilization method.

Discussion of Differences:

Changed Component	Change Description	Change Discussion on SE
Material	ABS to Polypropylene	Changed components because DMA may degrade components made from ABS or PC if contact duration is extended. The PP used in the changes is already used throughout the predicate device and has been fully tested for biocompatibility and vapor escape. No different questions of safety or effectiveness are raised.
Components	Added Luer Lock Adaptors LL-1C and LL-1DC, thin version Spike Adaptor, and a 17mm Vial Adaptor.	Added luer lock adaptors to allow luer lock to connections between two syringes and to allow connection to a catheter, also Spike Adaptor in thinner form and 17mm Vial Adaptor are similar or same design and dimensions as the existing predicate components. No different questions of safety or effectiveness are raised.
Labeling	DMA warning removed, directions for LL-1C and LL-1DC were added.	Edited the labeling in order to provide directions for using the added Luer Lock Adaptors and remove the warning which is no longer applicable. Also added labels for the new components. No different questions of safety or effectiveness are raised.

Performance Testing

Biocompatibility: Biocompatibility testing was performed on the Equashield materials according to FDA Guidance and ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. Testing included cytotoxicity, sensitization, irritation, systemic toxicity, and hemocompatibility according to standards set forth in ISO 10993-4, Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood, ISO 10993- 5, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity, ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization, and ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity. All testing passed.

Sterility: Sterilization validation was performed on the finish sterile Equashield components according to ISO 11135 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices and ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. Testing included pyrogenicity, bioburden, and EO residuals to standards set forth in ISO 10993-7 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals, ISO 11737-1 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products, and AAMI/ANSI ST72 bacterial endotoxins - test methods, routine monitoring, and alternatives to batch testing. All testing passed.

Package Integrity and Shelf Life: Packaging and Shelf Life validation was performed on aged Equashield packaging according to ASTM F1140 standard test methods for internal pressurization failure resistance of unrestrained packages, ASTM F129 standard test method for detecting seal leaks in porous medical packaging by dye penetration, and ASTM F88 standard test method for seal strength of flexible barrier materials. All testing passed.

Bench Performance: Performance testing was performed on the Equashield including visual inspection, detachment force, penetration force, and leak testing according to ISO 594-1 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements, ISO 594-2 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings, ISO 7886-1 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use, ISO 8536-4 Infusion equipment for medical use - Part 4: Systems for single use, gravity feed, and ISO 22413 Transfer sets for pharmaceutical preparations - Requirements and test methods.

Sharps Protection: Sharps protection testing was performed according to ISO 23908 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.

Drug/DMA Compatibility: Antineoplastic drug compatibility testing was performed to validate Equashield compatibility with antineoplastic drugs and DMA (N,N-dimethylacetamid). Equashield was found to be compatible with antineoplastic drugs and DMA.

Extractables Screening: Determine what compounds and their estimated concentrations are extracted from the Equashield Closed System Transfer Device for hazardous drugs (CSTD) under the conditions of the extractions (24 hours, 37oC and 50oC respectively) extracted in the following solvents: 50% ethanol, pH 3 (HCl adjusted) 0.9% saline, and 33% aqueous dimethylacetamide (DMA).

Leachables Screening and Health Risk Assessment (ISO 10993-17): Determine what compounds (and their estimated concentration) are leached from the Equashield Closed System Transfer Device (CSTD) assemblies at 25°C±2°C for 24 hours using four different hazardous drug carrier simulants. Drugs that were chosen carry warnings and traditionally represent in literature the most deleterious and corrosive drugs to devices, these drug simulants were carriers for Etoposide, Busulfan and Taxol along with a saturated aqueous solution of Mannitol representative for long-term treatment drugs Velcade and Vidaza.

Hazardous Vapors Containment: Hazardous vapor containment testing was performed on the Equashield to validate no escape of vapors from Equashield during use was performed using gas chromatography (GC) analysis using Flame Ionization Detection (FID). Testing met alcohol residual levels criteria.

Microbial Ingress Protection: Microbial ingress testing was performed on Equashield to validate microbial ingress protection after repetitive needle penetration of the septum. Testing results demonstrate Equashield was protected against microbial ingress for a period of 7 days after breaching the septum 10 times with the needle. The ability to prevent microbial ingress for up to 7 days should not be interpreted as modifying, extending, or superseding a manufacturer labeling recommendations for the storage and expiration dating. Refer to drug manufacturer's recommendations and USP compounding guidelines for shelf life and sterility information.

Particulates: Particulate contamination testing was performed on the Equashield according to USP 788 to demonstrate lack of contamination. Testing results demonstrated particulate levels in the Equashield are low and meet USP 788 requirements.

Substantial Equivalence Conclusion:

Performance testing on the proposed Equashield performed substantially equivalent (SE) to the performance testing on the predicate Equashield. Equivalence was determined using a side by side tabular comparison between the predicate and proposed Features, Intended Use, Labeling, Materials, Specifications, Performance Data, and Technological Aspects. The proposed device is Substantially Equivalent to the predicate device.

Based on the analysis of the comparison between the predicate and proposed devices regarding risk analysis, design controls, and performance evaluation the data shows the modification does not raise different questions of safety or efficacy and demonstrates substantial equivalence to the predicate device without the need for additional testing.