Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Ferre Hockensmith, Catalina

From: Qian, Bifeng
Sent: Wednesday, October 14, 2015 5:20 PM
To: Patel, Sapana
Cc: Murray III, Clarence; Claverie, Elizabeth F
Subject: RE: (b)(4) [redacted] deficiency K150219

Hi Sapana,

(b)(4)
[redacted]

Thanks,

BiFeng

From: Patel, Sapana
Sent: Wednesday, October 14, 2015 7:28 AM
To: Qian, Bifeng
Subject: FW: (b)(4) [redacted] deficiency K150219

Bifeng,

Please see the response from the sponsor regarding the biocompatibility testing.

Thank you

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
F: 301-847-8109
Sapana.patel@fda.hhs.gov

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From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Tuesday, October 13, 2015 4:46 PM
To: Patel, Sapana
Cc: 'Dorit Valal'; 'Marino Krihelj'
Subject: RE: (b)(4) [redacted] deficiency K150219

Ms. Patel,

(b)(4) [redacted]

Please let us know if FDA has additional questions during the review.

Regards,

Ray

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Tuesday, October 13, 2015 3:58 PM
To: Raymond Kelly <ray.k@arazygroup.com>
Subject: (b)(4) [redacted] deficiency K150219

Mr. Kelly,

(b)(4) [redacted] Please provide a response by COB Monday, 10/19/2015. If you have any additional questions please do not hesitate to contact me.

(b)(4) [redacted]

(b)(4) Deficiencies

[redacted]

Thank you,

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
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DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave
Silver Spring, MD 20993

Consult Memo 510 (k): K150219/S001

Date:	March 31, 2015
From:	BiFeng Qian, DAGRID/INCB
Through:	Clarence Murray III, Acting Branch Chief, DAGRID/INCB
To:	Sapana Patel, Lead Reviewer, DAGRID/GHDB
Trade Name:	Equashield Closed System drug Transfer Device (CSTD)
Common Name:	Closed System drug Transfer Device (CSTD)
Classification Name:	Intravascular Administration Set
Classification Regulation:	Class II (21 CFR 880.5440)
Product Code:	ONB
Sponsor:	Equashield Medical Ltd.
Consult Review:	(b)(4) [redacted]

Succinct Conclusion: ADDITIONAL INFORMATION REQUIRED

The information provided in this submission is insufficient to address the biocompatibility concerns. It is recommended that additional information be acquired in order to complete the review of this submission.

Submission Summary

Equashield Medical Ltd. has submitted a special 510(k) K150219 for their device "Equashield Closed System drug Transfer Device (CSTD)". The firm states that the subject device was originally cleared (b)(4) [redacted]

Upon evaluation of K150219/S001, several (b)(4) [redacted] deficiencies have been identified. **Please see the recommended deficiencies at the end of the memo.**

Device Description

The sponsor has stated/provided the following:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The products which will be marketed with this submission only include one, it is called the Reconstitution Set, and the model number is LL-1R. This tubing set does not require to be used with the Equashield System; it can be used independently and is a standalone device.

Name	*Model #*	*Description*	*Sizes*
Reconstitution Tubing	**LL-1R**	**Reconstitution Tubing Accessory**	NA

(b)(4) [redacted]

K150219 Trade Name	*K150219 Supplier Name*	*K150219 Supplier Trade Name*	*K132899 Trade Name*	*Supplier Name*	*Supplier Trade Name*	*Differences*
Equashield Connector	(b)(4) [redacted]		Equashield Syringe Unit Outer Sleeve	(b)(4) [redacted]		Identical
Equashield Liquid Needle			Equashield Syringe Unit Liquid Needle			Identical
Equashield Air Needle			Equashield Syringe Unit Air Needle			Identical
Equashield T-Connector			Equashield Y-Tubing Set Y-Connector			(b)(4) [redacted]
Equashield Tubing			Equashield Y-Tubing Set Tubing			Identical
Equashield Spike for Bag			Equashield Spike Adapter Body			(b)(4) [redacted]
Equashield Check Valve			Equashield Spike Adapter Body and Y-Tubing Set Y-Connector			
Equashield Dual Check Valve			Equashield Y-Tubing Set Y-Connector			
Equashield Cap			Equashield Y-Tubing Set Cap			Identical

The predicate device is indicated and currently used for reconstitution, the addition of the Reconstitution Tubing presents no changes to the Intended Use, Indications for Use, Principle of Operation, Mechanism of Action, or Conditions of Use.

The Equashield Closed System is supplied sterile and is indicated for single use. The sterilization method is Ethylene Oxide (EO).

Indications for Use

The sponsor has stated the following:

Closed System drug Transfer Device (CSTD) for preparation, reconstitution, compounding and administration of drugs, including antineoplastic and hazardous drugs. This closed system

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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.

(b)(4) [redacted]

A. Materials Used

The materials of each device component are identified in the Table below. The sponsor claims (b)(4) [redacted]

List of Parts and Materials – Reconstitution Tubing Accessory

Proposed Component Description (K150219)	*Proposed Device Material (K150219)*	*Predicate Device Material (K132899)*	*Predicate Component Description (K132899)*
(b)(4) [redacted]			

[1]>> Reviewer Comments:

- The material information provided is deemed adequate.

B. (b)(4) [redacted] ***Evaluation***

The sponsor states:

The Equashield Closed System has no direct contact to the patient but it serves as a conduit for liquids which then have patient contact. Through fluid flow some materials have indirect contact

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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for a limited duration that is less than 24 hours. All materials are biocompatible and are in compliance with the ISO 10993-1:2009 and with the FDA Blue Book Memorandum G95-1.

The sponsor has provided study reports for the following (b)(4) [redacted] testing, which were based on the device (b)(4) [redacted]

Test Category	Test Method	Protocol Number	Status	Report Number
(b)(4) [redacted]				

[2]>> Reviewer Comments:

- Recommend that the sponsor address the Biocompatibility Deficiency #1, as shown in the Section below.

C. (b)(4) [redacted] ***Testing and*** (b)(4) [redacted]

The sponsor states:

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

[3]>> Reviewer Comments:

- Recommend that the sponsor address the (b)(4) [redacted] Deficiencies #2 and #3, as shown in the Section below.

(b)(4) [redacted]

[4]>> Reviewer Comments:

- Recommend that the sponsor address the (b)(4) [redacted] Deficiency #4, as shown in the Section below.

(b)(4) Deficiencies [redacted]

[5]>> Reviewer Comments:

- Recommend that the sponsor address the (b)(4) [redacted] (b) Deficiency #5, as shown in the Section below.

Recommended K150219/S001 (b)(4) Deficiencies [redacted] Deficiencies

The following are the recommended deficiencies for the sponsor:

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Deficiencies

[redacted]

Digital Signature Concurrence Table	
Reviewer Sign-Off	Bifeng Qian -S 2015.03.31 22:30:57 -04'00'
Branch Chief Sign-Off	Clarence W. Murray Iii III -S Digitally signed by Clarence W. Murray Iii III -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300197254, cn=Clarence W. Murray Iii III -S Date: 2015.04.02 09:33:03 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ferre Hockensmith, Catalina

From: Qian, Bifeng
Sent: Tuesday, October 13, 2015 2:16 PM
To: Patel, Sapana; Murray III, Clarence; Claverie, Elizabeth F
Subject: (b)(4) [redacted] consult review: CON1519927 (K150219/S002)

Importance: High

Hi Sapana:

I have completed the biocompatibility consult review for CON1519927 (K150219/S002), which was limited only to the sponsor's response to the original (b)(4) [redacted] deficiencies identified in the FDA Additional Information Letter dated 04/02/2015 for K150219/S001 (Deficiencies #16 - #20).

(b)(4) Deficiencies

[redacted]

Clarence and Liz: Would you please let me know if you have any questions/concerns or please provide the branch/team leader concurrence? FYI, K150219/S002 is currently under an interactive review. Today is FDA Day 66.

Sapana: Please wait for our branch concurrence.

Thanks,

BiFeng

Recommended K150219/S002 (b)(4) [redacted] **Deficiency:**

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

[redacted]

BiFeng Qian, M.D., Ph.D.
Scientific Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiologic Health
U.S. Food and Drug Administration
WO66, Room 2519B
10903 New Hampshire Ave
Silver Spring, MD 20993
Phone: 301-796-2261
Fax: 301-847-8109
bifeng.qian@fda.hhs.gov

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Ferre Hockensmith, Catalina

From: Qian, Bifeng
Sent: Tuesday, October 13, 2015 3:37 PM
To: Patel, Sapana; Murray III, Clarence; Claverie, Elizabeth F
Subject: RE: Biocompatibility consult review: CON1519927 (K150219/S002)

(b)(4)
[redacted]

Thanks,

From: Patel, Sapana
Sent: Tuesday, October 13, 2015 3:32 PM
To: Murray III, Clarence; Qian, Bifeng; Claverie, Elizabeth F
Subject: RE: Biocompatibility consult review: CON1519927 (K150219/S002)

Thank you. Bifeng will a response by Monday be sufficient?

Thanks

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
F: 301-847-8109
Sapana.patel@fda.hhs.gov

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From: Murray III, Clarence
Sent: Tuesday, October 13, 2015 3:28 PM
To: Qian, Bifeng; Patel, Sapana; Claverie, Elizabeth F
Subject: RE: Biocompatibility consult review: CON1519927 (K150219/S002)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Deficiencies

Sapana - Please go ahead and send Bifeng's deficiencies to the sponsor. [redacted]

(b)(4) Deficiencies

(b)(4) Deficiencies

[redacted] Clarence

Clarence W. Murray, III, Ph.D.
Chemist
Infection Control Device Branch
FDA/CDRH/ODE/DAGRID
10903 New Hampshire Ave.
White Oak, Bldg. 66/ Room 2464
Silver Spring, MD 20993
301-796-0270 telephone
301-847-8109 fax

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From: Qian, Bifeng
Sent: Tuesday, October 13, 2015 2:55 PM
To: Patel, Sapana; Murray III, Clarence; Claverie, Elizabeth F
Subject: RE: Biocompatibility consult review: CON1519927 (K150219/S002)

Would you please wait for our branch concurrence? Thanks.

From: Patel, Sapana
Sent: Tuesday, October 13, 2015 2:47 PM
To: Qian, Bifeng; Murray III, Clarence; Claverie, Elizabeth F
Subject: RE: Biocompatibility consult review: CON1519927 (K150219/S002)

Thank you Bifeng. Do you want me to send the deficiency as this is under interactive review as you stated or await concurrence from your branch?

Thank you

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
F: 301-847-8109
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https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E

From: Qian, Bifeng
Sent: Tuesday, October 13, 2015 2:16 PM
To: Patel, Sapana; Murray III, Clarence; Claverie, Elizabeth F
Subject: Biocompatibility consult review: CON1519927 (K150219/S002)
Importance: High

Hi Sapana:

I have completed the biocompatibility consult review for CON1519927 (K150219/S002), which was limited only to the sponsor's response to the original (b)(4) [redacted] deficiencies identified in the FDA Additional Information Letter dated 04/02/2015 for K150219/S001 (Deficiencies #16 - #20).

(b)(4) Deficiencies

[redacted]

Clarence and Liz: Would you please let me know if you have any questions/concerns or please provide the branch/team leader concurrence? FYI, K150219/S002 is currently under an interactive review. Today is FDA Day 66.

Sapana: Please wait for our branch concurrence.

Thanks,

BiFeng

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Recommended K150219/S002 Biocompatibility Deficiency:

(b)(4) Deficiencies

[redacted]

BiFeng Qian, M.D., Ph.D.
Scientific Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiologic Health
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DAGRID/GHDB
WO66 RM2562
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-4968

Premarket Notification [510(k)] Review

Date: November 4, 2015
To: FILE
From: Sapana Patel
Subject: Traditional 510(k)# K150219/S001

Applicant: Equashield Medical Ltd

Device Trade Name: Equashield Closed System Drug Transfer Device (CSTD)

Contact: Raymond Kelly Iv

Contact Title: Official Correspondent

Correspondent Firm: Licensale Inc.

Phone: 203-880-4091 **Email:** ray.k@arazygroup.com

FDA Received Date: September 29, 2015

Due Date: November 6, 2015

Reg #: 880.5440 **Reg Name:** Intravascular Administration Set

Class: II **Product Code(s):** ONB

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K132899	ONB	Equashield Closed System Drug Transfer Device (cstd)	Equashield Medical Ltd

Review Summary

The subject device is an Intravascular Administration Set with the following 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. "It is for Rx use."

Recommendation

I recommend that the Equashield Closed System Drug Transfer Device (CSTD) is/are
Substantially Equivalent (SESE)

Review Team

Lead Reviewer	Sapana Patel, PharmD. (CDRH/ODE/DAGRID/GHDB)
Microbiology Consult	Ramesh Panguluri, Ph.D.
Biocompatibility Consult	BiFeng Qian, Ph.D.
Sterility Consult	Sreekanth Gutala, PhD.

Purpose and History

Equashield Medical LTD of Migdal Tefen, 24959, Israel submitted a premarket notification (510(k)) to introduce into US interstate Commerce a modification to the Equashield Closed System Drug Transfer Device. The Equashield System is considered a prescription Class II medical device regulated under 21 CFR 880.5440 as intravascular administration set under product code ONB.
The purpose of this premarket submission is to obtain premarket clearance to modify the Equashield Closed System Drug Transfer Device. (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Previously the system was cleared under several 510(k) s.

510(k) Number	Product Code
K083152	LHI
K091389	LHI
K101940	LHI
K132899	ONB

	Yes	No	N/A
Truthful and Accuracy Statement	X		
510(k) Statement	X		
Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity - Yes Standards Form Required 3: Standard but no declaration - Yes Standards Form Required	X		

Required Elements for 510(k) Summary (21 CFR 807.92)		**YES/NO**
	Clearly labeled "510(k) Summary"	N/A
	Submitter' s name, address, phone #, a contact person	N/A
	Date the summary was prepared	N/A
	The name of the device/trade name/common name/classification name	N/A
	An identification of the legally marketed predicate	N/A
	Description of the subject device	N/A
	Statement of intended use (indication)	N/A
Technological characters	if same, a summary of comparison of technological characters	N/A
Technological characters	If different, a summary of how do they compare to the predicate	N/A
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	N/A
Performance Data	Brief discussion of clinical data submitted, referenced, or relied on, including: - Description upon whom the device was tested, - Data obtained from the tests and especially:	N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	☐ Adverse events and complications ☐ Other information for SE determination	
	Conclusion that data demonstrate SE	
Required Elements for 510(k) Statement (21 CFR 807.93)		
	Signed verbatim statement	Yes

The submission purports the utilization of the following standards and/or guidance documents:

Recognition Number	Standard	Title of Standard	Reference Number and Date
6-11	ISO 594-1	Conical fittings with a 6% (Luer) luer taper for syringes, needles and certain other medical equipment- Part 1 general requirements.	1998
6-129	ISO 594-2	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 2 : Lock fittings	1998
6-304	ISO 7886-1	Sterile Hypodermic syringes for single use-Part 1: syringes for manual use	2010
6-318	ISO 8536-4	Infusion equipment for medical use-Part 4: Systems for single use, gravity feed	2010
2-156	ISO 10993-1	Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process	10993-1:2009 2013-01-15
	ISO 10993-4	Biological evaluation of medical devices- Part 4: selection of tests for interactions with blood	2002
2-153	ISO 10993-5	Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity	2009
5-40	ISO 14971	Medical devices-application of risk management to medical devices	2007
6-273	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.	2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Reviewer Comments

This section of the review is **ACCEPTABLE**. The Sponsor has provided a 510(k) statement in conformance to 21 CFR 807.93 that states they will make all information included in the premarket notification on safety and effectiveness available within 30 days of request. Sponsor has listed all standards to which they have conformed. There are no further questions regarding this section.

Device/System Description

Device Characteristics	Yes	No	Inadequate Or Marked
Is the intended use or fundamental technology new?	☐	☒	☐
Is the device life-supporting or life sustaining?	☐	☒	☐
Are there any direct or indirect patient contacting components?	☒	☐	☐
• Is the device or a component an implant?	☐	☒	☐
Does the device use software/firmware?	☐	☒	☐
Does the device or a component need sterilization (by manufacturer or user)?	☒	☐	☐
The device/system uses or is	a single use device(s) (SUD)		☐
Is the device a combination product?	N - Not a Part 3 Combination Product		☐
Is the device electrical (battery or wall powered)?	No, the device is not electrical		☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic
Yes	☐	☐	☐
No	☒	☒	☒
Unknown	☐	☐	☐

The subject device of this 510(k) is the addition of a reconstitution tubing which is an accessory to the previously cleared Equashield System (K132899). The Equashield system is a 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.

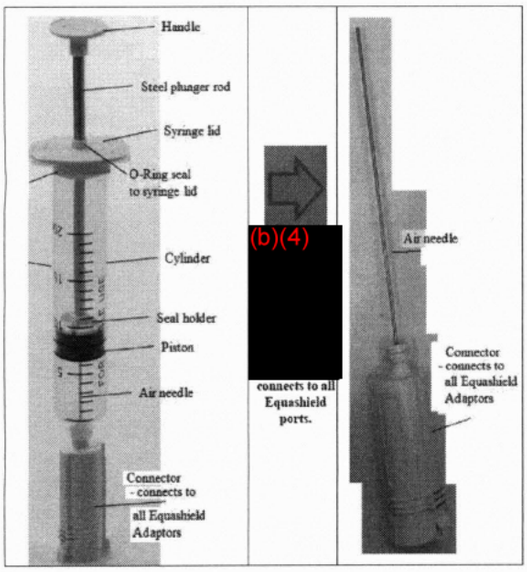
The proposed device is used by pharmacies to prepare, administer indirectly and transport hazardous drugs. The device should be used under clinical conditions by qualified clinicians and pharmacists. The device interfaces with other devices such as IV lines and bags. The Equashield components and accessories included in this submission also interface with each other. The device interacts with the patient indirectly through fluid path, the drug which is contained in the device is injected into an IV line or bag and that drug travels through the IV line to the patient.

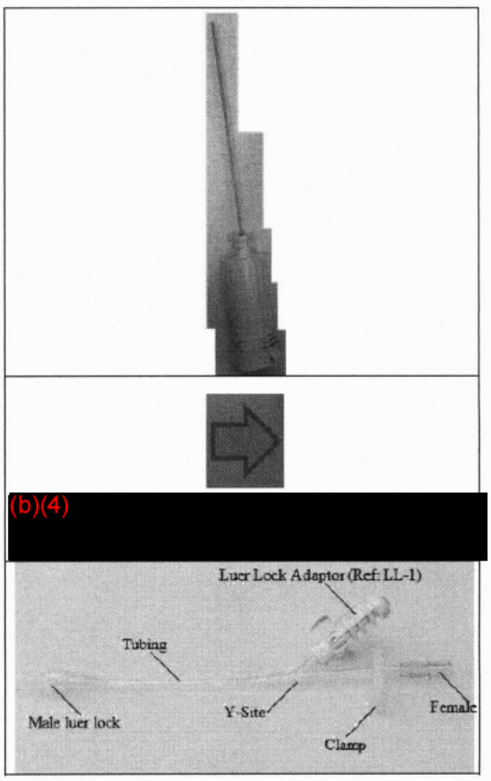
(b)(4)

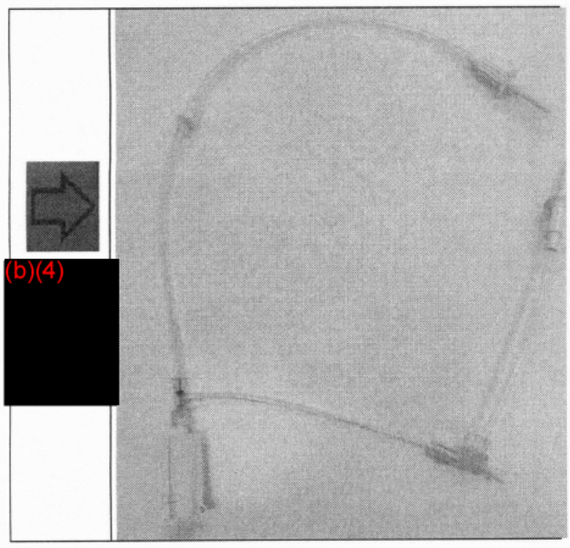
[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) [redacted]







The Reconstitution Tubing consists of:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Description and Manufacturing Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Diagram

[redacted]

The predicate device is indicated and currently used for reconstitution, it contains components and tubing sets, the addition of the Reconstitution Tubing presents no changes to the Intended Use, Indications for Use, Principle of operation, Mechanism of Action, or Conditions of Use.

Users of CSTD devices currently assemble Reconstitution Tubing sets in order to perform their daily tasks. This introduces potential delays in treatment depending on which components are readily available for construction of the reconstitution sets, may introduce contaminates into the system during assembly, and may produce Reconstitution Tubing sets which leak or do not provide microbial barrier.
On the request of users to provide a sterile, finished Reconstitution Tubing set which can prevent the need from constructing one potentially incorrectly, we are proposing this addition to the FDA cleared Equashield system. Every component in the Equashield system is packaged and sold separately.

List of sizes and models which clearance is requested for

Name	*Model #*	*Description*	*Sizes*
Reconstitution Tubing	**LL-1R**	**Reconstitution Tubing Accessory**	NA

K150219 Trade Name	*K150219 Supplier Name*	*K150219 Supplier Trade Name*	*K132899 Trade Name*	*Supplier Name*	*Supplier Trade Name*	*Differences*
Equashield Connector	(b)(4) [redacted]	(b)(4) [redacted]	Equashield Syringe Unit Outer Sleeve	(b)(4) [redacted]		Identical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Equashield Liquid Needle	(b)(4) [redacted]	Equashield Syringe Unit Liquid Needle	(b)(4) [redacted]	Identical
Equashield Air Needle		Equashield Syringe Unit Air Needle		Identical
Equashield T-Connector		Equashield Y-Tubing Set		(b)(4) [redacted]
Equashield Tubing		Equashield Y-Tubing Set		Identical
Equashield Spike for Bag		Equashield Spike Adapter Body		(b)(4) [redacted]
Equashield Check Valve		Equashield Spike Adapter Body and Y-Tubing Set Y-Connector		
Equashield Dual Check Valve		Equashield Y-Tubing Set Y-Connector		
Equashield Cap(Spike and Luer)		Equashield Y-Tubing Set Cap		Identical

Reviewer Recommendation

The Device Description is **ACCEPTABLE.** The sponsor has provided descriptions and materials of all components in the reconstitution set. The reconstitution set is an accessory to the Equashield System.

AI Needed:

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K150219 Rx/OTC: Rx

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☐	☐	☐	☐	☐	☐	☐
No	☐	☐	☐	☐	☐	☐	☐	☐
Unknown	☒	☒	☒	☒	☒	☒	☒	☐

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."

Predicate(s)

510(k)#: K132899 Rx/OTC: Rx

Intended Population:

Indications for Use: Closed system drug transfer device (cstd) for preparation, reconstruction, 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.

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Reviewer Recommendation

(b)(4)

[redacted]

Comparison of Technology to Predicate Devices

	Proposed Device	*Predicate Device (K132899)*	*Differences*
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.	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.	None
Classification	Class II	Class II	
Regulation Number	888.5440	888.5440	
Product Code	ONB	ONB	

No differences in regulatory classification, risk, or indications for use.

	Proposed Device	*Predicate Device (K132899)*	*Differences*
System components	**Vial Adaptor**	**Vial Adaptor**	**None**
	Syringe Unit	**Syringe Unit**	
	Spike Adaptor 1- for injection	**Spike Adaptor 1- for injection**	
	Spike Adaptor W- for withdrawal	**Spike Adaptor W- for withdrawal**	
	Luer Lock Adaptor	**Luer Lock Adaptor**	
	Male Luer Lock Connector	**Male Luer Lock Connector**	
	Female Luer Lock Connector	**Female Luer Lock Connector**	
	Protective Plug	**Protective Plug**	
	Y-Site Tubing (Accessory)	**Y-Site Tubing (Accessory)**	
	Secondary Tubing (Accessory)	**Secondary Tubing (Accessory)**	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

	Reconstitution Tubing (Accessory)	None	Accessory Added
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**	**None**
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.**	

(b)(4)

[redacted]

	Proposed Device	*Predicate Device (K132899)*	*Differences*
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.	None
	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.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

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.	None
Sharps Injury	Needles and their tips are permanently recessed deep inside a hard plastic housing, out of reach.	Needles and their tips are permanently recessed deep inside a hard plastic housing, out of reach.	
Device Type	Rx/Single Use	Rx/Single Use	
Target Users	Licensed Pharmacists/Health Care Professionals	Licensed Pharmacists/Health Care Professionals	
Environment	Hospitals and clinics	Hospitals and clinics	
Sterilization	EO/SAL (b)(4) [redacted]	EO/SAL 1 (b)(4) [redacted]	

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

Reviewer Recommendation
The Comparison of the Technology to Predicate Devices is **ACCEPTABLE.**

AI Needed:
(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Sponsor response to K150219/S001 on September 29, 2015:

(b)(4) Deficiencies

[redacted]

Labeling

Labeling Review Needed?	Yes ☒	No ☐
Usability Consult Needed?	Yes ☐	No ☒

A General Labeling Requirements

General Labeling Requirements	Yes	No	Inadequate or Marked
Is the prescription statement (or "Rx only") included?	☒	☐	☐
The indications for use are consistent with the IFU page?	☒	☐	☐
Appropriate contraindications provided?	☐	☒	☐
Appropriate warnings provided?	☐	☒	☐
Instructions are in accordance with the guidance (if applicable)?	☒	☐	☐
Appropriate labeling inside device?	☐	☐	☐
Appropriate label/indicator outside device?	☐	☐	☐
Appropriate Manual labeling?	☐	☐	☐
What MRI safety information does the labeling contain?		Not Needed	☐

Reviewer Recommendation

The Labeling is **ACCEPTABLE.**

AI Needed: (b)(4) Deficiencies

(b)(4) Deficie

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

Sterility Review Needed?	Yes ☒	No ☐
Sterility Consult Needed?	Yes ☒	No ☐

1. Sterilant: a. **Sterilization method** description (e.g., Steam (moist heat), EO, Radiation):	[redacted] Yes, Ethylene oxide
b. **Dose**, for radiation (e.g., 25 – 50 kGy):	N/A
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 *Biological*	Provided (b)(4) [redacted]
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	Provided
3. Sterility assurance level (SAL): (e.g., 10-6 for all devices (except 10-3 for devices that contact intact skin))	Provided
4. Is it labeled "Pyrogen Free"?	No observed pyrogen claims
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	Pyrogen tests provided. Falls under Biocompatibility review.
5. A description of the packaging	Provided

Reviewer Recommendation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

Biocompatibility

Biocompatibility Review Needed?	Yes ☒	No ☐
Biocompatibility Consult Needed?	Yes ☒	No ☐

The materials of each device component are identified in the Table below. The sponsor claims "(b)(4) [redacted]

(b)(4) [redacted]

List of Parts and Materials – Reconstitution Tubing Accessory

Proposed Component Description (K150219)	*Proposed Device Material (K150219)*	*Predicate Device Material (K132899)*	*Predicate Component Description (K132899)*

(b)(4) [redacted]

The sponsor states:

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The sponsor has provided study reports for the following biocompatibility testing, which were based on (b)(4) (b)(4)

Test Category	Test Method	Protocol Number	Status	Report Number
(b)(4)				

Reviewer Recommendation

The Biocompatibility is **ACCEPTABLE.** This section of the review was completed by BiFeng Qian.

AI Needed:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Test Category	Test Method	Status	Test Report Number
(b)(4)			

(b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

Software/Firmware

This device does not contain software/hardware.

EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

This device does not have an electrical component.

Performance Testing

A Bench Testing

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Testing

[redacted]

Reviewer Recommendation

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device: The intended use of the subject device is similar to that of the predicate device. The purpose of the submission is to introduce the reconstitution tubing set to the system. The technological characteristics of the device are similar and the sponsor has provided performance testing that the recosntitution tubing performs as expected.		
Do the devices have the same technological characteristics?	☒	☐

Original Deficiencies

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

Contact History

Email:	Response:
3/4/2015	3/5/2015
3/6/2015	3/12/2015
9/30/2015	10/1/2015
10/2/2015	10/9/2015
10/13/2015	10/14/2015
10/21/2015	10/22/2015
10/22/2015	10/23/2015
10/28/2015	10/29/2015 and 11/2/2015

Teleconference:
10/1/2015
10/6/2015
10/30/2015

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	
Division Sign-Off (optional)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Food and Drug Administration
CDRH/ODE/DAGRID/GHDB
WO66 RM2562
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-4968

Premarket Notification [510(k)] Review

Date: November 4, 2015
To: FILE
From: Sapana Patel
Subject: Traditional 510(k)# K150219/S001

Applicant: Equashield Medical Ltd
Device Trade Name: Equashield Closed System Drug Transfer Device (CSTD)
Contact: Raymond Kelly Iv
Contact Title: Official Correspondent
Correspondent Firm: Licensale Inc.
Phone: 203-880-4091 **Email:** ray.k@arazygroup.com
FDA Received Date: September 29, 2015
Due Date: November 6, 2015
Reg #: 880.5440 **Reg Name:** Intravascular Administration Set
Class: II **Product Code(s):** ONB

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K132899	ONB	Equashield Closed System Drug Transfer Device (cstd)	Equashield Medical Ltd

Review Summary

The subject device is an Intravascular Administration Set with the following 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. "It is for Rx use."

Recommendation

I recommend that the Equashield Closed System Drug Transfer Device (CSTD) is/are
Substantially Equivalent (SESE)

Review Team

Lead Reviewer	Sapana Patel, PharmD. (CDRH/ODE/DAGRID/GHDB)
Microbiology Consult	Ramesh Panguluri, Ph.D.
Biocompatibility Consult	BiFeng Qian, Ph.D.
Sterility Consult	Sreekanth Gutala, PhD.

Purpose and History

Equashield Medical LTD of Migdal Tefen, 24959, Israel submitted a premarket notification (510(k)) to introduce into US interstate Commerce a modification to the Equashield Closed System Drug Transfer Device. The Equashield System is considered a prescription Class II medical device regulated under 21 CFR 880.5440 as intravascular administration set under product code ONB.
The purpose of this premarket submission is to obtain premarket clearance to modify the Equashield Closed System Drug Transfer Device. The modification to the device is (b)(4) [redacted] (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4)

[redacted]

	Yes	No	N/A
Truthful and Accuracy Statement	X		
510(k) Statement	X		
Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity - Yes Standards Form Required 3: Standard but no declaration - Yes Standards Form Required	X		

Required Elements for 510(k) Summary (21 CFR 807.92)		YES/NO
	Clearly labeled "510(k) Summary"	N/A
	Submitter' s name, address, phone #, a contact person	N/A
	Date the summary was prepared	N/A
	The name of the device/trade name/common name/classification name	N/A
	An identification of the legally marketed predicate	N/A
	Description of the subject device	N/A
	Statement of intended use (indication)	N/A
Technological characters	if same, a summary of comparison of technological characters	N/A
Technological characters	If different, a summary of how do they compare to the predicate	N/A
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	N/A
Performance Data	Brief discussion of clinical data submitted, referenced, or relied on, including: - Description upon whom the device was tested, - Data obtained from the tests and especially: ☐ Adverse events and complications ☐ Other information for SE determination	N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

	Conclusion that data demonstrate SE	
Required Elements for 510(k) Statement (21 CFR 807.93)		
	Signed verbatim statement	Yes

The submission purports the utilization of the following standards and/or guidance documents:

Recognition Number	Standard	Title of Standard	Reference Number and Date
6-11	ISO 594-1	Conical fittings with a 6% (Luer) luer taper for syringes, needles and certain other medical equipment- Part 1 general requirements.	1998
6-129	ISO 594-2	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 2 : Lock fittings	1998
6-304	ISO 7886-1	Sterile Hypodermic syringes for single use-Part 1: syringes for manual use	2010
6-318	ISO 8536-4	Infusion equipment for medical use-Part 4: Systems for single use, gravity feed	2010
2-156	ISO 10993-1	Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process	10993-1:2009 2013-01-15
	ISO 10993-4	Biological evaluation of medical devices- Part 4: selection of tests for interactions with blood	2002
2-153	ISO 10993-5	Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity	2009
5-40	ISO 14971	Medical devices-application of risk management to medical devices	2007
6-273	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.	2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Reviewer Comments

This section of the review is **ACCEPTABLE**. The Sponsor has provided a 510(k) statement in conformance to 21 CFR 807.93 that states they will make all information included in the premarket notification on safety and effectiveness available within 30 days of request. Sponsor has listed all standards to which they have conformed. There are no further questions regarding this section.

Device/System Description

Device Characteristics	Yes	No	Inadequate Or Marked
Is the intended use or fundamental technology new?	☐	☒	☐
Is the device life-supporting or life sustaining?	☐	☒	☐
Are there any direct or indirect patient contacting components?	☒	☐	☐
• Is the device or a component an implant?	☐	☒	☐
Does the device use software/firmware?	☐	☒	☐
Does the device or a component need sterilization (by manufacturer or user)?	☒	☐	☐
The device/system uses or is	a single use device(s) (SUD)		☐
Is the device a combination product?	N - Not a Part 3 Combination Product		☐
Is the device electrical (battery or wall powered)?	No, the device is not electrical		☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic
Yes	☐	☐	☐
No	☒	☒	☒
Unknown	☐	☐	☐

(b)(4) Description

[redacted]

The proposed device is used by pharmacies to prepare, administer indirectly and transport hazardous drugs. The device should be used under clinical conditions by qualified clinicians and pharmacists. The device interfaces with other devices such as IV lines and bags. The Equashield components and accessories included in this submission also interface with each other. The device interacts with the patient indirectly through fluid path, the drug which is contained in the device is injected into an IV line or bag and that drug travels through the IV line to the patient.

(b)(4) Description

[redacted]

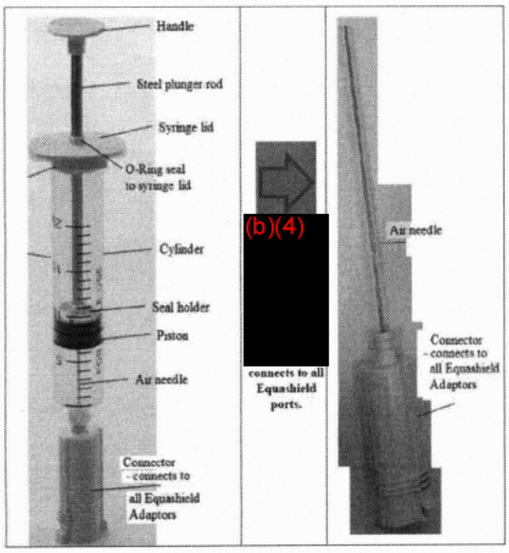
(b)(4) Description

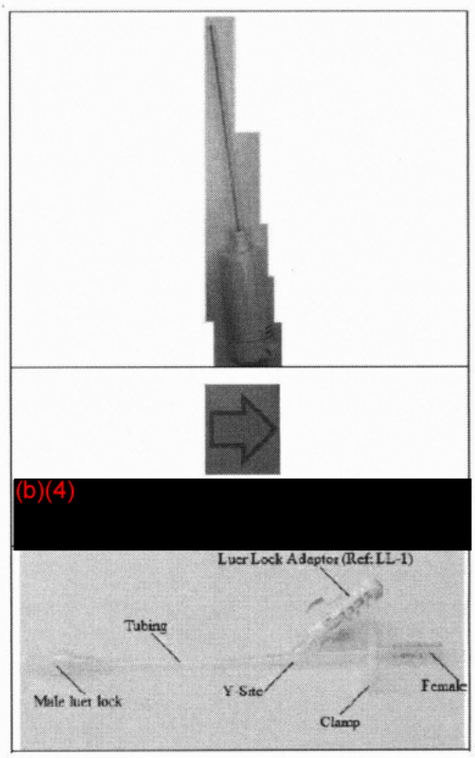
[redacted]

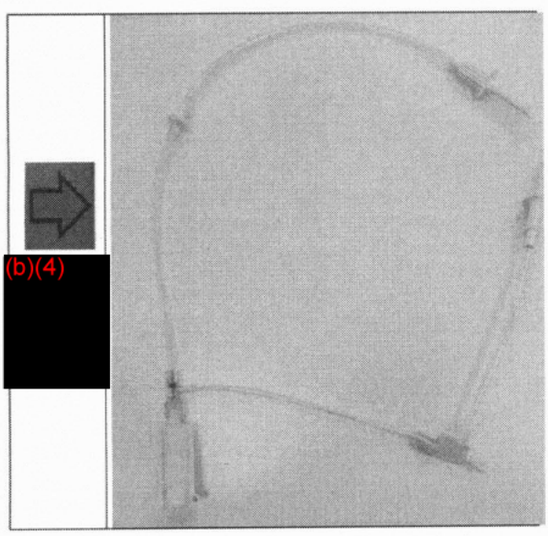
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Description

[redacted]







The Reconstitution Tubing consists of:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Diagrams

[redacted]

(b)(4) Diagrams

[redacted]

Description	Material

(b)(4) Description

[redacted]

(b)(4) Description

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Description

[redacted]

(b)(4) Description

[redacted]

List of sizes and models which clearance is requested for

Name	*Model #*	*Description*	*Sizes*
Reconstitution Tubing	**LL-1R**	**Reconstitution Tubing Accessory**	NA

K150219 Trade Name	*K150219 Supplier Name*	*K150219 Supplier Trade Name*	*K132899 Trade Name*	*Supplier Name*	*Supplier Trade Name*	*Differenc es*
Equashield Connector	(b)(4) [redacted]		Equashield Syringe Unit Outer Sleeve	(b)(4) [redacted]		Identical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Equashield Liquid Needle	(b)(4) [redacted]	Equashield Syringe Unit Liquid Needle	(b)(4) [redacted]	Identical
Equashield Air Needle	[redacted]	Equashield Syringe Unit Air Needle	[redacted]	Identical
Equashield T-Connector	[redacted]	Equashield Y-Tubing Set	[redacted]	(b)(4) [redacted]
Equashield Tubing	[redacted]	Equashield Y-Tubing Set	[redacted]	Identical
Equashield Spike for Bag	[redacted]	Equashield Spike Adapter Body	[redacted]	(b)(4) [redacted]
Equashield Check Valve	[redacted]	Equashield Spike Adapter Body and Y-Tubing Set Y-Connector	[redacted]	[redacted]
Equashield Dual Check Valve	[redacted]	Equashield Y-Tubing Set Y-Connector	[redacted]	[redacted]
Equashield Cap(Spike and Luer)	[redacted]	Equashield Y-Tubing Set Cap	[redacted]	Identical

Reviewer Recommendation

(b)(4) Deficiencies (b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K150219 Rx/OTC: Rx

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☐	☐	☐	☐	☐	☐	☐
No	☐	☐	☐	☐	☐	☐	☐	☐
Unknown	☒	☒	☒	☒	☒	☒	☒	☐

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."

Predicate(s)

510(k)#: K132899 Rx/OTC: Rx

Intended Population:

Indications for Use: Closed system drug transfer device (cstd) for preparation, reconstruction, 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.

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Reviewer Recommendation

(b)(4) Deficiencies

[redacted]

Comparison of Technology to Predicate Devices

	Proposed Device	*Predicate Device (K132899)*	*Differences*
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.	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.	None
Classification	Class II	Class II	
Regulation Number	888.5440	888.5440	
Product Code	ONB	ONB	

No differences in regulatory classification, risk, or indications for use.

	Proposed Device	*Predicate Device (K132899)*	*Differences*
System components	**Vial Adaptor**	**Vial Adaptor**	**None**
	Syringe Unit	**Syringe Unit**	
	Spike Adaptor 1- for injection	**Spike Adaptor 1- for injection**	
	Spike Adaptor W- for withdrawal	**Spike Adaptor W- for withdrawal**	
	Luer Lock Adaptor	**Luer Lock Adaptor**	
	Male Luer Lock Connector	**Male Luer Lock Connector**	
	Female Luer Lock Connector	**Female Luer Lock Connector**	
	Protective Plug	**Protective Plug**	
	Y-Site Tubing (Accessory)	**Y-Site Tubing (Accessory)**	
	Secondary Tubing (Accessory)	**Secondary Tubing (Accessory)**	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

	Reconstitution Tubing (Accessory)	None	Accessory Added
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**	**None**
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.**	

(b)(4)

[redacted]

	Proposed Device	*Predicate Device (K132899)*	*Differences*
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.	None
	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.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

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.	None
Sharps Injury	Needles and their tips are permanently recessed deep inside a hard plastic housing, out of reach.	Needles and their tips are permanently recessed deep inside a hard plastic housing, out of reach.	
Device Type	Rx/Single Use	Rx/Single Use	
Target Users	Licensed Pharmacists/Health Care Professionals	Licensed Pharmacists/Health Care Professionals	
Environment	Hospitals and clinics	Hospitals and clinics	
Sterilization	(b)(4) [redacted]		

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

Reviewer Recommendation

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Sponsor response to K150219/S001 on September 29, 2015:

(b)(4) Deficiencies

[redacted]

Labeling

Labeling Review Needed?	Yes ☒	No ☐
Usability Consult Needed?	Yes ☐	No ☒

A General Labeling Requirements

General Labeling Requirements	Yes	No	Inadequate or Marked
Is the prescription statement (or "Rx only") included?	☒	☐	☐
The indications for use are consistent with the IFU page?	☒	☐	☐
Appropriate contraindications provided?	☐	☒	☐
Appropriate warnings provided?	☐	☒	☐
Instructions are in accordance with the guidance (if applicable)?	☒	☐	☐
Appropriate labeling inside device?	☐	☐	☐
Appropriate label/indicator outside device?	☐	☐	☐
Appropriate Manual labeling?	☐	☐	☐
What MRI safety information does the labeling contain?		Not Needed	☐

Reviewer Recommendation
The Labeling is **ACCEPTABLE.**

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

Sterility Review Needed?	Yes ☒	No ☐
Sterility Consult Needed?	Yes ☒	No ☐

1. Sterilant:	[redacted]
a. **Sterilization method** description (e.g., Steam (moist heat), EO, Radiation):	Yes, Ethylene oxide
b. **Dose**, for radiation (e.g., 25 – 50 kGy):	N/A
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 *Biological*	Provided (b)(4) [redacted]
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	Provided
3. Sterility assurance level (SAL): (e.g., 10-6 for all devices (except 10-3 for devices that contact intact skin))	Provided
4. Is it labeled "Pyrogen Free"?	No observed pyrogen claims
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	Pyrogen tests provided. Falls under Biocompatibility review.
5. A description of the packaging	Provided

Reviewer Recommendation

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

Biocompatibility

Biocompatibility Review Needed?	Yes ☒	No ☐
Biocompatibility Consult Needed?	Yes ☒	No ☐

The materials of each device component are identified in the Table below. The sponsor claims "*No new materials are being introduced, all materials were biocompatibility tested in K132899*".

List of Parts and Materials – Reconstitution Tubing Accessory

Proposed Component Description (K150219)	*Proposed Device Material (K150219)*	*Predicate Device Material (K132899)*	*Predicate Component Description (K132899)*

(b)(4)

[redacted]

The sponsor states:

The Equashield Closed System has no direct contact to the patient but it serves as a conduit for liquids which then have patient contact. Through fluid flow some materials have indirect contact for a limited duration that is less than 24 hours. All materials are biocompatible and are in compliance with the ISO 10993-1:2009 and with the FDA Blue Book Memorandum G95-1.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

The sponsor has provided study reports for the following biocompatibility testing, which were based on the device cleared under K132899.

Test Category	Test Method	Protocol Number	Status	Report Number
(b)(4) [redacted]				

Reviewer Recommendation
(b)(4) Deficiencies [redacted] (b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

Software/Firmware

This device does not contain software/hardware.

EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

This device does not have an electrical component.

Performance Testing

A Bench Testing

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

(b)(4) Testing

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(b)(4) Testing

[redacted]

Reviewer Recommendation

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device: The intended use of the subject device is similar to that of the predicate device. The purpose of the submission is to introduce the reconstitution tubing set to the system. The technological characteristics of the device are similar and the sponsor has provided performance testing that the recosntitution tubing performs as expected.		
Do the devices have the same technological characteristics?	☒	☐

Original Deficiencies

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

[redacted]

Contact History

Email:	Response:
3/4/2015	3/5/2015
3/6/2015	3/12/2015
9/30/2015	10/1/2015
10/2/2015	10/9/2015
10/13/2015	10/14/2015
10/21/2015	10/22/2015
10/22/2015	10/23/2015
10/28/2015	10/29/2015 and 11/2/2015

Teleconference:
10/1/2015
10/6/2015
10/30/2015

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sapana Patel -S Digitally signed by Sapana Patel -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sapana Patel -S, 0.9.2342.19200300.100.1.1=2001554957 Date: 2015.11.04 17:14:00 -05'00'
Branch Chief Sign-Off	Richard C. Chapman -S 2015.11.04 17:38:14 -05'00'
Division Sign-Off (optional)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

November 5, 2015

Equashield Medical Ltd
c/o Mr. Raymond Kelly IV
Licensale Inc.
57 Lazy Brook Rd.
Monroe, Connecticut 06468

Re: K150219
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: September 25, 2015
Received: September 29, 2015

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

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" (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 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,

Tina Kiang
-S

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

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Department of Health & Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Office of Device Evaluation & Office of In-Vitro Diagnostics and Radiological Health

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K150219 Date Received by DCC: 1/30/2015

Lead Reviewer: Sapana Patel

Branch: GHDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments?		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments?		
3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments?		
4. The submission includes only summary-level information (i.e., NO test reports with performance data). *Note that if performance data are provided and are conducted under design validation (**21 CFR 820.30(g)**), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	X	
Comments?		

Does the submission meet all 4 criteria above?

- Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional using the form below and apply the Traditional checklist.

Questions? Contact FDA/CDRH/OCE/DIU at CDRH-FOIA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):		X		X
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
Comments? The Sponsor has not submitted Form 3514, CDRH Premarket Review Submission Cover Sheet				
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			X
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*			X	
b) Statement contains all elements per 21 CFR 807.93	X			
Comments? Statement has typed signature, please have statement signed by certifier				
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			X
Comments? Have statement signed by certifier				
6) Submission contains Class III Summary and Certification. *See recommended* content.		X		X
Comments? Does not contain Class III Summary				
7) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
8) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	

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B. Device Description				
9)				
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
11) A description of all device modification(s) including rationale for each modification.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 10(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	X			
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				

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a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))		X		X
Comments? Accessory contains T-connector, check valve and dual check valve which could not be located in previous submission as being cleared. If not cleared, include analysis why the components do not raise any new questions of safety and effectiveness.				
D. Design Control Activities				
17) Design Control Activities Summary includes all of the following:				
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis.	X			
b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	X			
c) Declaration of conformity with design controls, including: *All 3 must be present to answer "Yes."* *i.* Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. *ii.* Statement that manufacturing facility is in conformance with design control procedure requirements as specified in *21 CFR 820.30*. *iii.* Statement is signed by the individual responsible for these activities.	X			
E. Proposed Labeling (see also 21 CFR part 801)				
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	X			
Comments? Labeling for accessory was not clear to explain purpose of reconsitution bag and clarify if syringe included in CTSD is to be used or a luer syringe is to be used for reconstitution				
19) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	X			

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Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sapana Patel -S Digitally signed by Sapana Patel -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sapana Patel -S, 0.9.2342.19200300.100.1.1=2001554957 Date: 2015.02.05 12:32:59 -05'00'
Branch Chief Sign-Off (digital signature optional)*	Digitally signed by Richard C. Chapman -A Date: 2015.02.05 13:13:11 -05'00'
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with with decision required. Branch and Division digital signature optional.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K150219 Date Received by DCC: 1/30/2015

Lead Reviewer: Sapana Patel

Branch: GHDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments?		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments?		
3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments?		
4) The submission includes only summary-level information (i.e., NO test reports with performance data). *Note that if performance data are provided and are conducted under design validation (**21 CFR 820.30(g)**), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	X	
Comments?		

Does the submission meet all 4 criteria above?

- (●) Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- ( ) No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional using the form below and apply the Traditional checklist.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIS-TATUS@fda.hhs.gov or 301-796-8118

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

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Comments?		
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c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
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a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*			X	
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Comments? Statement has typed signature, please have statement signed by certifier				
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			X
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B. Device Description				
9)				
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
11) A description of all device modification(s) including rationale for each modification.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 10(a) and (b) and 12 above) of each component or accessory.	X			
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C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
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c) Declaration of conformity with design controls, including: *All 3 must be present to answer "Yes."* *i.* Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. *ii.* Statement that manufacturing facility is in conformance with design control procedure requirements as specified in *21 CFR 820.30*. *iii.* Statement is signed by the individual responsible for these activities.	X			

E. Proposed Labeling (see also 21 CFR part 801)

18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	X			
Comments? Labeling for accessory was not clear to explain purpose of reconsitution bag and clarify if syringe included in CTSD is to be used or a luer syringe is to be used for reconstitution				
19) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	X			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table		
Reviewer Sign-Off	Sapana Patel -S	Digitally signed by Sapana Patel -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sapana Patel -S, 0.9.2342.19200300.100.1.1=2001554957 Date: 2015.02.05 12:32:59 -05'00'
Branch Chief Sign-Off (digital signature optional)*		Digitally signed by Richard C. Chapman -A Date: 2015.02.05 13:13:11 -05'00'
Division Sign-Off (digital signature optional)*		

* Branch and Division review of checklist and concurrence with with decision required. Branch and Division digital signature optional.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))		X		X
Comments? Accessory contains T-connector, check valve and dual check valve which could not be located in previous submission as being cleared. If not cleared, include analysis why the components do not raise any new questions of safety and effectiveness.				
D. Design Control Activities				
17) Design Control Activities Summary includes all of the following:				
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis.	X			
b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	X			
c) Declaration of conformity with design controls, including: *All 3 must be present to answer "Yes."* *i.* Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. *ii.* Statement that manufacturing facility is in conformance with design control procedure requirements as specified in *21 CFR 820.30*. *iii.* Statement is signed by the individual responsible for these activities.	X			
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18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
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Comments? Labeling for accessory was not clear to explain purpose of reconsitution bag and clarify if syringe included in CTSD is to be used or a luer syringe is to be used for reconstitution				
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DAGID/GHDB
WO66 RM2562
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-4968

Premarket Notification [510(k)] Review

Pre-Review Reminders

☐ ← Click this checkbox to delete the directions in gray text below (Enable Content above first, if present).

Blue text indicates the text is clickable. Clicking may display tips and/or directions specific to that sentence (e.g., "Appropriate Manual Labeling" below) or section (e.g., "Premarket Notification [510(k)] Review" above); it may also link to a website, form or CARS report.

Dark purple text indicates that network connectivity is required for that element to perform an automated function

Post-Review Reminders

☐ Update memo Review Summary below (ensure the Indications for Use are accurate)

☐ Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility

☐ Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).

☐ For SE Decisions: Upload the SE Letter, IFU page and 510(k) Summary (if included) in DocMan

To add reminders, type the reminder in the text field to the left, and press the Tab key.

Date: April 2, 2015
To: FILE
From: Sapana Patel
Subject: Traditional 510(k)# K150219/S001

Applicant: Equashield Medical Ltd

Device Trade Name: Equashield Closed System Drug Transfer Device (cstd)

Contact: Raymond Kelly Iv

Contact Title: Official Correspondent

Correspondent Firm: Licensale Inc.

Phone: 203-880-4091 **Email:** ray.k@arazygroup.com

FDA Received Date: February 9, 2015

Due Date: May 10, 2015

Reg #: 880.5440 **Reg Name:** Intravascular Administration Set

Class: II **Product Code(s):** ONB

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K132899	ONB	Equashield Closed System Drug Transfer Device (cstd)	Equashield Medical Ltd

Review Summary

The subject device is an Intravascular Administration Set with the following 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. "It is for Rx use.

Recommendation

I recommend that the Equashield Closed System Drug Transfer Device (cstd) is/are in need of Additional Information (AINN)

Review Team

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Lead Reviewer	Sapana Patel (CDRH/ODE/DAGID/GHDB)
Microbiology Consult	Ramesh Panguluri, Ph.D.
Biocompatibility	Bifeng Qian, Ph.D.
Sterility	Sreekanth Gutala, PhD.

Purpose and History

TPLC Information Recall Information Historyfalls

Equashield Medical LTD of Migdal Tefen, 24959, Israel submitted a traditional premarket notification (510(k)) to introduce into US interstate Commerce a modification to the Equashield Closed System Drug Transfer Device. The Equashield System is considered a prescription Class II medical device regulated under 21 CFR 880.5440 as intravascular administration set under product code ONB. Equashield Medical had initially submitted a special 510(k) for the modification, however due to this being a fairly new product code and data to be reviewed; it was converted to a traditional 510(k).

The purpose of this premarket submission is to obtain premarket clearance to modify the Equashield Closed System Drug Transfer Device. The modification to the device is (b)(4) [redacted] (b)(4)

Previously the system was cleared under several 510(k) s.

510(k) Number	Product Code
K083152	LHI
K091389	LHI
K101940	LHI
K132899	ONB

	Yes	No	N/A
Truthful and Accuracy Statement	X		
510(k) Statement	X		
Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity - Yes Standards Form Required 3: Standard but no declaration - Yes Standards Form Required	X		

Required Elements for 510(k) Summary (21 CFR 807.92)		YES/NO
	Clearly labeled "510(k) Summary"	N/A
	Submitter' s name, address, phone #, a contact person	N/A
	Date the summary was prepared	N/A
	The name of the device/trade name/common name/classification name	N/A
	An identification of the legally marketed predicate	N/A
	Description of the subject device	N/A
	Statement of intended use (indication)	N/A

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Recommendation

I recommend that the Equashield Closed System Drug Transfer Device (cstd) is/are in need of Additional Information (AINN)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

	Technological characters	if same, a summary of comparison of technological characters	N/A
		If different, a summary of how do they compare to the predicate	N/A
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	N/A
		Brief discussion of clinical data submitted, referenced, or relied on, including: - Description upon whom the device was tested, - Data obtained from the tests and especially: ☐ Adverse events and complications ☐ Other information for SE determination	N/A
		Conclusion that data demonstrate SE	
Required Elements for <u>510(k) Statement</u> (21 CFR 807.93)			
		Signed verbatim statement	Yes

The submission purports the utilization of the following standards and/or guidance documents:

Recognition Number	Standard	Title of Standard	Reference Number and Date
6-11	ISO 594-1	Conical fittings with a 6% (Luer) luer taper for syringes, needles and certain other medical equipment- Part 1 general requirements.	1998
6-129	ISO 594-2	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 2 : Lock fittings	1998
6-304	ISO 7886-1	Sterile Hypodermic syringes for single use-Part 1: syringes for manual use	2010
6-318	ISO 8536-4	Infusion equipment for medical use-Part 4: Systems for single use, gravity feed	2010
2-156	ISO 10993-1	Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process	10993-1:2009 2013-01-15
	ISO 10993-4	Biological evaluation of medical devices- Part 4: selection of tests for interactions with blood	2002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2-153	ISO 10993-5	Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity	2009
5-40	ISO 14971	Medical devices-application of risk management to medical devices	2007
6-273	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.	2011

Reviewer Comments

This section of the review is **ACCEPTABLE**. The Sponsor has provided a 510(k) statement which states they will make all information included in the premarket notification on safety and effectiveness available within 30 days of request. Sponsor has listed all standards to which it has conformed. There are no further questions regarding this section.

Device/System Description

Device Characteristics	Yes	No	Inadequate Or Marked
Is the intended use or fundamental technology new?	☐	☒	☐
Is the device life-supporting or life sustaining?	☐	☒	☐
Are there any direct or indirect patient contacting components?	☒	☐	☐
• Is the device or a component an implant?	☐	☒	☐
Does the device use software/firmware?	☐	☒	☐
Does the device or a component need sterilization (by manufacturer or user)?	☒	☐	☐
The device/system uses or is a single use device(s) (SUD)			☐
Is the device a combination product? N - Not a Part 3 Combination Product			☐
Is the device electrical (battery or wall powered)? No, the device is not electrical			☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic
Yes	☐	☐	☐
No	☒	☒	☒
Unknown	☐	☐	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		Statement of intended use (indication)	N/A
	Technological characters	if same, a summary of comparison of technological characters	N/A
		If different, a summary of how do they compare to the predicate	N/A
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	N/A
		Brief discussion of clinical data submitted, referenced, or relied on, including: - Description upon whom the device was tested, - Data obtained from the tests and especially: ☐ Adverse events and complications ☐ Other information for SE determination	N/A
		Conclusion that data demonstrate SE	
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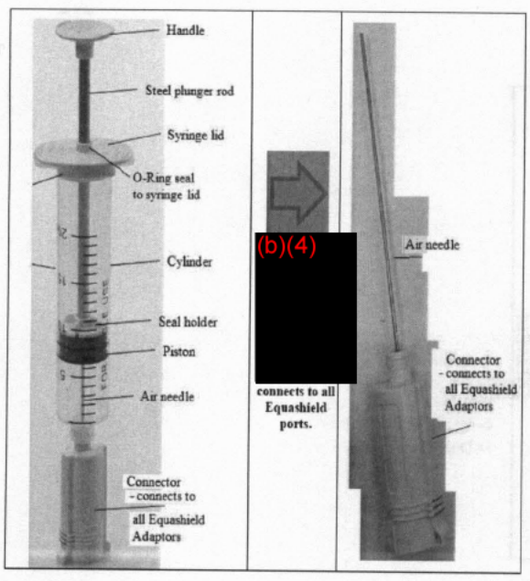
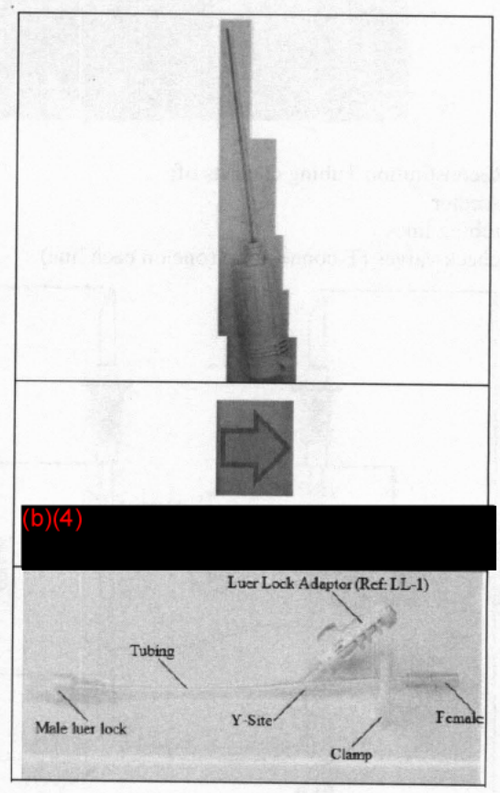
(b)(4)
(b)(4)
[redacted] The Equashield system is a closed system drug transfer device (CSTD) for safe preparation, reconstitution, compounding and administration of drugs, including antineoplastic and hazardous drugs. This closed system mechanically prohibits the transfer of environmental contaminants 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.

The proposed device is used by pharmacy to prepare, administer indirectly and transport hazardous drugs. The device should be used under clinical conditions by qualified clinicians and pharmacists. The device interfaces with other devices such as IV lines and bags. The Equashield components and accessories included in this submission also interface with each other. The device interacts with the patient indirectly through fluid path, the drug which is contained in the device is injected into an IV line or bag and that drug travels through the IV line to the patient.

(b)(4)
[redacted]





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The Reconstitution tubing connects a liquid path which is a standard IV bag into a spike which provides the diluent for reconstitution of the drug vial and also connects a standard empty IV bag (pressure equalization bag) which collects displaced air from the drug vial when reconstitution occurs.

An Equashield syringe unit connected to a male luer lock connector can be used as the syringe for reconstitution or the user may use a standard syringe with a male luer lock.

The syringe can be removed between reconstitution of different vials and a new syringe attached. The dual check valve prevents any kind of flow out of the open port during the syringe exchange and prevents any back flow from the drug vial and ports are free of any drug during all stages of working with the system, only harmless diluents are there.

The connector piece of the reconstitution tubing will connect to the Equashield vial adaptor which is connected to the drug vial to allow for reconstitution of the drug vials with the attached diluent. As the diluent enters the drug vial, the air from within the drug vial will be displaced into the empty pressure equalization bag.

(b)(4) Diagram

[redacted]

The predicate device is indicated and currently used for reconstitution, it contains components and tubing sets, the addition of the Reconstitution Tubing presents no changes to the Intended Use, Indications for Use, Principle of operation, Mechanism of Action, or Conditions of Use.

Users of CSTD devices currently assemble Reconstitution Tubing sets in order to perform their daily tasks. This introduces potential delays in treatment depending on which components are readily available for construction of the reconstitution sets, may introduce contaminates into the system during assembly, and may produce Reconstitution Tubing sets which leak or do not provide microbial barrier.

(b)(4) [redacted] we are proposing this addition to the FDA cleared Equashield system. Every component in the Equashield system is packaged and sold separately.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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List of sizes and models which clearance is requested for

Name	*Model #*	*Description*	*Sizes*
Reconstitution Tubing	**LL-1R**	**Reconstitution Tubing Accessory**	NA

K150219 Trade Name	*K150219 Supplier Name*	*K150219 Supplier Trade Name*	*K132899 Trade Name*	*Supplier Name*	*Supplier Trade Name*	*Differences*
Equashield Connector	(b)(4) [redacted]		Equashield Syringe Unit Outer Sleeve	(b)(4) [redacted]		Identical
Equashield Liquid Needle			Equashield Syringe Unit Liquid Needle			Identical
Equashield Air Needle			Equashield Syringe Unit Air Needle			Identical
Equashield T-Connector			Equashield Y-Tubing Set			(b)(4) [redacted]
Equashield Tubing			Equashield Y-Tubing Set			Identical
Equashield Spike for Bag			Equashield Spike Adapter Body			(b)(4) [redacted]
Equashield Check Valve			Equashield Spike Adapter Body and Y-Tubing Set Y-Connector			
Equashield Dual Check Valve			Equashield Y-Tubing Set Y-Connector			
Equashield Cap(Spike and Luer)			Equashield Y-Tubing Set Cap			Identical

Reviewer Recommendation

(b)(4) [redacted]

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(b)(4)
(b)(4)
(b)(4) [redacted] we are proposing this addition to the FDA cleared Equashield system. Every component in the Equashield system is packaged and sold separately.

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AI Needed:

(b)(4) Deficiencies

[redacted]

Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K150219 Rx/OTC:

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☐	☐	☐	☐	☐	☐	☐
No	☐	☐	☐	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

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."

Predicate(s)

510(k)#: K132899 Rx/OTC: Rx

Intended Population:

Indications for Use: Closed system drug transfer device (cstd) for preparation, reconstruction, 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.

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer Recommendation

The Comparison of the Indications for Use is **ACCEPTABLE.** The Indications for Use for the predicate device and subject device are identical. (b)(4) [redacted] There are no other concerns regarding the Indications for Use.

Comparison of Technology to Predicate Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Proposed Device	*Predicate Device (K132899)*	*Differences*
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.	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.	None
Classification	Class II	Class II	
Regulation Number	888.5440	888.5440	
Product Code	ONB	ONB	

No differences in regulatory classification, risk, or indications for use.

	Proposed Device	*Predicate Device (K132899)*	*Differences*
System Components	**Vial Adaptor**	**Vial Adaptor**	**None**
	Syringe Unit	**Syringe Unit**	
	Spike Adaptor 1- for injection	**Spike Adaptor 1- for injection**	
	Spike Adaptor W- for withdrawal	**Spike Adaptor W- for withdrawal**	
	Luer Lock Adaptor	**Luer Lock Adaptor**	
	Male Luer Lock Connector	**Male Luer Lock Connector**	
	Female Luer Lock Connector	**Female Luer Lock Connector**	
	Protective Plug	**Protective Plug**	
	Y-Site Tubing (Accessory)	**Y-Site Tubing (Accessory)**	
	Secondary Tubing (Accessory)	**Secondary Tubing (Accessory)**	
	(b)(4) [redacted]		
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**	**None**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Release RH on 04-18-2016

	Proposed Device	*Predicate Device (K132899)*	*Differences*
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.	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.	None
Classification	Class II	Class II	
Regulation Number	888.5440	888.5440	
Product Code	ONB	ONB	

No differences in regulatory classification, risk, or indications for use.

	Proposed Device	*Predicate Device (K132899)*	*Differences*
System components	**Vial Adaptor**	**Vial Adaptor**	**None**
	Syringe Unit	**Syringe Unit**	
	Spike Adaptor 1- for injection	**Spike Adaptor 1- for injection**	
	Spike Adaptor W- for withdrawal	**Spike Adaptor W- for withdrawal**	
	Luer Lock Adaptor	**Luer Lock Adaptor**	
	Male Luer Lock Connector	**Male Luer Lock Connector**	
	Female Luer Lock Connector	**Female Luer Lock Connector**	
	Protective Plug	**Protective Plug**	
	Y-Site Tubing (Accessory)	**Y-Site Tubing (Accessory)**	
	Secondary Tubing (Accessory)	**Secondary Tubing (Accessory)**	
	(b)(4) [redacted]		
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**	**None**

Questions? Contact FDA/CDRH/OGE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released on 04-18-2016

AI Needed:

(b)(4) Deficiencies

[redacted]

Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K150219 Rx/OTC:

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☐	☐	☐	☐	☐	☐	☐
No	☐	☐	☐	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

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."

Predicate(s)

510(k)#: K132899 Rx/OTC: Rx

Intended Population:

Indications for Use: Closed system drug transfer device (cstd) for preparation, reconstruction, 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.

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer Recommendation

The Comparison of the Indications for Use is **ACCEPTABLE.** The Indications for Use for the predicate device and subject device are identical. (b)(4) [redacted] (b)(4) There are no other concerns regarding the Indications for Use.

Comparison of Technology to Predicate Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

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.**	

The Reconstitution Tubing is very similar to the Equashield Syringe Unit, in that it splits two fluid paths, liquid and air, between with respect to the drug vial. No new materials, designs, or components are being added. The Equashield System validations and testing used to support SE in (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted] **No new or different questions of safety or effectiveness are raised.**

	Proposed Device	*Predicate Device (K132899)*	*Differences*
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.	None
	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.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

	Proposed Device	*Predicate Device (K132899)*	*Differences*
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.	None
Sharps Injury	Needles and their tips are permanently recessed deep inside a hard plastic housing, out of reach.	Needles and their tips are permanently recessed deep inside a hard plastic housing, out of reach.	
Device Type	Rx/Single Use	Rx/Single Use	
Target Users	Licensed Pharmacists/Health Care Professionals	Licensed Pharmacists/Health Care Professionals	
Environment	Hospitals and clinics	Hospitals and clinics	
Sterilization	EO/SAL (b)(4) [redacted]	EO/SAL (b)(4) [redacted]	

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

Reviewer Recommendation

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

	Proposed Device	*Predicate Device (K132899)*	*Differences*
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.	None
Sharps Injury	Needles and their tips are permanently recessed deep inside a hard plastic housing, out of reach.	Needles and their tips are permanently recessed deep inside a hard plastic housing, out of reach.	
Device Type	Rx/Single Use	Rx/Single Use	
Target Users	Licensed Pharmacists/Health Care Professionals	Licensed Pharmacists/Health Care Professionals	
Environment	Hospitals and clinics	Hospitals and clinics	
Sterilization	EO/SAL (b)(4) [redacted]	EO/SAL (b)(4) [redacted]	

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

Reviewer Recommendation

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DIDSTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

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.**	

The Reconstitution Tubing is very similar to the Equashield Syringe Unit, in that it splits two fluid paths, liquid and air, between with respect to the drug vial. No new materials, designs, or components are being added. The Equashield System validations and testing used to support S(b)(4)
(b)(4)
(b)(4)
No new or different questions of safety or effectiveness are raised.

	Proposed Device	***Predicate Device (K132899)***	***Differences***
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.	None
	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.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Labeling

Labeling Review Needed?	Yes ☒	No ☐
Usability Consult Needed?	Yes ☐	No ☒

A General Labeling Requirements

General Labeling Requirements	Yes	No	Inadequate or Marked
Is the prescription statement (or "Rx only") included?	☒	☐	☐
Adequate instructions for OTC use?	☐	☐	☐
The indications for use are consistent with the IFU page?	☒	☐	☐
Appropriate contraindications provided?	☐	☒	☐
Appropriate warnings provided?	☐	☒	☐
Instructions are in accordance with the guidance (if applicable)?	☒	☐	☐
Appropriate labeling inside device?	☐	☐	☐
Appropriate label/indicator outside device?	☐	☐	☐
Appropriate Manual labeling?	☐	☐	☐
What MRI safety information does the labeling contain?		Not Needed	☐

Reviewer Recommendation

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

Sterility Review Needed?	Yes ☒	No ☐
Sterility Consult Needed?	Yes ☒	No ☐

1. Sterilant:	[redacted]
a. **Sterilization method** description (e.g., Steam (moist heat), EO, Radiation):	Yes, Ethylene oxide
b. **Dose**, for radiation (e.g., 25 – 50 kGy):	N/A
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 *Biological*	Provided (b)(4) [redacted]
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	Provided

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

Sterility Review Needed?	Yes ☒	No ☐
Sterility Consult Needed?	Yes ☒	No ☐

1. Sterilant: a. **Sterilization method** description (e.g., Steam (moist heat), EO, Radiation):	Yes, Ethylene oxide
b. **Dose**, for radiation (e.g., 25 – 50 kGy):	N/A
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 *Biological*	Provided (b)(4) [redacted]
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	Provided

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Labeling

Labeling Review Needed?	Yes ☒	No ☐
Usability Consult Needed?	Yes ☐	No ☒

A General Labeling Requirements

General Labeling Requirements	Yes	No	Inadequate or Marked
Is the prescription statement (or "Rx only") included?	☒	☐	☐
Adequate instructions for OTC use?	☐	☐	☐
The indications for use are consistent with the IFU page?	☒	☐	☐
Appropriate contraindications provided?	☐	☒	☐
Appropriate warnings provided?	☐	☒	☐
Instructions are in accordance with the guidance (if applicable)?	☒	☐	☐
Appropriate labeling inside device?	☐	☐	☐
Appropriate label/indicator outside device?	☐	☐	☐
Appropriate Manual labeling?	☐	☐	☐
What MRI safety information does the labeling contain?		Not Needed	☐

Reviewer Recommendation

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. Sterility assurance level (SAL): (e.g., 10-6 for all devices (except 10-3 for devices that contact intact skin))	Provided
4. Is it labeled "Pyrogen Free"?	No observed pyrogen claims
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	Pyrogen tests provided. Falls under Biocompatibility review.
5. A description of the packaging	Provided

Reviewer Recommendation

(b)(4)

[redacted]

Biocompatibility

Biocompatibility Review Needed?	Yes ☒	No ☐
Biocompatibility Consult Needed?	Yes ☒	No ☐

The materials of each device component are identified in the Table below. The sponsor claims "*No new materials are being introduced; all materials were biocompatibility tested in K132899*".

List of Parts and Materials – Reconstitution Tubing Accessory

Proposed Component Description (K150219)	*Proposed Device Material (K150219)*	*Predicate Device Material (K132899)*	*Predicate Component Description (K132899)*

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

The sponsor states:

The Equashield Closed System has no direct contact to the patient but it serves as a conduit for liquids which then have patient contact. Through fluid flow some materials have indirect contact for a limited duration that is less than 24 hours. All materials are biocompatible and are in compliance with the ISO 10993-1:2009 and with the FDA Blue Book Memorandum G95-1.

The sponsor has provided study reports for the following biocompatibility testing, which were based on the device cleared under K132899.

Test Category	Test Method	Protocol Number	Status	Report Number
(b)(4) [redacted]				

Reviewer Recommendation

(b)(4) Deficiencies [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

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The sponsor has provided study reports for the following biocompatibility testing, which were based on the device cleared under K132899.

Test Category	Test Method	Protocol Number	Status	Report Number
(b)(4) [redacted]				

Reviewer Recommendation
(b)(4) Deficiencies [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

3. Sterility assurance level (SAL): (e.g., 10-6 for all devices (except 10-3 for devices that contact intact skin))	Provided
4. Is it labeled "Pyrogen Free"?	No observed pyrogen claims
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	Pyrogen tests provided. Falls under Biocompatibility review.
5. A description of the packaging	Provided

Reviewer Recommendation

(b)(4) Deficiencies

[redacted]

Biocompatibility

Biocompatibility Review Needed?	Yes ☒	No ☐
Biocompatibility Consult Needed?	Yes ☒	No ☐

The materials of each device component are identified in the Table below. The sponsor claims "*No new materials are being introduced; all materials were biocompatibility tested in K132899*".

List of Parts and Materials – Reconstitution Tubing Accessory

Proposed Component Description (K150219)	*Proposed Device Material (K150219)*	*Predicate Device Material (K132899)*	*Predicate Component Description (K132899)*
(b)(4) [redacted]			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

Software/Firmware

This device does not contain software/hardware.

EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

This device does not have an electrical component.

Performance Testing

A **Bench Testing**

Bench Testing Summary for (b)(4) Testing

(b)(4) Testing

[redacted]

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

-796-8118

Software/Firmware

This device does not contain software/hardware.

EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

This device does not have an electrical component.

Performance Testing

A Bench Testing

Bench Testing Summary for (b)(4) Testing [redacted]

(b)(4) Testing

[redacted]

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

Reviewer Recommendation

(b)(4) Deficiencies

[redacted]

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Released by CDRH on 04-18-2016

(b)(4) Testing

[redacted]

Reviewer Recommendation

(b)(4) Deficiencies

[redacted]

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TATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

(b)(4) Testing

[redacted]

SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device:		
Do the devices have the same technological characteristics?	☐	☐

Original Deficiencies

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

[redacted]

SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device:		
Do the devices have the same technological characteristics?	☐	☐

Original Deficiencies

Device Description

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

[redacted]

Contact History

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sapana Patel -S Digitally signed by Sapana Patel -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sapana Patel -S, 0.9.2342.19200300.100.1.1=2001554957 Date: 2015.04.02 12:44:48 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Sterility Consult Review

Consult Number: CON155289

Document Number: K150219/S001

Applicant: Equashield LLC; POB 12, Tefen Industrial Park, Migdal, Tefen 24959, Isreal

Trade Name: Equashield Closed System drug Transfer Device (CSTD)

Consult Type: Sterility

Requestor: Sapna Patel, Pharmacist
Sapna.patel@fda.hhs.gov; Ph: 240) 402-4968

Requestor Home: CDRH\ODE\DAGRID\GHDB

Requested Consultant: Sreekanth Gutala, Ph.D.
Sreekanth.gutala@fda.hhs.gov ; Ph:301-796-7007

Gatekeeper / Consultant: Elizabeth Claverie, M.S; Branch Chief, CDRH\ODE\DAGRID\INCB
elizabeth.claverie@fda.hhs.gov ; Ph:301-796-6298

Consultant Home: CDRH\ ODE\ DAGID\ INCB

Date Requested: March 12, 2015

Due Date: March 30, 2015

Background Information

The sponsor Equashield LLC submitted Premarket 510(k) Notification for the Equashield Closed System drug Transfer Device (CSTD). Equashield LLC had submitted a 510K (K150219/S001) for this device. This submission was converted to Traditional from special 510(K) by lead reviewer.

NOTE: This consult review is only limited to sterility and shelf life information for the subject device, Equashield Closed System drug Transfer Device (CSTD).

SUMMARY and CONCLUSION: Additional information required. The deficiencies are mentioned at the end of this memo.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills and also prevents microbial ingress.

DEVICE DESCRIPTION

Principle of Operation (There are no changes to the Principle of Operation):
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.

Mechanism of Action (There are no changes to the Mechanism of Action):
The Equashield system is a 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.

Conditions of Use (There are no changes to the Conditions of Use):
The proposed device is used by pharmacy to prepare, administer indirectly, and transport hazardous drugs. The device should be used under clinical conditions by qualified clinicians and pharmacists. The device is not an implant but is used to inject drugs into IV lines or bags. The device interfaces with other devices such as IV lines and bags. The Equashield components and accessories included in this submission also interface with each other; these interactions are described in the following section. The device interacts with the patient indirectly through fluid path, the drug which is contained in the device is injected into an IV line or bag and that drug travels through the IV to the patient.

The predicate device is indicated and currently used for reconstitution, it contains components and tubing sets, the addition of the Reconstitution Tubing presents no changes to the Intended Use, Indications for Use, Principle of Operation, Mechanism of Action, or Conditions of Use.
The predicate device (K132899) was designed, manufactured, and tested as a multiple component system including 3 extension tubes (Y-Site Tubing, Secondary Tubing, and Reconstitution Tubing).
(b)(4)
[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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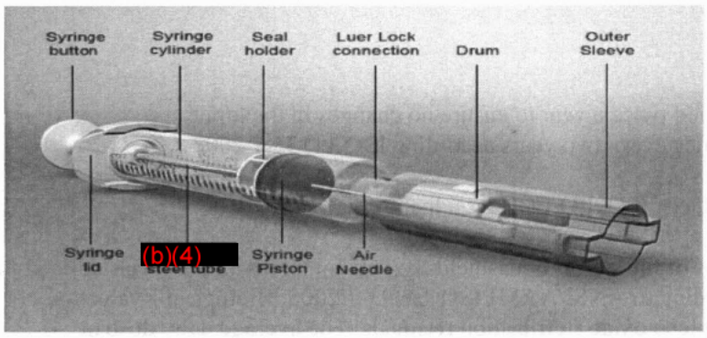

STERILIZATION AND SHELF LIFE

The sponsor provided the following information:

This section includes:
- Sterilization Method
- Validation method
- SAL
- EO residuals

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Sterilization

[redacted]

Shelf Life

The firm claims that the proposed shelf life/ expiration date is for 2 years. The shelf life of 2 years is based off of the manufacturing date on the individual labeling of each lot, 2 years post expiration date is the expiration date of the product.

Summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life:

(b)(4)

[redacted]

Summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Testing [redacted]

Reviewer's Comments: The sponsor indicated that the subject device is intended to be sterilized (b)(4) [redacted]

K90-1 review elements:

1. Sterilant: a. **Sterilization method** description (e.g., Steam (moist heat), EO, Radiation):	Yes, Ethylene oxide
b. **Dose**, for radiation (e.g., 25 – 50 kGy):	N/A
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 *Biological*	Provided (b)(4) [redacted] (b)(4)
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	Provided
3. Sterility assurance level (SAL): (e.g., 10-6 for all devices (except 10-3 for devices that contact intact skin))	Provided
4. Is it labeled "Pyrogen Free"?	No observed pyrogen claims
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	Pyrogen tests provided. Falls under Biocompatibility review.
5. A description of the packaging	Provided

(b)(4) Deficiencies [redacted]

DEFICIENCIES: The firm should be asked to address the following deficiencies /clarifications:

(b)(4) Deficiencies [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-19-2016

(b)(4) Deficiencies

[redacted]

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sreekanth Gutala -S Digitally signed by Sreekanth Gutala -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000540490, cn=Sreekanth Gutala -S Date: 2015.03.31 15:04:21 -04'00'
Branch Chief Sign-Off	Clarence W. Murray Iii III -S Digitally signed by Clarence W. Murray Iii III -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300197254, cn=Clarence W. Murray Iii III -S Date: 2015.03.31 23:32:40 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Instructions for Use

Precautions:

- This device should only be used under the supervision of a Pharmacist or Health Care Professional and after having read these instructions carefully!
- CAUTION: U.S. law restricts this device to sale by or on the order of a Pharmacist or Health Care Professional
- This device is not intended to be used with light sensitive solutions, fat emulsions, lipids, blood, or blood products.
- Not to be used with high-pressure infusion systems.

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.

Symbols:

	Do not re-use (single use)		Do not re-sterilize
	Expiration date		Do not use if package is damaged
LOT	Lot Number		Dispose of used materials safely, according to your local regulations
REF	Catalog Number		Consult Instructions for use
STERILE EO	Sterilized using ethylene oxide	DEHP	Device Does not contain plasticizers or DEHP
	Manufacturer	Latex	Device Does not contain natural rubber latex components

Device Description: Equashield is not an IV Administration Set, it 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 plasticizers or 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Components:
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 1), 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:
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.

Reconstitution Tubing – this accessory consists of a T-Connector (equivalent of an Equashield Luer Lock Adaptor (LL-1) permanently attached to a conical connector). The tubing is very similar to the Y-Connector Tubing which extends from the main IV bag through a check valve (T-connector), in a similar manner the other end of the T travels from the pressure equalization bag through a check valve into the T-connector. Just like the Y-Tubing splits two fluid paths the T-Tubing (Reconstitution Tubing) also splits two fluid paths. The T-Tubing or Reconstitution Tubing as it is called is very similar to the Y-Tubing. It is made from the same materials, fabricated using the same validated methods, and was tested in the same manner. The Tubing Accessory is intended to be attached in a T-split line between the Equashield Syringe Unit and two IV bags.

It consists of:

- T-Connector.
- Two tubing lines with standard clamps to block flow in tubing.
- Two Check Valves (T-Connectors) (one on each line).

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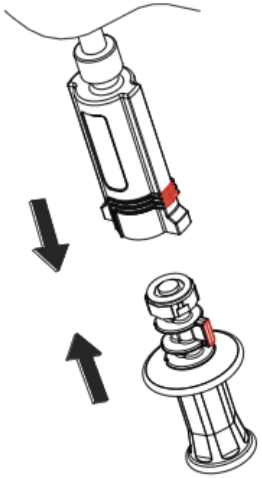
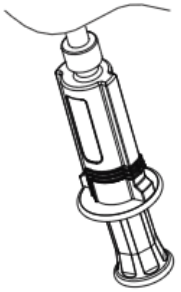
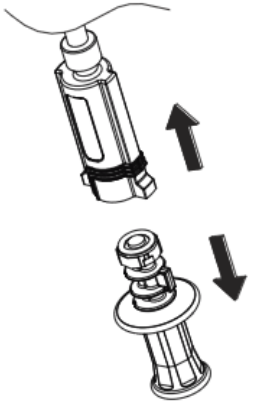
Directions for Use:

Protective Plug REF: PP-1	
Closed System Plug for additional mechanical protection for EQUASHIELD's connectors.	EQUASHIELD Closed System Connector.

Connection of the Protective Plug	1  Align the red orientation marks and slide the Protective Plug into any EQUASHIELD connector.	2  Done.	3  Pull to disconnect.

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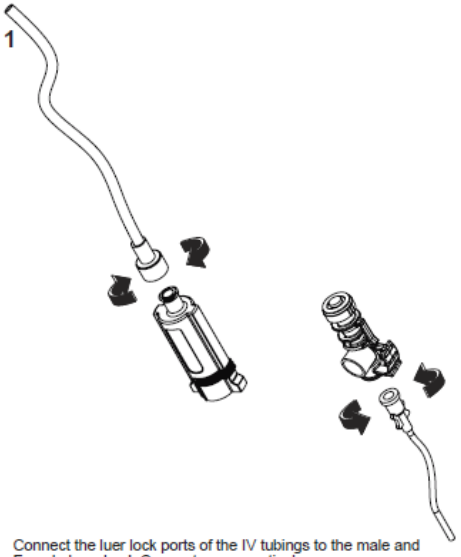
Female Luer Lock Connector	Male Luer Lock Connector	Luer Lock Adaptor
REF: FC-1	REF: MC-1	REF: LL-1
Closed System female Connector for connection of two IV tubing segments.	Closed System male Connector for connection of two IV tubing segments.	Closed system Adaptor for connection of two IV tubing set segments or for injection into Luer Lock port.

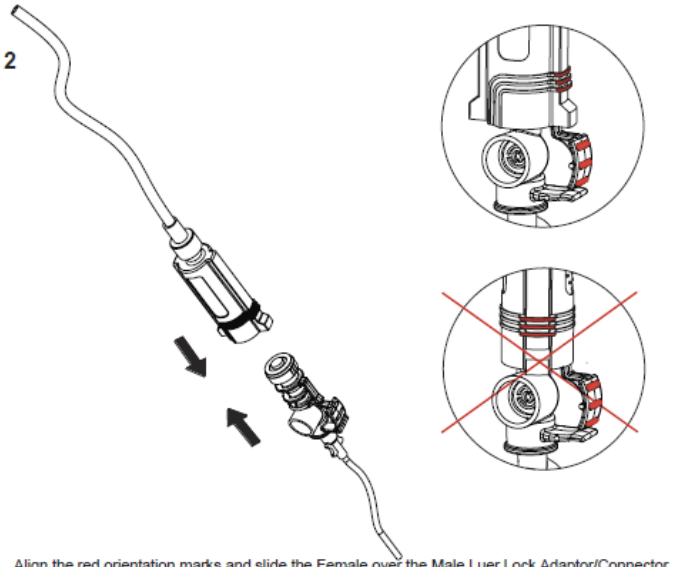
Connection of two IV tubing segments

1



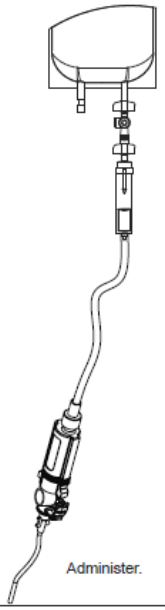
Connect the luer lock ports of the IV tubings to the male and Female Luer Lock Connectors respectively.

2



Align the red orientation marks and slide the Female over the Male Luer Lock Adaptor/Connector. **Do not twist or rotate during or after connection.**

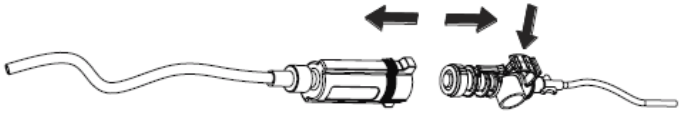
3



Administer.

4

Push the lever to disconnect.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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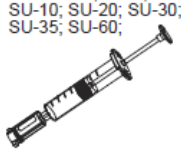
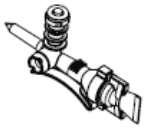
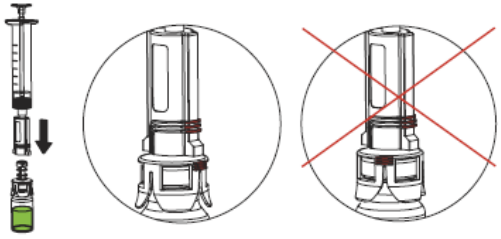
Syringe Unit	Vial Adaptor	Spike Adaptor	Spike Adaptor-W	Luer Lock Adaptor
REF: SU-3; SU-5; SU-10; SU-20; SU-30; SU-35; SU-60;	REF: VA-13; VA-20; VA-20C; VA-28;	REF: SA-1;	REF: SA-W	REF: LL-1
				
Closed system Syringe Unit for drug transfer.	Vial Adaptor for closed system vial access.	Closed system Spike Adaptor for injection into infusion bag and for infusion administration.	Spike Adaptor for Withdrawal of diluent from a bag.	Closed system Adaptor for injection into Luer Lock port.

Transfer from vial to Syringe Unit

1

Click the Vial Adaptor on the vial and remove the protective cap.

2



Align the red orientation marks and slide the Syringe Unit over the adaptor. **Do not twist or rotate during or after connection.**

3

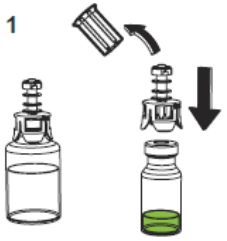
Invert and withdraw the liquid. **Never inject into the vial when in upside down position.**

4

Pull the Syringe Unit from the Vial Adaptor.

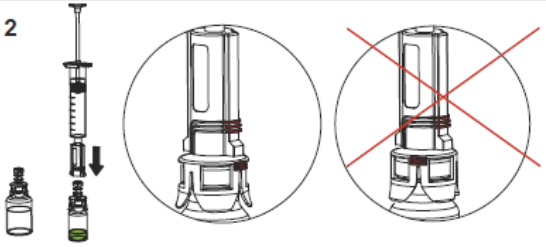
Drug reconstitution and transfer

1



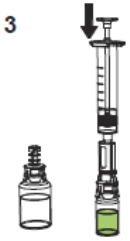
Click Vial Adaptor on the vial and remove the protective cap.

2



Align the red orientation marks and slide the Syringe Unit pre-filled with diluent over the adaptor. **Do not twist or rotate during or after the connection.**

3



Inject the diluent into the vial.

4

Invert and withdraw the diluted drug. **Never inject into the vial in upside down position.**

5

Pull the Syringe Unit from the Vial Adaptor.

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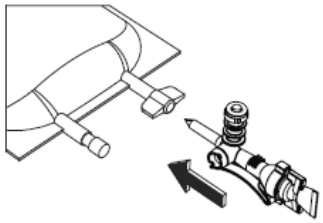
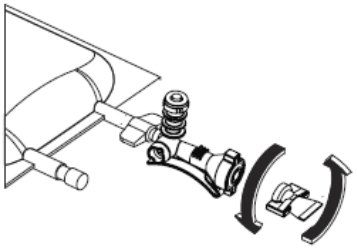
Injection into infusion bag and infusion administration

1



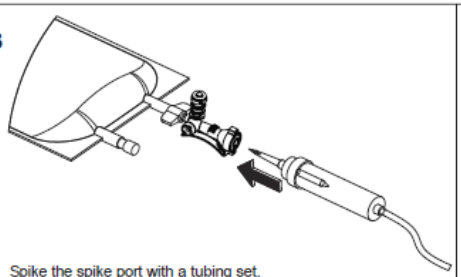
Connect the Spike Adaptor to the infusion bag.

2



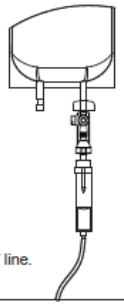
Twist off the spike port seal.

3



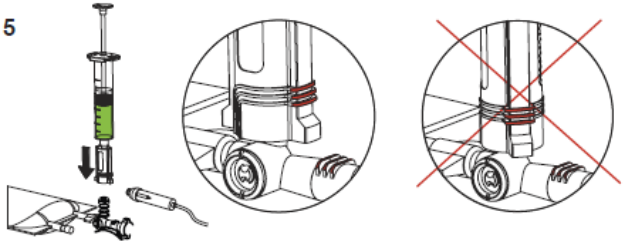
Spike the spike port with a tubing set.

4



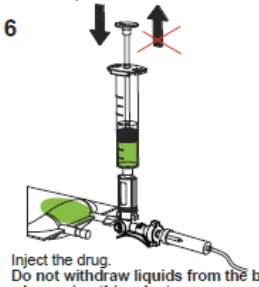
Prime the IV line.

5



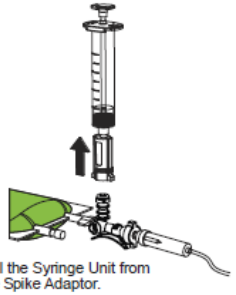
Align the red orientation marks and slide the Syringe Unit over the Spike Adaptor.
Do not twist or rotate during or after connection.

6



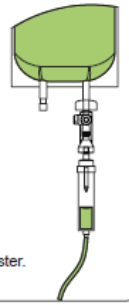
Inject the drug.
Do not withdraw liquids from the bag when using this adaptor.

7



Pull the Syringe Unit from the Spike Adaptor.

8



Administer.

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Reconstitution Set intended to be used for reconstituting Powdered Drugs
Directions for Using Reconstitution Tubing on Next page

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Setup:

1) Connect the liquid path to the diluent bag (A) (not included) by inserting the spike into the spike port of the diluent bag (A).

2) Connect the other spike into a second empty IV Bag (B) (not included). This will be used to capture air to equalize pressure and collect unwanted diluent.

3) Connect any standard luer lock syringe (not included) to the Check Valve's female luer lock port (C).

4) Hang or place the diluent bag (A) higher than rest of the system components. The bag (B) can be placed anywhere and at any height higher than the other system components.

Initial Priming:

5) Prime the tubing set by drawing at least 15 ml of diluent from the diluent bag into the syringe by pulling the syringe plunger. Then hold the syringe upright (luer lock up - plunger bottom) and push the syringe plunger until syringe is empty. The Dual Check valve (C) ensures that this action pushes the air from the syringe followed by the priming diluents only into the empty bag (B) and nothing into bag (a), thereby priming the whole set.

Operation:

6) Ensure the Vial Adaptor/s from the Equashield System is connected to the desired drug vial/s (not illustrated here).

7) Connect the adaptor (D) to the Vial Adaptor on the vial (see instructions for use of the Vial Adaptor).

8) Draw diluent into the syringe up to the exact volume to be injected by pulling the syringe plunger connected at port "C".

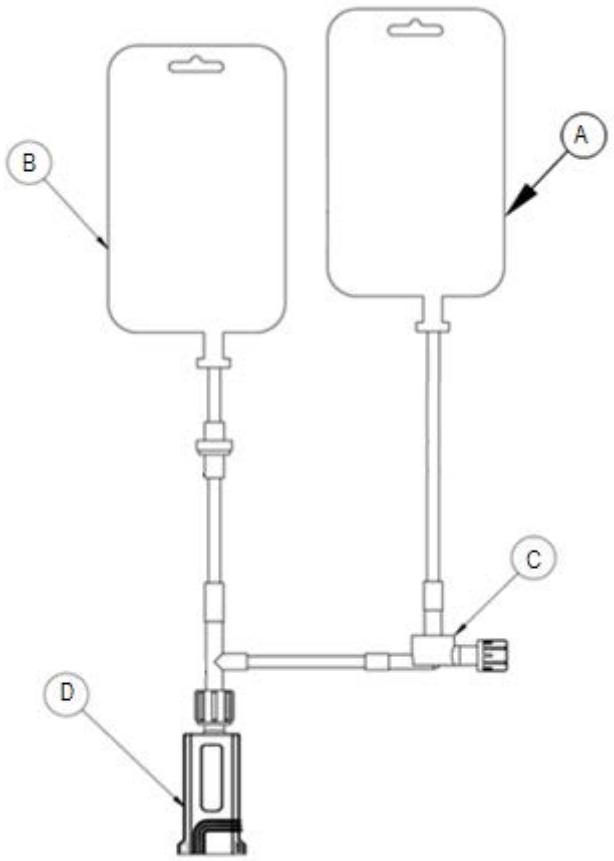
Note: steps 7 and 8 are interchangeable if desired.

9) Hold the vial upright and depress the syringe until the desired amount of diluent is injected into the vial. As diluent fills the vial, the air from the vial is pushed only into the bag (B) and trapped there.

9a) If another dose of diluent is required to be injected into the same vial, simply refill the syringe with diluent, hold the vial upright and inject the desired dose as described in steps 8 and 9.

10) Disconnect the adaptor (D) from the Vial Adaptor.

11) Repeat steps 6-10 for next drug vials.



Ordering and Catalogue Information Chart

Name	***Model #***	***Description***	***Sizes***
Vial Adaptor	VA-13 VA-13/2 VA-20 VA-20/2 VA-20C VA-20C/2 VA-28 VA-28/2	Adaptor to the medication vial	13mm, 20mm, 28mm vial neck sizes
Syringe Unit	SU-1 SU-1/2 SU-3 SU-3/2 SU-5 SU-5/2 SU-10 SU-10/2 SU-20 SU-20/2 SU-30 SU-30/2 SU-35 SU-35/2 SU-60 SU-60/2 SU-EZ60 SU-EZ60/2	Piston syringe	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 35ml, 60ml
Spike Adaptor	SA-1	Adaptor to inject into the infusion bag	Single size
	SA-W	Adaptor withdraw from infusion bag	
Luer Lock Adaptor	LL-1	Adaptor to a female luer lock port	
Male Luer Lock Connector	MC-1	Adaptor to female luer lock port of an IV tubing	
Female Luer Lock connector	FC-1	Adaptor to male luer lock port	
Protective Plug	PP-1	Plug that protects against foreign objects openings during transport	
Y-Site Tubing	LL-1Y	Luer Lock Adaptor with Y-Site Tubing	
Secondary Tubing	SA-1S	Spike Adaptor-1 with Secondary Tubing Accessory and a drip chamber	
Reconstitution Tubing	LL-1R	For reconstitution	

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Instructions for Use

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STERILE EO	Sterilized using ethylene oxide	DEHP	Device Does not contain plasticizers or DEHP
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Device Description: Equashield is not an IV Administration Set, it 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 plasticizers or 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Components:
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 1), 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:
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.

Reconstitution Tubing – this accessory consists of a T-Connector (equivalent of an Equashield Luer Lock Adaptor (LL-1) permanently attached to a conical connector). The tubing is very similar to the Y-Connector Tubing which extends from the main IV bag through a check valve (T-connector), in a similar manner the other end of the T travels from the pressure equalization bag through a check valve into the T-connector. Just like the Y-Tubing splits two fluid paths the T-Tubing (Reconstitution Tubing) also splits two fluid paths. The T-Tubing or Reconstitution Tubing as it is called is very similar to the Y-Tubing. It is made from the same materials, fabricated using the same validated methods, and was tested in the same manner. The Tubing Accessory is intended to be attached in a T-split line between the Equashield Syringe Unit and two IV bags.

It consists of:

- T-Connector.
- Two tubing lines with standard clamps to block flow in tubing.
- Two Check Valves (T-Connectors) (one on each line).

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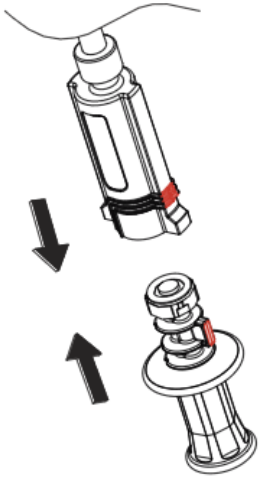
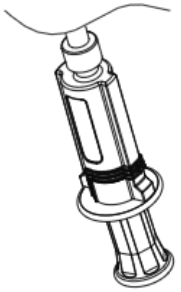
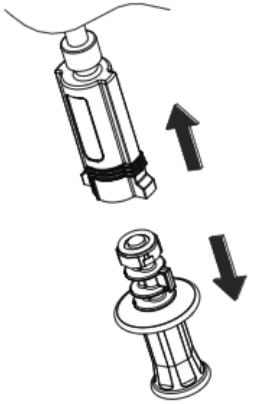
Directions for Use:

Protective Plug REF: PP-1	
Closed System Plug for additional mechanical protection for EQUASHIELD's connectors.	EQUASHIELD Closed System Connector.

Connection of the Protective Plug	1  Align the red orientation marks and slide the Protective Plug into any EQUASHIELD connector.	2  Done.	3  Pull to disconnect.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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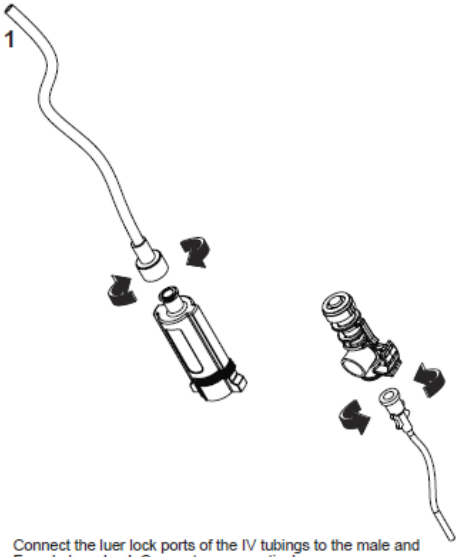
Female Luer Lock Connector	Male Luer Lock Connector	Luer Lock Adaptor
REF: FC-1	REF: MC-1	REF: LL-1
Closed System female Connector for connection of two IV tubing segments.	Closed System male Connector for connection of two IV tubing segments.	Closed system Adaptor for connection of two IV tubing set segments or for injection into Luer Lock port.

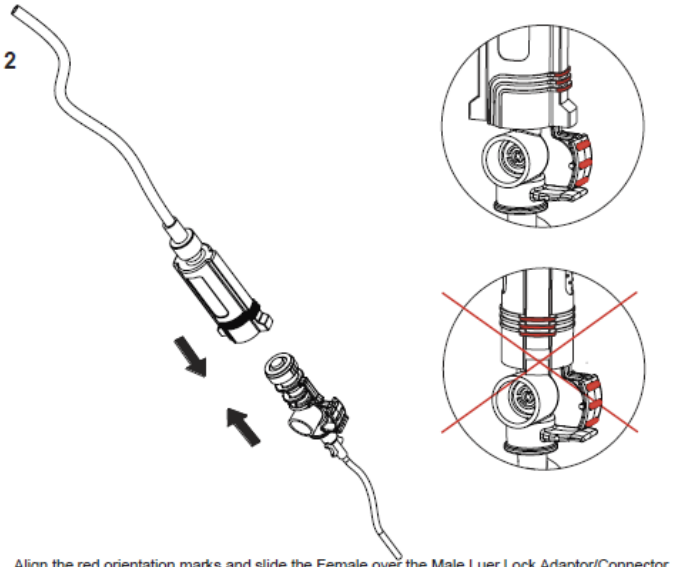
Connection of two IV tubing segments

1



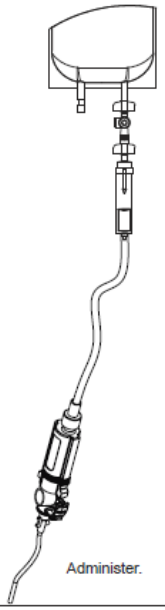
Connect the luer lock ports of the IV tubings to the male and Female Luer Lock Connectors respectively.

2



Align the red orientation marks and slide the Female over the Male Luer Lock Adaptor/Connector. **Do not twist or rotate during or after connection.**

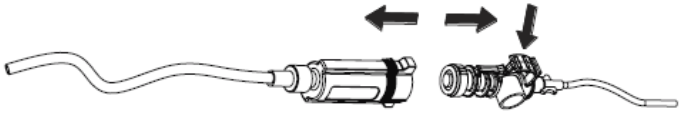
3



Administer.

4

Push the lever to disconnect.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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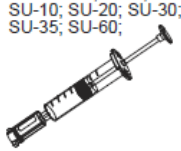
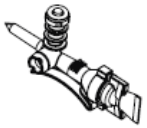
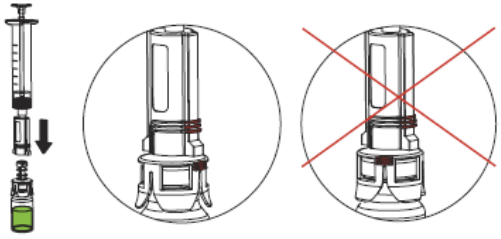
Syringe Unit	Vial Adaptor	Spike Adaptor	Spike Adaptor-W	Luer Lock Adaptor
REF: SU-3; SU-5; SU-10; SU-20; SU-30; SU-35; SU-60;	REF: VA-13; VA-20; VA-20C; VA-28;	REF: SA-1;	REF: SA-W	REF: LL-1
				
Closed system Syringe Unit for drug transfer.	Vial Adaptor for closed system vial access.	Closed system Spike Adaptor for injection into infusion bag and for infusion administration.	Spike Adaptor for Withdrawal of diluent from a bag.	Closed system Adaptor for injection into Luer Lock port.

Transfer from vial to Syringe Unit

1

Click the Vial Adaptor on the vial and remove the protective cap.

2



Align the red orientation marks and slide the Syringe Unit over the adaptor. **Do not twist or rotate during or after connection.**

3

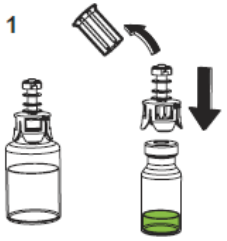
Invert and withdraw the liquid. **Never inject into the vial when in upside down position.**

4

Pull the Syringe Unit from the Vial Adaptor.

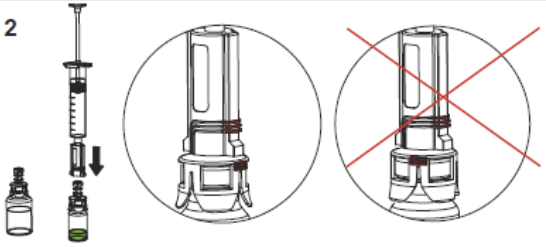
Drug reconstitution and transfer

1



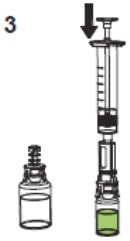
Click Vial Adaptor on the vial and remove the protective cap.

2



Align the red orientation marks and slide the Syringe Unit pre-filled with diluent over the adaptor. **Do not twist or rotate during or after the connection.**

3



Inject the diluent into the vial.

4

Invert and withdraw the diluted drug. **Never inject into the vial in upside down position.**

5

Pull the Syringe Unit from the Vial Adaptor.

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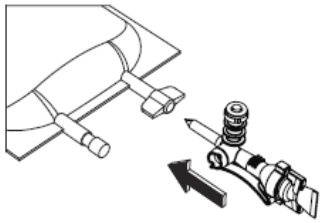
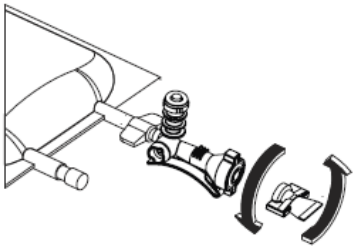
Injection into infusion bag and infusion administration

1



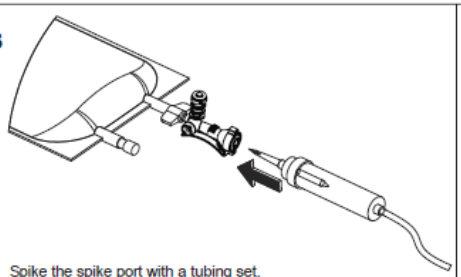
Connect the Spike Adaptor to the infusion bag.

2



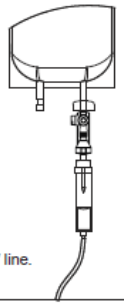
Twist off the spike port seal.

3



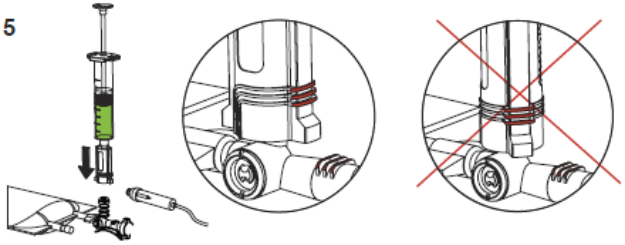
Spike the spike port with a tubing set.

4



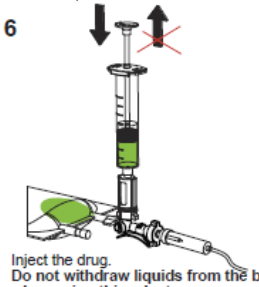
Prime the IV line.

5



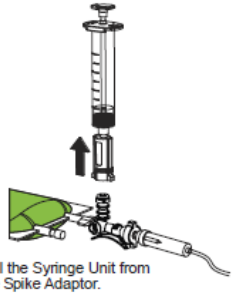
Align the red orientation marks and slide the Syringe Unit over the Spike Adaptor.
Do not twist or rotate during or after connection.

6



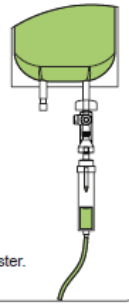
Inject the drug.
Do not withdraw liquids from the bag when using this adaptor.

7



Pull the Syringe Unit from the Spike Adaptor.

8



Administer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Setup:

1) Connect the liquid path to the diluent bag (A) (not included) by inserting the spike into the spike port of the diluent bag (A).

2) Connect the other spike into a second empty IV Bag (B) (not included). This will be used to capture air to equalize pressure and collect unwanted diluent.

3) Connect any standard luer lock syringe (not included) to the Check Valve's female luer lock port (C).

4) Hang or place the diluent bag (A) higher than rest of the system components. The bag (B) can be placed anywhere and at any height higher than the other system components.

Initial Priming:

5) Prime the tubing set by drawing at least 15 ml of diluent from the diluent bag into the syringe by pulling the syringe plunger. Then hold the syringe upright (luer lock up - plunger bottom) and push the syringe plunger until syringe is empty. The Dual Check valve (C) ensures that this action pushes the air from the syringe followed by the priming diluents only into the empty bag (B) and nothing into bag (a), thereby priming the whole set.

Operation:

6) Ensure the Vial Adaptor/s from the Equashield System is connected to the desired drug vial/s (not illustrated here).

7) Connect the adaptor (D) to the Vial Adaptor on the vial (see instructions for use of the Vial Adaptor).

8) Draw diluent into the syringe up to the exact volume to be injected by pulling the syringe plunger connected at port "C".

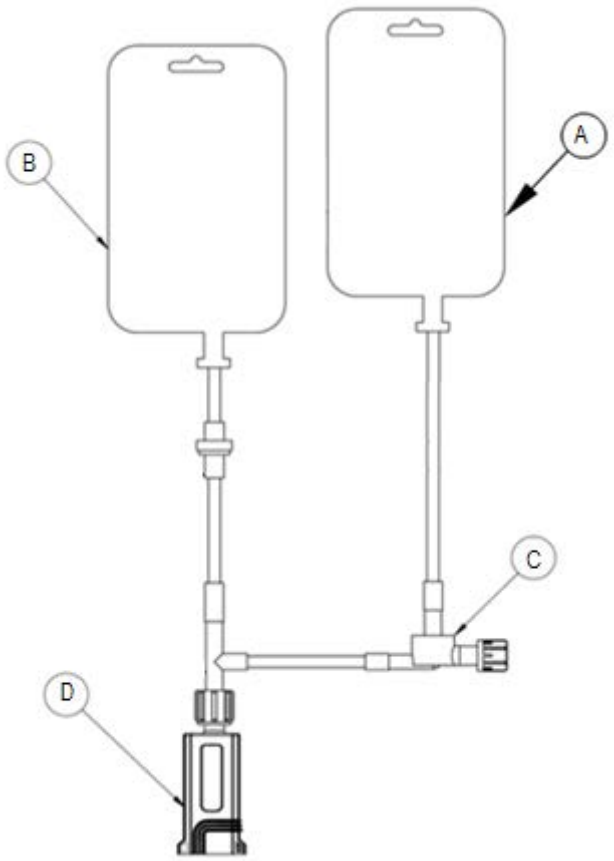
Note: steps 7 and 8 are interchangeable if desired.

9) Hold the vial upright and depress the syringe until the desired amount of diluent is injected into the vial. As diluent fills the vial, the air from the vial is pushed only into the bag (B) and trapped there.

9a) If another dose of diluent is required to be injected into the same vial, simply refill the syringe with diluent, hold the vial upright and inject the desired dose as described in steps 8 and 9.

10) Disconnect the adaptor (D) from the Vial Adaptor.

11) Repeat steps 6-10 for next drug vials.



Ordering and Catalogue Information Chart

Name	***Model #***	***Description***	***Sizes***
Vial Adaptor	VA-13 VA-13/2 VA-20 VA-20/2 VA-20C VA-20C/2 VA-28 VA-28/2	Adaptor to the medication vial	13mm, 20mm, 28mm vial neck sizes
Syringe Unit	SU-1 SU-1/2 SU-3 SU-3/2 SU-5 SU-5/2 SU-10 SU-10/2 SU-20 SU-20/2 SU-30 SU-30/2 SU-35 SU-35/2 SU-60 SU-60/2 SU-EZ60 SU-EZ60/2	Piston syringe	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 35ml, 60ml
Spike Adaptor	SA-1	Adaptor to inject into the infusion bag	Single size
	SA-W	Adaptor withdraw from infusion bag	
Luer Lock Adaptor	LL-1	Adaptor to a female luer lock port	
Male Luer Lock Connector	MC-1	Adaptor to female luer lock port of an IV tubing	
Female Luer Lock connector	FC-1	Adaptor to male luer lock port	
Protective Plug	PP-1	Plug that protects against foreign objects openings during transport	
Y-Site Tubing	LL-1Y	Luer Lock Adaptor with Y-Site Tubing	
Secondary Tubing	SA-1S	Spike Adaptor-1 with Secondary Tubing Accessory and a drip chamber	
Reconstitution Tubing	LL-1R	For reconstitution	

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Instructions for Use

Precautions:

- This device should only be used under the supervision of a Pharmacist or Health Care Professional and after having read these instructions carefully!
- CAUTION: U.S. law restricts this device to sale by or on the order of a Pharmacist or Health Care Professional
- This device is not intended to be used with light sensitive solutions, fat emulsions, lipids, blood, or blood products.
- Not to be used with high-pressure infusion systems.

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.

Symbols:

	Do not re-use (single use)		Do not re-sterilize
	Expiration date		Do not use if package is damaged
LOT	Lot Number		Dispose of used materials safely, according to your local regulations
REF	Catalog Number		Consult Instructions for use
STERILE EO	Sterilized using ethylene oxide	DEHP	Device Does not contain plasticizers or DEHP
	Manufacturer	Latex	Device Does not contain natural rubber latex components

Device Description: Equashield is not an IV Administration Set, it 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 plasticizers or 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Components:
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 1), 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:
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.

Reconstitution Tubing – this accessory consists of a T-Connector (equivalent of an Equashield Luer Lock Adaptor (LL-1) permanently attached to a conical connector). The tubing is very similar to the Y-Connector Tubing which extends from the main IV bag through a check valve (T-connector), in a similar manner the other end of the T travels from the pressure equalization bag through a check valve into the T-connector. Just like the Y-Tubing splits two fluid paths the T-Tubing (Reconstitution Tubing) also splits two fluid paths. The T-Tubing or Reconstitution Tubing as it is called is very similar to the Y-Tubing. It is made from the same materials, fabricated using the same validated methods, and was tested in the same manner. The Tubing Accessory is intended to be attached in a T-split line between the Equashield Syringe Unit and two IV bags.

It consists of:

- T-Connector.
- Two tubing lines with standard clamps to block flow in tubing.
- Two Check Valves (T-Connectors) (one on each line).

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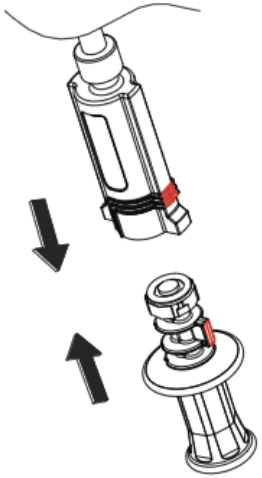
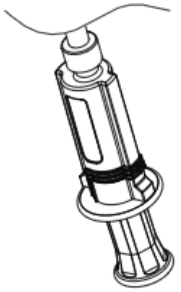
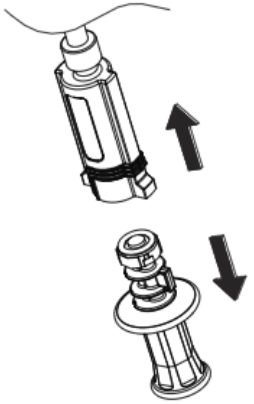
Directions for Use:

Protective Plug REF: PP-1	
Closed System Plug for additional mechanical protection for EQUASHIELD's connectors.	EQUASHIELD Closed System Connector.

Connection of the Protective Plug	1  Align the red orientation marks and slide the Protective Plug into any EQUASHIELD connector.	2  Done.	3  Pull to disconnect.

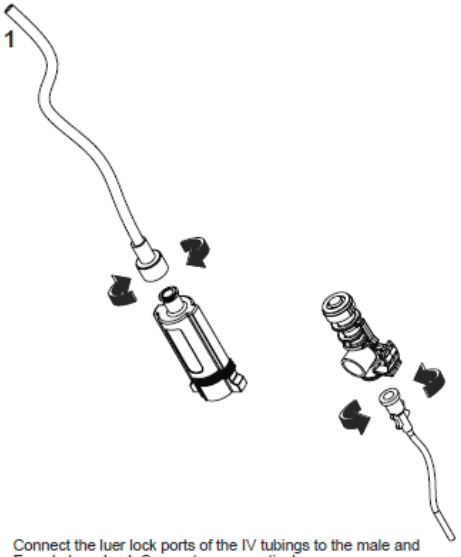
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Female Luer Lock Connector	Male Luer Lock Connector	Luer Lock Adaptor
REF: FC-1	REF: MC-1	REF: LL-1
Closed System female Connector for connection of two IV tubing segments.	Closed System male Connector for connection of two IV tubing segments.	Closed system Adaptor for connection of two IV tubing set segments or for injection into Luer Lock port.

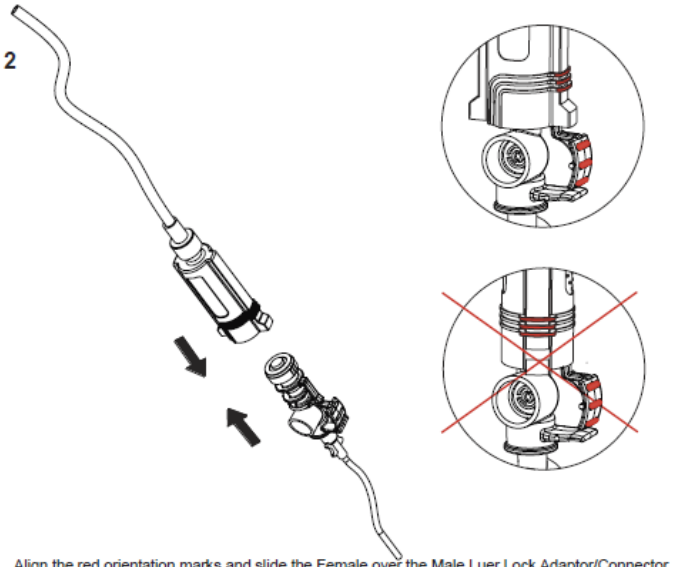
Connection of two IV tubing segments

1



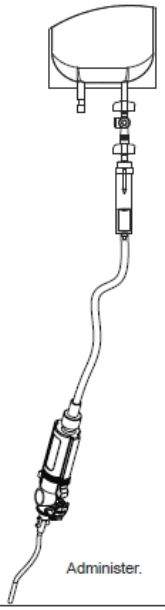
Connect the luer lock ports of the IV tubings to the male and Female Luer Lock Connectors respectively.

2



Align the red orientation marks and slide the Female over the Male Luer Lock Adaptor/Connector. **Do not twist or rotate during or after connection.**

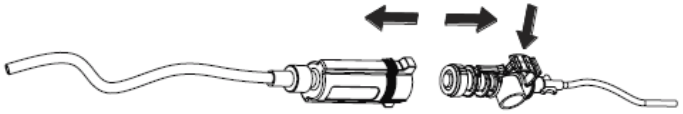
3



Administer.

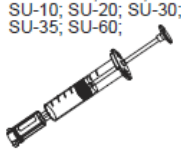
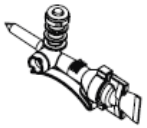
4

Push the lever to disconnect.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

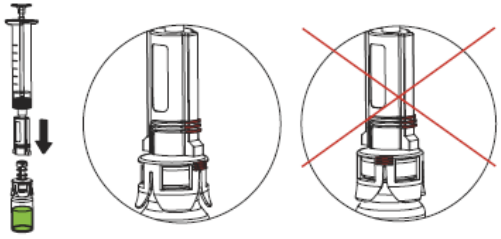
Syringe Unit	Vial Adaptor	Spike Adaptor	Spike Adaptor-W	Luer Lock Adaptor
REF: SU-3; SU-5; SU-10; SU-20; SU-30; SU-35; SU-60;	REF: VA-13; VA-20; VA-20C; VA-28;	REF: SA-1;	REF: SA-W	REF: LL-1
				
Closed system Syringe Unit for drug transfer.	Vial Adaptor for closed system vial access.	Closed system Spike Adaptor for injection into infusion bag and for infusion administration.	Spike Adaptor for Withdrawal of diluent from a bag.	Closed system Adaptor for injection into Luer Lock port.

Transfer from vial to Syringe Unit

1

Click the Vial Adaptor on the vial and remove the protective cap.

2



Align the red orientation marks and slide the Syringe Unit over the adaptor. **Do not twist or rotate during or after connection.**

3

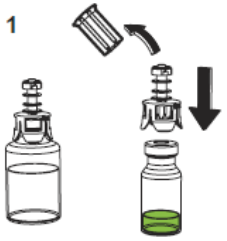
Invert and withdraw the liquid. **Never inject into the vial when in upside down position.**

4

Pull the Syringe Unit from the Vial Adaptor.

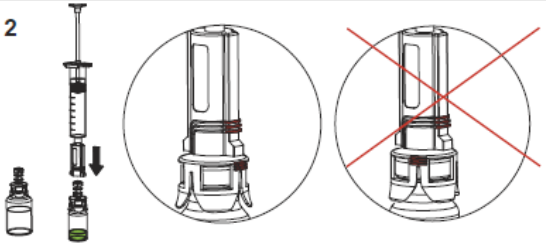
Drug reconstitution and transfer

1



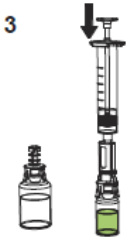
Click Vial Adaptor on the vial and remove the protective cap.

2



Align the red orientation marks and slide the Syringe Unit pre-filled with diluent over the adaptor. **Do not twist or rotate during or after the connection.**

3



Inject the diluent into the vial.

4

Invert and withdraw the diluted drug. **Never inject into the vial in upside down position.**

5

Pull the Syringe Unit from the Vial Adaptor.

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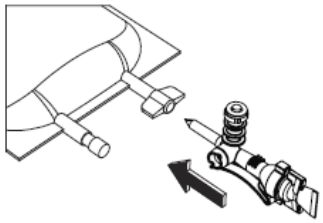
Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

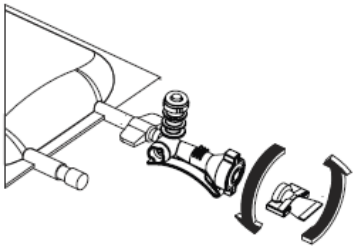
Injection into infusion bag and infusion administration

1



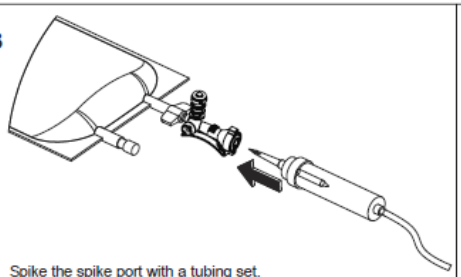
Connect the Spike Adaptor to the infusion bag.

2



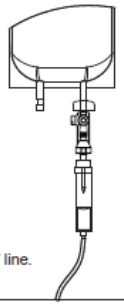
Twist off the spike port seal.

3



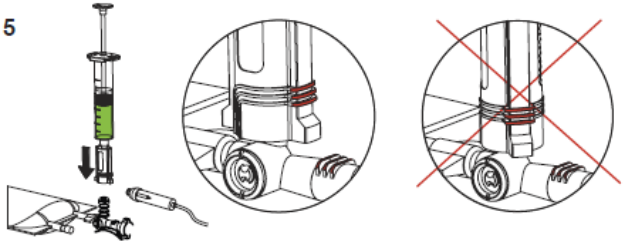
Spike the spike port with a tubing set.

4



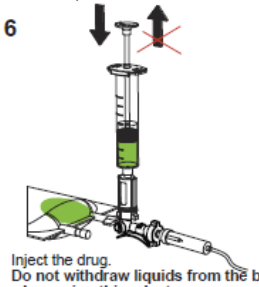
Prime the IV line.

5



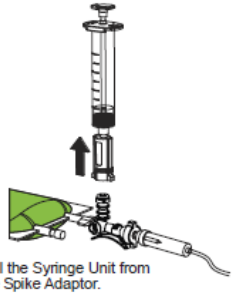
Align the red orientation marks and slide the Syringe Unit over the Spike Adaptor.
Do not twist or rotate during or after connection.

6



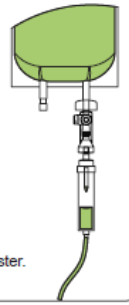
Inject the drug.
Do not withdraw liquids from the bag when using this adaptor.

7



Pull the Syringe Unit from the Spike Adaptor.

8



Administer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Setup:

1) Connect the liquid path to the diluent bag (A) (not included) by inserting the spike into the spike port of the diluent bag (A).

2) Connect the other spike into a second empty IV Bag (B) (not included). This will be used to capture air to equalize pressure and collect unwanted diluent.

3) Connect any standard luer lock syringe (not included) to the Check Valve's female luer lock port (C).

4) Hang or place the diluent bag (A) higher than rest of the system components. The bag (B) can be placed anywhere and at any height higher than the other system components.

Initial Priming:

5) Prime the tubing set by drawing at least 15 ml of diluent from the diluent bag into the syringe by pulling the syringe plunger. Then hold the syringe upright (luer lock up - plunger bottom) and push the syringe plunger until syringe is empty. The Dual Check valve (C) ensures that this action pushes the air from the syringe followed by the priming diluents only into the empty bag (B) and nothing into bag (a), thereby priming the whole set.

Operation:

6) Ensure the Vial Adaptor/s from the Equashield System is connected to the desired drug vial/s (not illustrated here).

7) Connect the adaptor (D) to the Vial Adaptor on the vial (see instructions for use of the Vial Adaptor).

8) Draw diluent into the syringe up to the exact volume to be injected by pulling the syringe plunger connected at port "C".

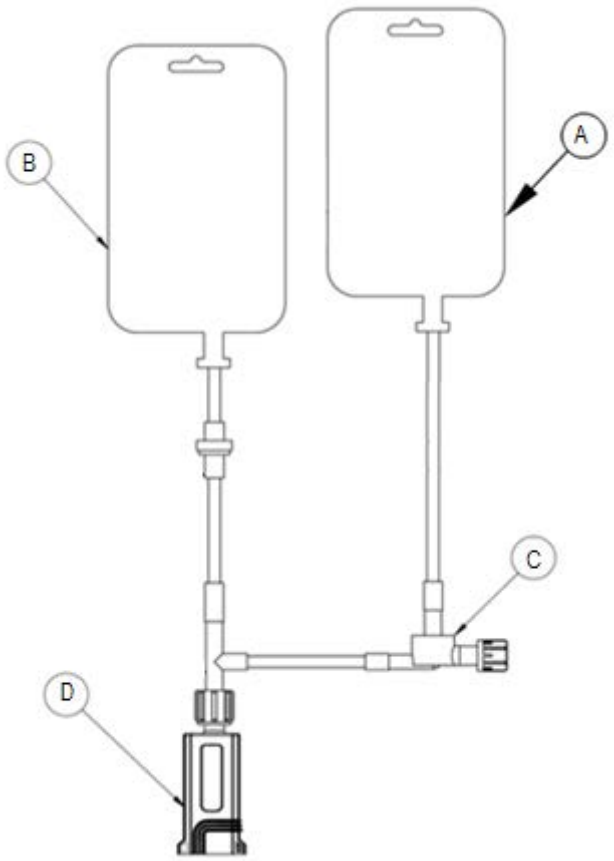
Note: steps 7 and 8 are interchangeable if desired.

9) Hold the vial upright and depress the syringe until the desired amount of diluent is injected into the vial. As diluent fills the vial, the air from the vial is pushed only into the bag (B) and trapped there.

9a) If another dose of diluent is required to be injected into the same vial, simply refill the syringe with diluent, hold the vial upright and inject the desired dose as described in steps 8 and 9.

10) Disconnect the adaptor (D) from the Vial Adaptor.

11) Repeat steps 6-10 for next drug vials.



Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

EQUASHIELD®

Closed System for Drug Transfer.

Reconstitution Tubing **REF: LL-1R**

EQUASHIELD Medical Ltd. POB 12, Tefen Industrial Park 24959, Israel

Consult Instructions For Use

Rx Only

CE 0483

Single Use Only

Do Not Re-sterilize

Do Not use if package is demaged

STERILE EO

PEEL ▶ OPEN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Reconstitution Set Packaging

The packaging for the Reconstitution tubing set is the same packaging used for the Y Connector tubing set and the Secondary tubing set.

The tubing sets are individually packed so that they remain sterile during storage. The unit container is sealed in a tamper-evident manner. The sets are packed and sterilized in such a way that there are no flattened portions or kinks in the tubing when they are ready for use.

Proposed shelf life/ expiration date: The proposed device is supplied sterile; it has a 2 year shelf life. The shelf life of 2 years is based off of the manufacturing date on the individual labeling of each lot, 2 years post expiration date is the expiration date of the product.

Summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life:

(b)(4) [redacted]

Description of Packaging:
The tubing sets are packaged in a peel pouch (blister) made of (b)(4) [redacted]. All packaging materials are identified in the figures and table below:

The blister is comprised of (b)(4) [redacted] The specifications of the materials are provided in the table below:

Item	Material Specifications	Supplier
(b)(4) [redacted]		

Shelf Pack Box:
The individual blisters are packed in a printed shelf-box. All packaging materials are hereby identified in the figures and table below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Figure 2: Component Printed Shelf Box

The specifications of the system component printed shelf box are hereby provided in the table below:

Item	Material Specifications	Dimensions (mm)	Supplier
Shelf Pack	Top Layer: E-Flute with Laminated Coating Bottom Layer: Folded Carton – Duplex Gray Back	400x134x160 & 400x270x160	(b)(4) [redacted]

<u>Shipper Box:</u>
The printed shelf boxes are packed in shipper box. All packaging materials are hereby identified in the figures and table below:

Figure 3: Component Shipper Box

The specifications of the system component printed shelf box are hereby provided in the table below:

Item	Material Specifications	Dimensions (mm)	Supplier
Shelf Pack	C- Flute 141 Brown	410x285x171	(b)(4) [redacted]

Package testing:

(b)(4)

[redacted]

Table 1: (b)(4) Test Results

(b)(4)

[redacted]

(b)(4) Testing

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Declaration of Conformity with Design Controls

Verification Activities As required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

_____ *March 4, 2015*
Dorit Valal
Programs Manager
Equashield

Manufacturing Facility The manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

_____ *March 4, 2015*
Dorit Valal
Programs Manager
Equashield

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Premarket Notification 510(k) Statement
(As Required By 21 CFR 807.93)

I certify that, in my capacity as *Programs Manager of Equashield*, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Dorit Valal
(Signature of Certifier)

Dorit Valal
(Typed Name)

March 4, 2015
(Date)

*(Premarket Notification [510(k)] Number)
*For a new submission, leave the 510(k) number blank.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Premarket Notification Truthful And Accurate Statement
[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as *Programs Manager of Equashield*, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Dorit Valal
(Signature)

Dorit Valal
(Typed Name)

March 4, 2015
(Date)

*(Premarket Notification [510(k)] Number)
*For a new submission, leave the 510(k) number blank.
Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

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Dorit Valal
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Dorit Valal
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Dorit Valal
(Signature)

Dorit Valal
(Typed Name)

March 4, 2015
(Date)

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Sterilization

This section includes:

- Sterilization Method
- Validation method
- SAL
- EO residuals

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Sterilization

[redacted]

(b)(4) Testing

[redacted]

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Shelf Life

The system and/or the air-inlet device are individually packed so that they remain sterile during storage. The unit container is sealed in a tamper-evident manner. The systems and/or the air-inlet devices are packed and sterilized in such a way that there are no flattened portions or kinks when they are ready for use.

Proposed shelf life/ expiration date: The proposed device is supplied sterile; it has a 2 year shelf life. The shelf life of 2 years is based off of the manufacturing date on the individual labeling of each lot, 2 years post expiration date is the expiration date of the product.

Summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life:

(b)(4)

[redacted]

Summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate:

(b)(4)

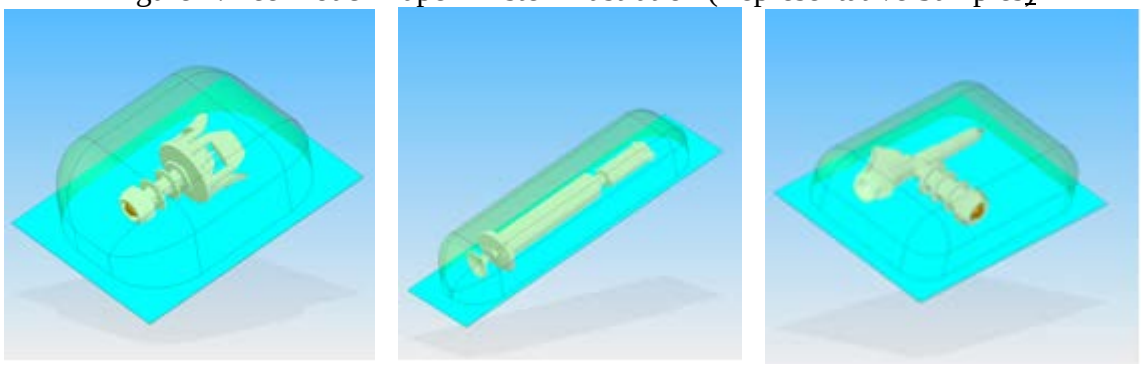
[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Description of Packaging:

Individual (sterile) Packaging: The Equashield System's components are packaged in a peel pouch (blister) made of (b)(4) [redacted] All packaging materials are identified in the figures and table below:

Figure 1: Peel Pouch Paper Blister Illustration (Representative Samples)



Vial Adaptor | Syringe Unit | Spike Adaptor

The blister is comprised of paper and film. The specifications of the materials are provided in the table below:

Item	Material Specifications	Supplier
(b)(4) [redacted]		

Shelf Pack Box:

The individual blisters are packed in a printed shelf-box. All packaging materials are hereby identified in the figures and table below:

Figure 2: Component Printed Shelf Box

The specifications of the system component printed shelf box are hereby provided in the table below:

Item	Material Specifications	Dimensions (mm)	Supplier
Shelf Pack	Top Layer: E-Flute with Laminated Coating Bottom Layer: Folded Carton – Duplex Gray Back	400x134x160 & 400x270x160	(b)(4) [redacted]

Shipper Box:

The printed shelf boxes are packed in shipper box. All packaging materials are hereby identified in the figures and table below:

Figure 3: Component Shipper Box

The specifications of the system component printed shelf box are hereby provided in the table below:

Item	Material Specifications	Dimensions (mm)	Supplier
Shelf Pack	(b)(4) [redacted]	410x285x171	(b)(4) [redacted]

The shelf life for the Equashield System was determined after completion of a real time aging study of 2 years.

Shelf Life Testing: (b)(4) [redacted]

life of 2 years in no way negatively affects the devices sterility, function, safety, effectiveness, or SE to the device in its post-sterile state nor to the predicate device.

(b)(4)

[redacted]

These components represent the Equashield System single unit packages for all parts which include the same packaging materials and process.

The shelf life of the device is 2 years.

The following attached studies were performed on the pouch real time aged at 2 years to validate the packaging shelf life:

Test Description	Results
(b)(4) [redacted]	

The Shelf Life study for the Equashield System included the following tests:

(b)(4)

[redacted]

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(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Thrid Party Testing

(b)(4) Thrid Party Testing

(b)(4) Thrid Party Testing

(b)(4) Thrid Party Testing

(b)(4) Thrid Party Testing

(b)(4) Thrid Party Testing

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PROTOCOL FOR SHELF-LIFE VALIDATION EQUASHIELD™ SYSTEM

TWO YEARS

Author: (b)(6) [redacted]

1. PROTOCOL APPROVALS

Department Manager	Name	Signature	Date
QA /RA Manager	(b)(6) [redacted]		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-5198

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Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Sterilization

This section includes:

- Sterilization Method
- Validation method
- SAL

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Sterilization

[redacted]

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

PROTOCOL FOR SHELF-LIFE VALIDATION EQUASHIELD™ SYSTEM

TWO YEARS

Author: (b)(6) [redacted]

1. PROTOCOL APPROVALS

Department Manager	Name	Signature	Date
QA /RA Manager	(b)(6) [redacted]		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-5198

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Biocompatibility

The following table contains a list of materials which indirectly contact patients through contact with liquids which travel through the device and then have patient contact. Biocompatibility assessments were performed on each of these materials to ensure that they are biocompatible for their intended duration of patient contact. The Equashield Closed System has no direct contact to the patient but it serves as a conduit for liquids which then have patient contact. Through fluid flow some materials have indirect contact for a limited duration that is less than 24 hours, they are listed in the table below. All materials are biocompatible and are in compliance with the ISO 10993-1:2009 and with the FDA Blue Book Memorandum G95-1. The biocompatibility tests and reports are provided in this application. All tests passed successfully and met predetermined acceptance criteria.

Table of Indirect Patient Contacting Materials
List of Parts and Materials – Reconstitution Tubing Accessory

Proposed Component Description (K150219)	*Proposed Device Material (K150219)*	*Predicate Device Material (K132899)*	*Predicate Component Description (K132899)*
(b)(4) [redacted]			

*See drawing specification below.

No new manufacturing materials were introduced.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Drawing Specifications

[redacted]

No new materials are being introduced, all materials were biocompatibility tested in (b)(4) [redacted]

Users of CSTD devices currently assemble Reconstitution Tubing sets in order to perform their daily tasks. This introduces potential delays in treatment depending on which components are readily available for construction of the reconstitution sets, may introduce contaminates into the system during assembly, and may produce Reconstitution Tubing sets which leak or do not provide microbial barrier.

On the request of users to provide a sterile, finished Reconstitution Tubing set which can prevent the need from constructing one potentially incorrectly, we are proposing this addition to the FDA cleared Equashield system.

Testing Completed

Test Category	Test Method	Protocol Number	Status	Report Number
(b)(4) [redacted]				

Please see biocompatibility study reports. Extracts used were (b)(4) [redacted] and (b)(4) [redacted] studies were not attempted with (b)(4) [redacted].

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Testing

[redacted]

Please see the following test reports:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

TOXIKON
ADVANCING YOUR INNOVATION

FINAL GLP REPORT: 13-01410-G1

L929 NEUTRAL RED UPTAKE CYTOTOXICITY TEST (4 CONCENTRATIONS) – ISO

Test Article
Finished Sterile Equashield System including extension set, reconstitution set, and y set as part of system.

21 CFR Part 58 Compliance
GLP for Nonclinical Laboratory Studies

Report Date
June 19, 2013

Study Director
Ryan Ross, B.S.

Sponsor
Equashield Medical Limited
Tefen Industrial Park
P.O. Box 12 24959
Israel

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Bench Testing Summary (b)(4) Testing [redacted]

(b)(4) Testing [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Performance Test (b)(4) Testing

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Bench Testing Summary (b)(4) Testing

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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[redacted] Test [redacted]

[redacted]

(b)(4) Testing

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(b)(4) Thrid Party Testing

(b)(4) Thrid Party Testing

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List of Parts in Reconstitution Tubing Set
which will be marketed in this submission

The products which will be marketed with this submission only include one, it is call the Reconstitution Set, and the model number is LL-1R. This tubing set does not require use with the Equashield system, it can be used independently and is a standalone device.

Name	***Model #***	***Description***	***Sizes***
Reconstitution Tubing	**LL-1R**	**Reconstitution Tubing Accessory**	NA

Below is a table describing each component of the Reconstitution Tubing set. The tubing set is made up from 510(k) cleared components.

Proposed Components	***Illustration Location (K150219)***	***Predicate Component Description (K132899)***
Connector	#1 Drawing	Syringe Unit (Outer Sleeve)
Air Needle	#1 Drawing	Syringe Unit (Air Needle)
T-Connector	#2 Drawing	Y-Tubing Set (Y-Connector)
Tubing	#3 Drawing	Y-Tubing Set (Tubing)
Spike for Bag	#3 Drawing	Spike Adapter (Body)
Check Valve	#4 Drawing	Spike Adapter (Body) / Y-Tubing Set (Y-Connector)
Dual Check Valve	#5 Drawing	Spike Adapter (Body)
Cap	#5 Drawing	Y-Tubing Set (Cap)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Drawings

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Premarket Notification 510(k) Statement
(As Required By 21 CFR 807.93)

I certify that, in my capacity as *Programs Manager of Equashield*, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(Signature of Certifier)

Dorit Valal
(Typed Name)

October 1, 2015
(Date)

K150219
*(Premarket Notification [510(k)] Number)
*For a new submission, leave the 510(k) number blank.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Premarket Notification 510(k) Statement
(As Required By 21 CFR 807.93)

I certify that, in my capacity as *Programs Manager of Equashield*, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

_____
(Signature of Certifier)

Dorit Valal
(Typed Name)

October 1, 2015
(Date)

K150219
*(Premarket Notification [510(k)] Number)
*For a new submission, leave the 510(k) number blank.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Tuesday, October 13, 2015 4:46 PM
To: Patel, Sapana
Cc: 'Dorit Valal'; 'Marino Kriheli'
Subject: RE: Biocompatibility deficiency K150219

Ms. Patel,

Please see the attached (b)(4) which describes and references the (b)(4)

(b)(4)

Please let us know if FDA has additional questions during the review.

Regards,

Ray

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Tuesday, October 13, 2015 3:58 PM
To: Raymond Kelly <ray.k@arazygroup.com>
Subject: Biocompatibility deficiency K150219

Mr. Kelly,

The biocompatibility expert has the following deficiency regarding your responses. Please provide a response by COB Monday, 10/19/2015. If you have any additional questions please do not hesitate to contact me.

(b)(4)

Thank you,

Sapana Patel. PharmD.

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
F: 301-847-8109
Sapana.patel@fda.hhs.gov

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From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Thursday, March 12, 2015 1:48 PM
To: Patel, Sapana
Subject: K150219 - Biocompatibility 2 of 4

Hi Sapana,

Please see attached (b) (4) [redacted] section.

Please let me know if you have any other questions.

Thank you,

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
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Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
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From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Thursday, March 12, 2015 1:49 PM
To: Patel, Sapana
Subject: FW: K150219 - Device Description 3 of 4

Hi Sapana,

Attached is the (b)(4) [redacted].

Thank you,

Ray

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Friday, March 06, 2015 9:00 PM
To: Raymond Kelly
Subject: K150219

Ray

Please review the components that are missing for review of the 510(k). If you can provide all necessary documents by

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3/13/2015 that would be appreciated. I will work with you on that time line as well and you can provide documents as you receive them.

If you can provide a detailed list of (b)(4) [redacted] that will be marketed with this submission.

Sterility:

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Please let me know if you have any other questions.

Thank you,

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

F: 301-847-8109
Sapana.patel@fda.hhs.gov

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Sapana Patel. PharmD.
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From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Thursday, March 12, 2015 1:47 PM
To: Patel, Sapana
Subject: K150219 - Performance Testing 1 of 4

Hi Sapana,

Attached is the bench testing section for the proposed (b)(4) [redacted]

I will send 4 emails, this is 1 of 4.

Thanks,

Ray

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Please let me know if you have any other questions.

Thank you,

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
F: 301-847-8109
Sapana.patel@fda.hhs.gov

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Sapana Patel. PharmD.
Pharmacist
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From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Thursday, March 12, 2015 1:49 PM
To: Patel, Sapana
Subject: FW: K150219 - Sterility and Shelf Life 4 of 4

Hi Sapana,

(b)(4)

[redacted]

Sterility:

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I will send other requests for AI in separate emails so it does not become confusing.

Thank you for your considerations in this matter.

Ray Kelly

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Monday, March 09, 2015 7:21 AM
To: Raymond Kelly
Subject: RE: K150219

You can send all documents directly to me via email by 3/15/2015 and I will include them in your file. You can send them as you receive them or all at the same time.

Thank you.

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Wednesday, March 25, 2015 2:57 PM
To: Patel, Sapana
Subject: RE: K150219

Hi Sapana,

(b)(4) Deficiencies

[redacted]

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Wednesday, March 25, 2015 2:02 PM
To: Raymond Kelly
Subject: RE: K150219

Just to clarify, my understanding was (b)(4) Deficiencies [redacted].

(b)(4) Deficiencies [redacted] are added.

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
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From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Wednesday, March 25, 2015 1:59 PM
To: Patel, Sapana
Subject: RE: K150219

Hi Sapana,

(b)(4) Deficiencies [redacted].

Thanks,

Ray

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Wednesday, March 25, 2015 1:38 PM
To: Raymond Kelly
Subject: RE: K150219

(b)(4) Deficiencies [redacted]

Thanks

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
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From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Wednesday, March 25, 2015 9:58 AM
To: Patel, Sapana
Subject: RE: K150219

Hi, yes, please see sponsor response below:

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Wednesday, March 25, 2015 9:41 AM
To: Raymond Kelly
Subject: RE: K150219

Mr. Kelly,

(b)(4) Deficiencies [redacted]

Thank you

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Wednesday, March 25, 2015 8:56 AM
To: Patel, Sapana
Subject: RE: K150219

Hi Sapana,

Please see the sponsor provided attached table for clarification.

Thanks,

Ray

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Friday, March 20, 2015 12:31 PM
To: Raymond Kelly
Subject: K150219

Mr. Kelly,

(b)(4) Deficiencies [redacted]

Thank you. If you can provide that by next Wednesday that is appreciated.

Thanks

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
F: 301-847-8109
Sapana.patel@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Wednesday, March 25, 2015 11:08 AM
To: Patel, Sapana
Subject: RE: K150219

(b)(4) Deficiencies [redacted].

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Wednesday, March 25, 2015 10:41 AM
To: Raymond Kelly
Subject: K150219

Mr. Kelly, I just want to clarify (b)(4) Deficiencies [redacted]

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
F: 301-847-8109
Sapana.patel@fda.hhs.gov

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Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

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)*
K150219

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)*

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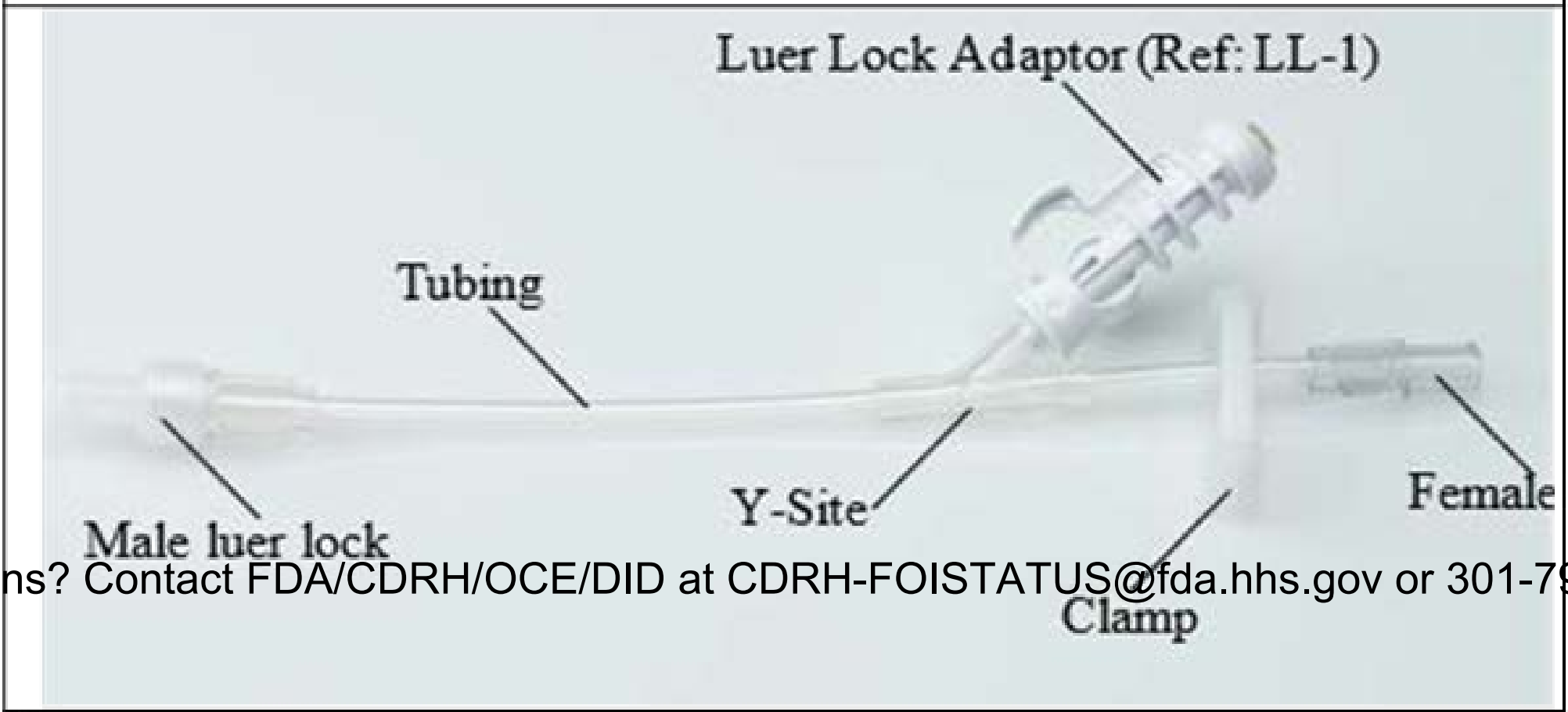

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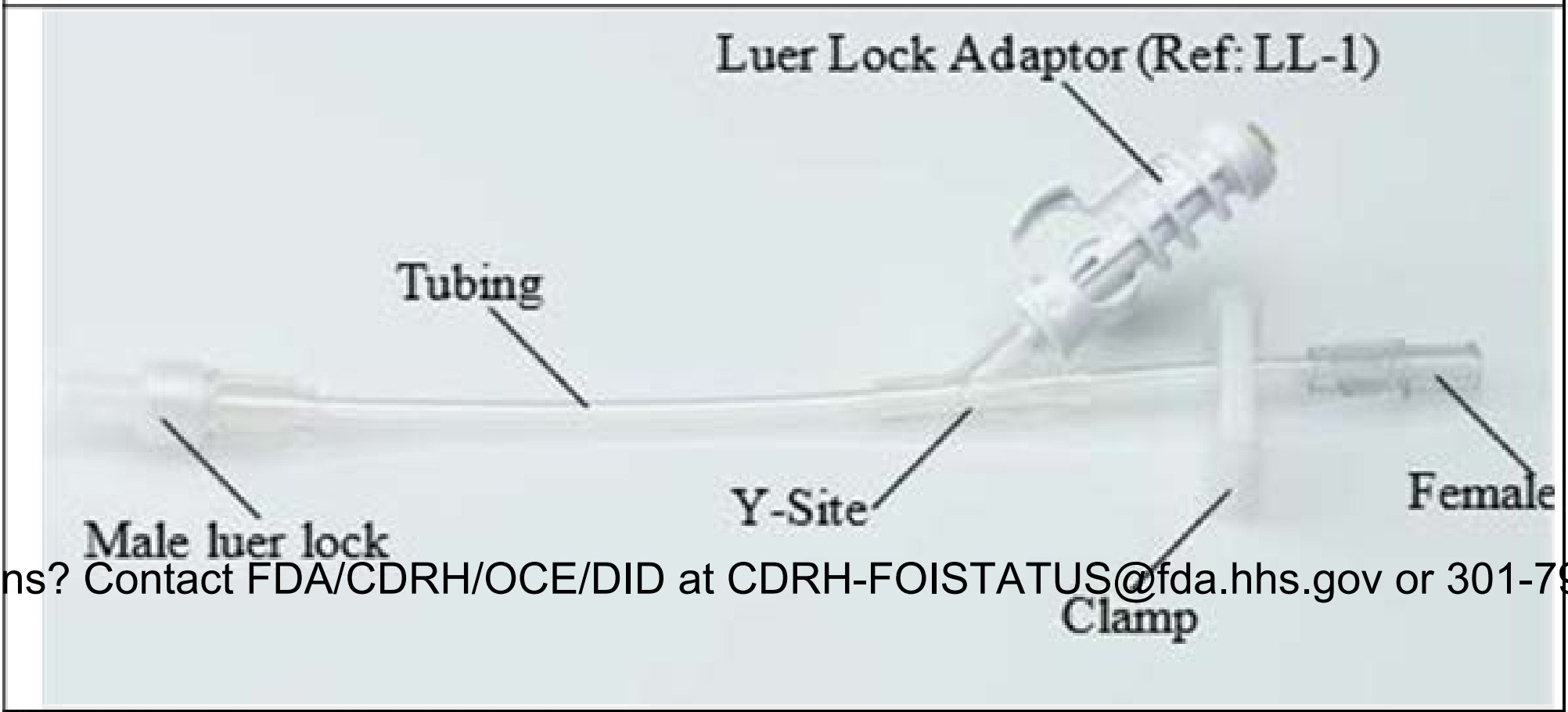

ns? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-79

13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.		☒		
b) Submission includes a description (as detailed in item 11(e) and (f) and 12 above) of each component or accessory.		☒		
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.		☒		

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uest # 2016-388
ID at CDRH-FOI

F. Shelf Life

26) Proposed shelf life/expiration date stated	☒			
27) For sterile devices, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.		☒		
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.		☒		

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G. Biocompatibility

If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
☒ are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
☐ are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
☐ Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	☒	☐		☐
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	☒	☐		☐
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria and results provided for each completed test, or a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).		☒		

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G. Biocompatibility

If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
☒ are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
☐ are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
☐ Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
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30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	☒	☐		☐
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria and results provided for each completed test, or a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).		☒		

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J. Performance Data - General If IVD device, select 'N/A' and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.		☒		
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			☒	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.		☒		
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or use alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			☒	

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37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			☒	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.		☒		
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or use alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			☒	

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Sapana Patel. PharmD.
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General Hospital Devices Branch
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From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Tuesday, October 13, 2015 2:04 PM
To: Patel, Sapana
Subject: RE: K150219

Hi Ms. Patel,

(b)(4) Deficiencies [redacted]

Thanks,

Ray

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Tuesday, October 13, 2015 10:09 AM
To: Raymond Kelly <ray.k@arazygroup.com>
Subject: K150219

Mr. Kelly,

(b)(4) Deficiencies [redacted]

October 16th, 2015. Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Thank you

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
F: 301-847-8109
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Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
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From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Friday, October 09, 2015 12:41 PM
To: Patel, Sapana
Cc: 'Marino Kriheli'; 'Dorit Valal'
Subject: RE: K150219

Dear Ms. Patel,

Please accept the attached (b)(4) [redacted]

Please let me know if FDA requires additional information.

Thank you,

Ray

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Friday, October 09, 2015 12:07 PM
To: Raymond Kelly <ray.k@arazygroup.com>
Subject: FW: K150219

Mr. Kelly thank you for providing (b)(4) Deficiencies [redacted].

Released under FOIA Request # 2016-388, Released by CDRH on 04-18-2016

FDA recommends (b)(4) Deficiencies [redacted]

Please refer to ISO 15223-1:2010 for symbols the Agency recognizes.

Thank you

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
F: 301-847-8109
Sapana.patel@fda.hhs.gov

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From: Raymond Kelly [mailto:ray.k@arazygroup.com]
Sent: Thursday, October 01, 2015 6:02 AM
To: Patel, Sapana
Subject: RE: K150219

Hi Ms. Patel,

We sent you the 510((b)(4) Deficiencies [redacted]

(b)(4) [redacted]
D fi i i

Thank you,

Ray Kelly

From: Patel, Sapana [mailto:Sapana.Patel@fda.hhs.gov]
Sent: Wednesday, September 30, 2015 2:33 PM
To: Raymond Kelly <ray.k@arazygroup.com>

Subject: K150219 Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Good Afternoon Mr. Kelly,

(b)(4) Deficiencies [redacted]

It is appreciated if the information can be provided by Monday 10/5/2015.

Thank you.

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
F: 301-847-8109
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K150219 Trade Name	K150219 Supplier Name	K150219 Supplier Trade Name	K132899 Trade Name	Supplier Name	Supplier Trade Name	Differences
Equashield Connector	(b)(4) [redacted]		Equashield Syringe Unit Outer Sleeve	(b)(4) [redacted]		Identical
Equashield Liquid Needle			Equashield Syringe Unit Liquid Needle			Identical
Equashield Air Needle			Equashield Syringe Unit Air Needle			Identical
Equashield T-Connector			Equashield Y-Tubing Set Y-Connector			(b)(4) [redacted]
Equashield Tubing			Equashield Y-Tubing Set Tubing			Identical
Equashield Spike for Bag			Equashield Spike Adapter Body			(b)(4) [redacted]
Equashield Check Valve			Equashield Spike Adapter Body and Y-Tubing Set Y-Connector			
Equashield Dual Check Valve			Equashield Y-Tubing Set Y-Connector			
Equashield Cap			Equashield Y-Tubing Set Cap			Identical

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

Premarket Notification 510(k) Statement
(As Required By 21 CFR 807.93)

I certify that, in my capacity as *Programs Manager of Equashield*, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(Signature of Certifier)

Dorit Valal
(Typed Name)

October 1, 2015
(Date)

K150219
*(Premarket Notification [510(k)] Number)
*For a new submission, leave the 510(k) number blank.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

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)*
K150219

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
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Device Name

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Indications for Use *(Describe)*

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

November 5, 2015

Equashield Medical Ltd
c/o Mr. Raymond Kelly IV
Licensale Inc.
57 Lazy Brook Rd.
Monroe, Connecticut 06468

Re: K150219
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: September 25, 2015
Received: September 29, 2015

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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" (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 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,

Tina Kiang
-S

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

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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)*
K150219

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

K150219
Equashield Medical Ltd
Equashield Closed System Drug Transfer Device (cstd)

Mr. Kelly,

We have begun the review of the 510(k) submission for the Equashield Closed System Drug Transfer Device (CSTD). It cannot be determined if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information. Your submission is considered to be "on hold" pending formal responses to these questions to the CDRH Document Management Center.

(b)(4) Deficiencies

[redacted]

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(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

(b)(4) Deficiencies

[redacted]

_____

Sapana Patel, PharmD.
Pharmacist
General Hospital Devices Branch
Division of Anesthesiology, General Hospital, Respiratory,
Infection Control, & Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
P: 240-402-4968
E: Sapana.patel@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Thrid Party Testing

(b)(4) Thrid Party Testing

(b)(4) Thrid Party Testing

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(b)(4) Thrid Party Testing

(b)(4) Thrid Party Testing

From: Panguluri, Ramesh K
To: Patel, Sapana
Cc: Murray III, Clarence; Qian, Bifeng; Gutala, Sreekanth
Subject: RE: K150219/S001 (CON155288)
Date: Tuesday, March 31, 2015 3:19:50 PM

Sapana,

(b)(4) Deficiencies

[redacted]

Thanks

Kapil

From: Patel, Sapana
Sent: Tuesday, March 31, 2015 10:38 AM
To: Panguluri, Ramesh K
Cc: Murray III, Clarence; Qian, Bifeng; Gutala, Sreekanth
Subject: RE: K150219/S001 (CON155288)

Thank you Ramesh for getting back to me. Can you please provide me a deficiency in the correct format so I can include it when I put the file on hold. An email will be sufficient.

Sapana Patel. PharmD.
Pharmacist
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices & Radiological Health
FDA
WO-66 Rm 2562
P: 240-402-4968
F: 301-847-8109
Sapana.patel@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E

From: Panguluri, Ramesh K
Sent: Tuesday, March 31, 2015 10:15 AM
To: Patel, Sapana
Cc: Murray III, Clarence; Qian, Bifeng; Gutala, Sreekanth
Subject: RE: K150219/S001 (CON155288)

Sapana,

(b)(4) Deficiencies [redacted]

Thanks

Kapil Panguluri, PhD

From: Patel, Sapana
Sent: Monday, March 30, 2015 10:04 PM
To: Panguluri, Ramesh K
Cc: Murray III, Clarence; Qian, Bifeng; Gutala, Sreekanth
Subject: RE: K150219/S001 (CON155288)

Ramesh,

This submission was converted to a traditional as stated in CTS which is why a consult was assigned. I had also emailed all pertinent information to all consultants when the consults were assigned by Clarence. Due to this being a new product code and claims in the intended use (b)(4) [redacted] (b)(4) [redacted] was the reason for the consult. I am approaching my SI date and would appreciate if this can be reviewed. I will resend the additional information that was submitted by the sponsor to you when it was converted.

Thanks

Sapana Patel. PharmD.
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General Hospital Devices Branch
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https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E

From: Panguluri, Ramesh K
Sent: Monday, March 30, 2015 4:10 PM
To: Patel, Sapana
Cc: Murray III, Clarence; Qian, Bifeng; Gutala, Sreekanth
Subject: K150219/S001 (CON155288)

Hi Sapana,

(b)(4) Deficiencies

[redacted]

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Thanks

Kapil Panguluri, PhD

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-388; Released by CDRH on 04-18-2016

EQUASHIELD®

Closed System for Drug Transfer.

Reconstitution Tubing **REF: LL-1R**

Single Use Only

Do not use if package is damaged

Do Not Re-sterilize

Consult Instructions For Use

Rx Only

Gravity feed only

Freefrom Pyrogens

This device is to be used by or on the instruction of a physician or a licensed practitioner

EQUASHIELD Medical Ltd. POB 12, Tefen Industrial Park 24959, Israel

LOT:XX-XXXXX
EXP:XX/XXXX

PEEL ▶ OPEN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records released Under FOIA Request #2016-385; Released by CDRH on 04-28-2016

Equashield Closed System drug Transfer Device (CSTD) IFU

Instructions for Use

Precautions:

- This device should only be used under the supervision of a Pharmacist or Health Care Professional and after having read these instructions carefully!
- CAUTION: U.S. law restricts this device to sale by or on the order of a Pharmacist or Health Care Professional
- This device is not intended to be used with blood or blood products.
- Not to be used with high-pressure infusion systems.
- Prevention of microbial ingress has been substantiated to a time period of 7 days. Equashield does not extend the sterility and use date of the drug beyond manufacturer recommendations. Please refer to individual drug labeling or USP compounding guidelines for beyond use dating of a drug.
- Multiple reconnection of components has been substantiated up to 10 times.
- Caution this device contains components made from ABS and polycarbonate and is not intended to be used with drugs containing DMA in concentrations greater than 33%.
- Caution: "This device is not intended to be a substitute for drug reconstitution which requires ISO class 5 environment admixing or the use of a Biological Safety Cabinet (BSC) or laminar flow hood".

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.

Symbols:

	Do not re-use (single use)		Do not re-sterilize
	Expiration date		Do not use if package is damaged
LOT	Lot Number		Dispose of used materials safely, according to your local regulations
REF	Catalog Number		Consult Instructions for use
STERILE EO	Sterilized using ethylene oxide		The device is not made with DEHP
	Manufacturer		The device is not made with natural rubber latex

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records released Under FOIA Request #2016-385; Released by CDRH on 04-28-2016

Equashield Closed System drug Transfer Device (CSTD) IFU

Device Description: Equashield is not an IV Administration Set, it 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 plasticizers or 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.

Shelf Life: This device has a shelf life of 2 years from the manufacturing date. Please ensure the Expiration Date on the product label has not been exceeded before using this product.

Components:
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 1), 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:
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.

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.

Reconstitution Tubing –consists of a T connector permanently attached to a conical connector. The tubing is very similar to the Y-Connector Tubing which extends from the main IV bag through a check valve, in a similar manner the other end of the T travels from the pressure equalization bag through a check valve into the T-connector. Just like the Y-Tubing splits two fluid paths the Reconstitution Tubing also splits two fluid paths.

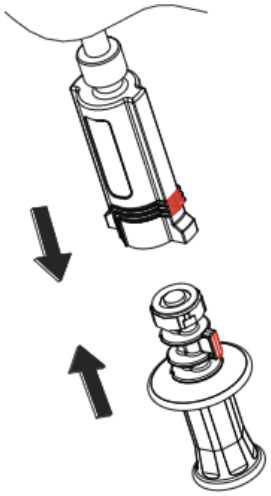
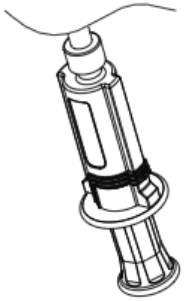
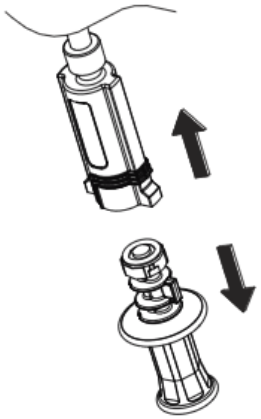
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records released Under FOIA Request #2016-387; Released by CDRH on 04-28-2016

Equashield Closed System drug Transfer Device (CSTD)
IFU

Directions for Use:

Protective Plug REF: PP-1	
 Closed System Plug for additional mechanical protection for EQUASHIELD's connectors.	 EQUASHIELD Closed System Connector.

Connection of the Protective Plug	1  Align the red orientation marks and slide the Protective Plug into any EQUASHIELD connector.	2  Done.	3  Pull to disconnect.

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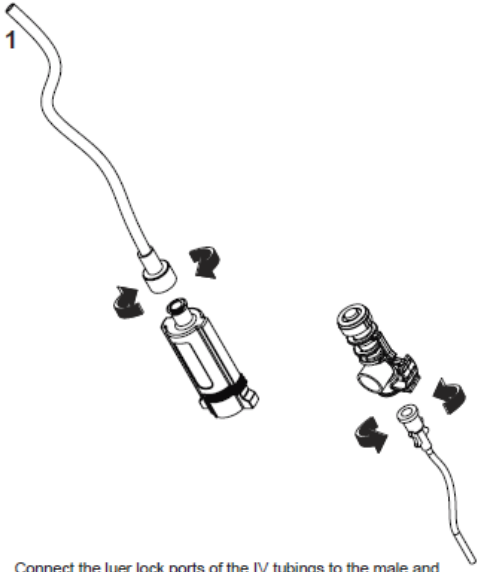
Equashield Closed System drug Transfer Device (CSTD)

IFU

Female Luer Lock Connector	Male Luer Lock Connector	Luer Lock Adaptor
REF: FC-1	REF: MC-1	REF: LL-1
Closed System female Connector for connection of two IV tubing segments.	Closed System male Connector for connection of two IV tubing segments.	Closed system Adaptor for connection of two IV tubing set segments or for injection into Luer Lock port.

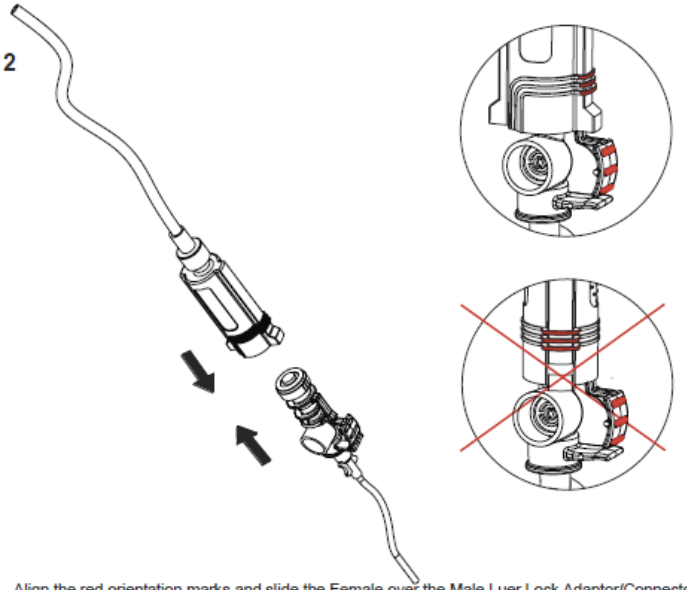
Connection of two IV tubing segments

1



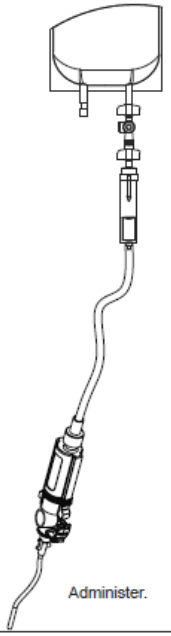
Connect the luer lock ports of the IV tubings to the male and Female Luer Lock Connectors respectively.

2



Align the red orientation marks and slide the Female over the Male Luer Lock Adaptor/Connector. **Do not twist or rotate during or after connection.**

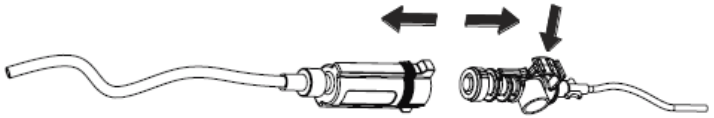
3



Administer.

4

Push the lever to disconnect.



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Equashield Closed System drug Transfer Device (CSTD)

IFU

Syringe Unit	Vial Adaptor	Spike Adaptor	Spike Adaptor-W	Luer Lock Adaptor
REF: SU-3; SU-5; SU-10; SU-20; SU-30; SU-35; SU-60;	REF: VA-13; VA-20; VA-20C; VA-28;	REF: SA-1;	REF: SA-W	REF: LL-1
Closed system Syringe Unit for drug transfer.	Vial Adaptor for closed system vial access.	Closed system Spike Adaptor for injection into infusion bag and for infusion administration.	Spike Adaptor for Withdrawal of diluent from a bag.	Closed system Adaptor for injection into Luer Lock port.

Transfer from vial to Syringe Unit

1. Click the Vial Adaptor on the vial and remove the protective cap.
2. Align the red orientation marks and slide the Syringe Unit over the adaptor. **Do not twist or rotate during or after connection.**
3. Invert and withdraw the liquid. **Never inject into the vial when in upside down position.**
4. Pull the Syringe Unit from the Vial Adaptor.

Drug reconstitution and transfer

1. Click Vial Adaptor on the vial and remove the protective cap.
2. Align the red orientation marks and slide the Syringe Unit pre-filled with diluent over the adaptor. **Do not twist or rotate during or after the connection.**
3. Inject the diluent into the vial.
4. Invert and withdraw the diluted drug. **Never inject into the vial in upside down position.**
5. Pull the Syringe Unit from the Vial Adaptor.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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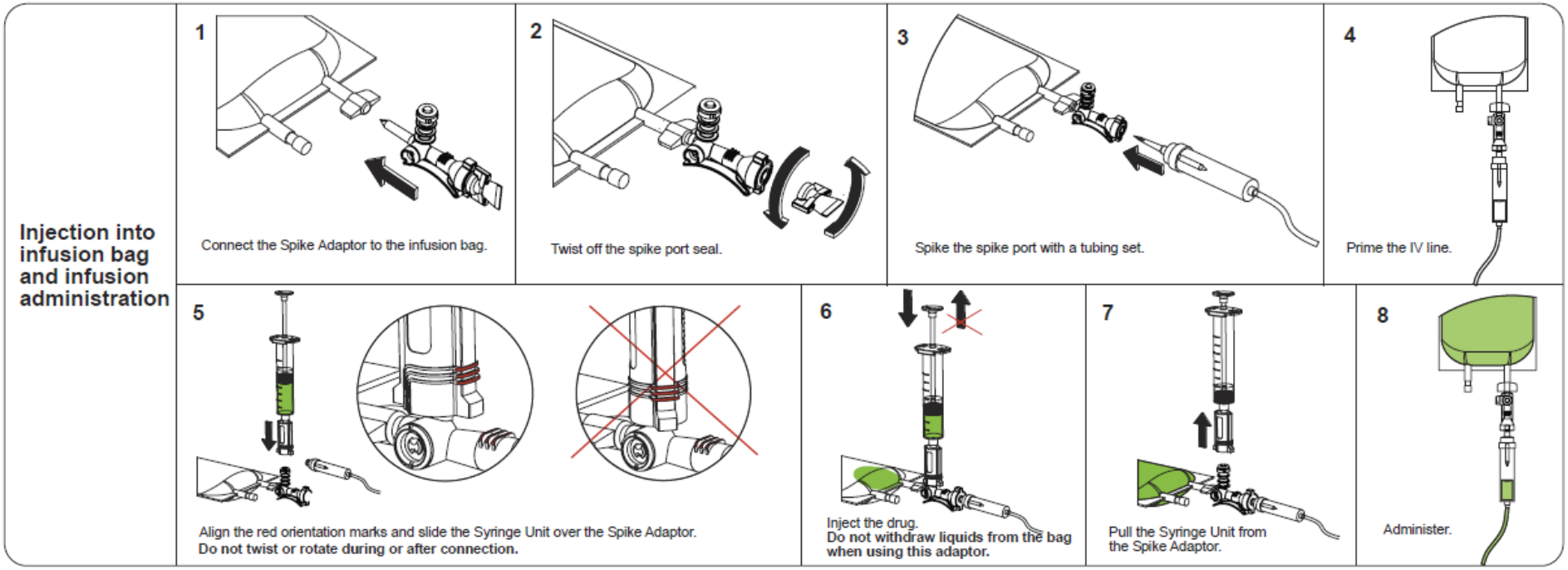
Equashield Closed System drug Transfer Device (CSTD) IFU



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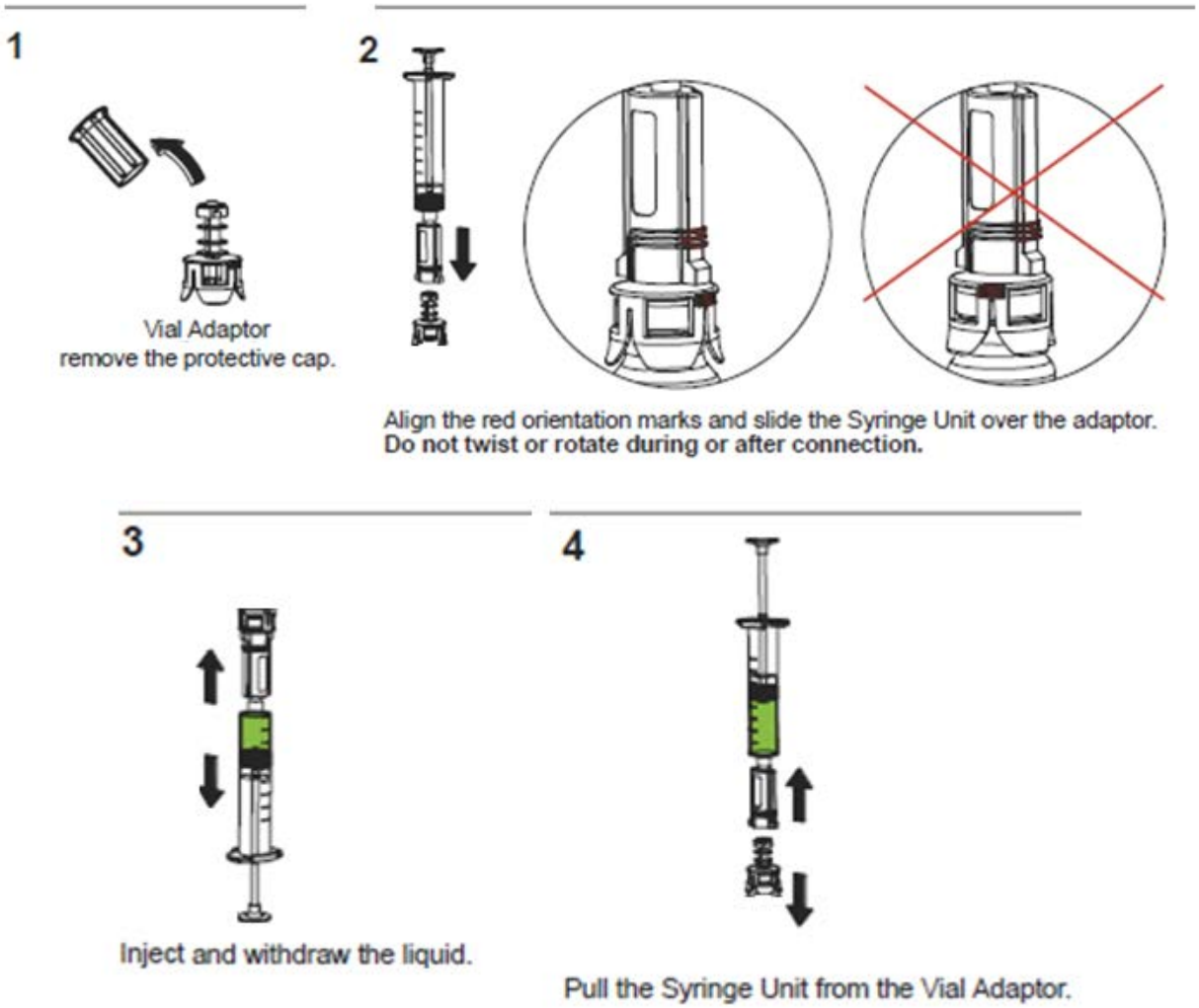
Equashield Closed System drug Transfer Device (CSTD) IFU

Instructions for Use of Vial Adaptor:



Reconstitution Set intended to be used for reconstituting Powdered Drugs. Directions for Using Reconstitution Tubing on Next page.

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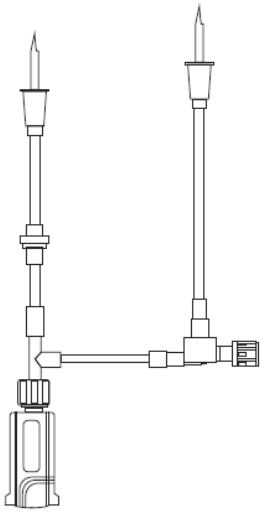
Equashield Closed System drug Transfer Device (CSTD) IFU

Reconstitution Tubing

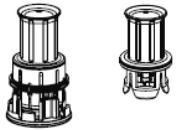
REF: LL-1R

Tubing set for closed system reconstitution of drugs in their vials.



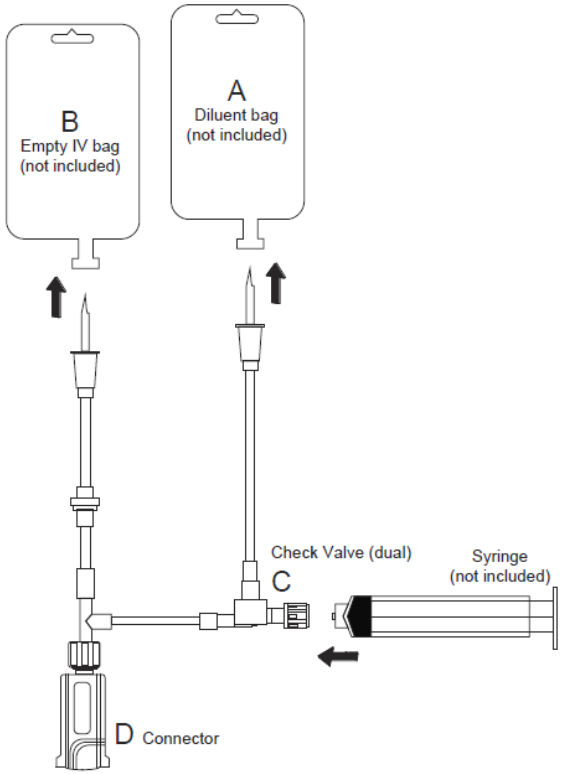
Vial Adaptor

REF: VA-13/2; VA-20/2; VA-20C/2; VA-28/2; VA-13; VA-20; VA-20C; VA-28;



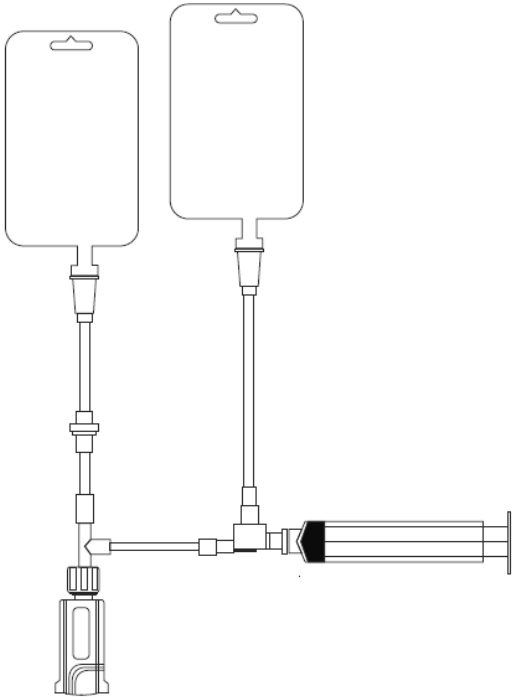
Vial Adaptor for closed system vial access.
The special Vial Adaptor VA-20C shall only be used with extra thick vial rubber stoppers.

1



Spike the diluent bag (A) by the liquid path. Spike the empty IV bag (B) by the second spike. This will be used to capture air to equalize pressure and collect waste diluent. Connect any standard luer lock syringe to the Check Valve's luer lock port (C). This syringe can be used in next steps to prime the set.

2



Hang or place the diluent bag (A) higher than rest of the system components. The bag (B) can be placed anywhere.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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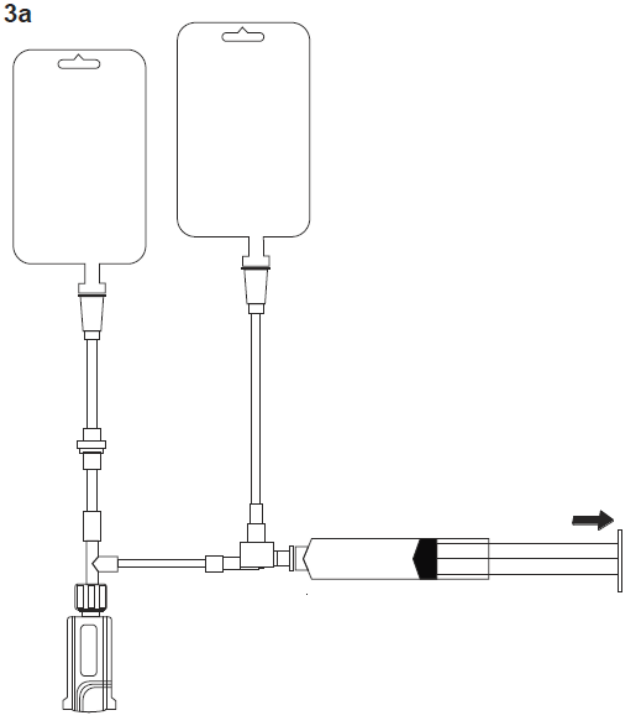
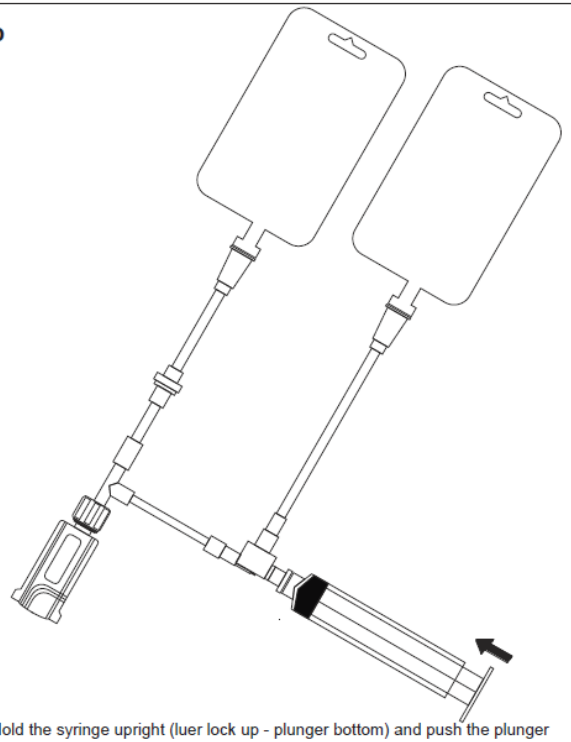
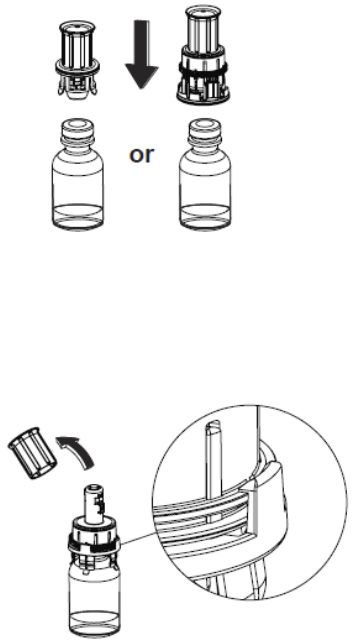
Equashield Closed System drug Transfer Device (CSTD) IFU

3a	3b	4
		
Prime the tubing set by drawing at least 15 ml of diluent from the diluent bag into the syringe by pulling the syringe plunger.	Hold the syringe upright (luer lock up - plunger bottom) and push the plunger until syringe is empty. The Dual Check valve (C) ensures that this action pushes the air bubbles from the syringe and primes the whole set. In this step diluent flows only into the empty bag (B) and nothing into bag (a).	Click the Vial Adaptor firmly onto the drug vial and ensure snapping of all 4 locking elements. Remove the protective cap. Disinfect the access port septum before each repeated connection by wiping the septum over a minimum period of 5 seconds with a sterile 70% isopropyl alcohol prep pad.

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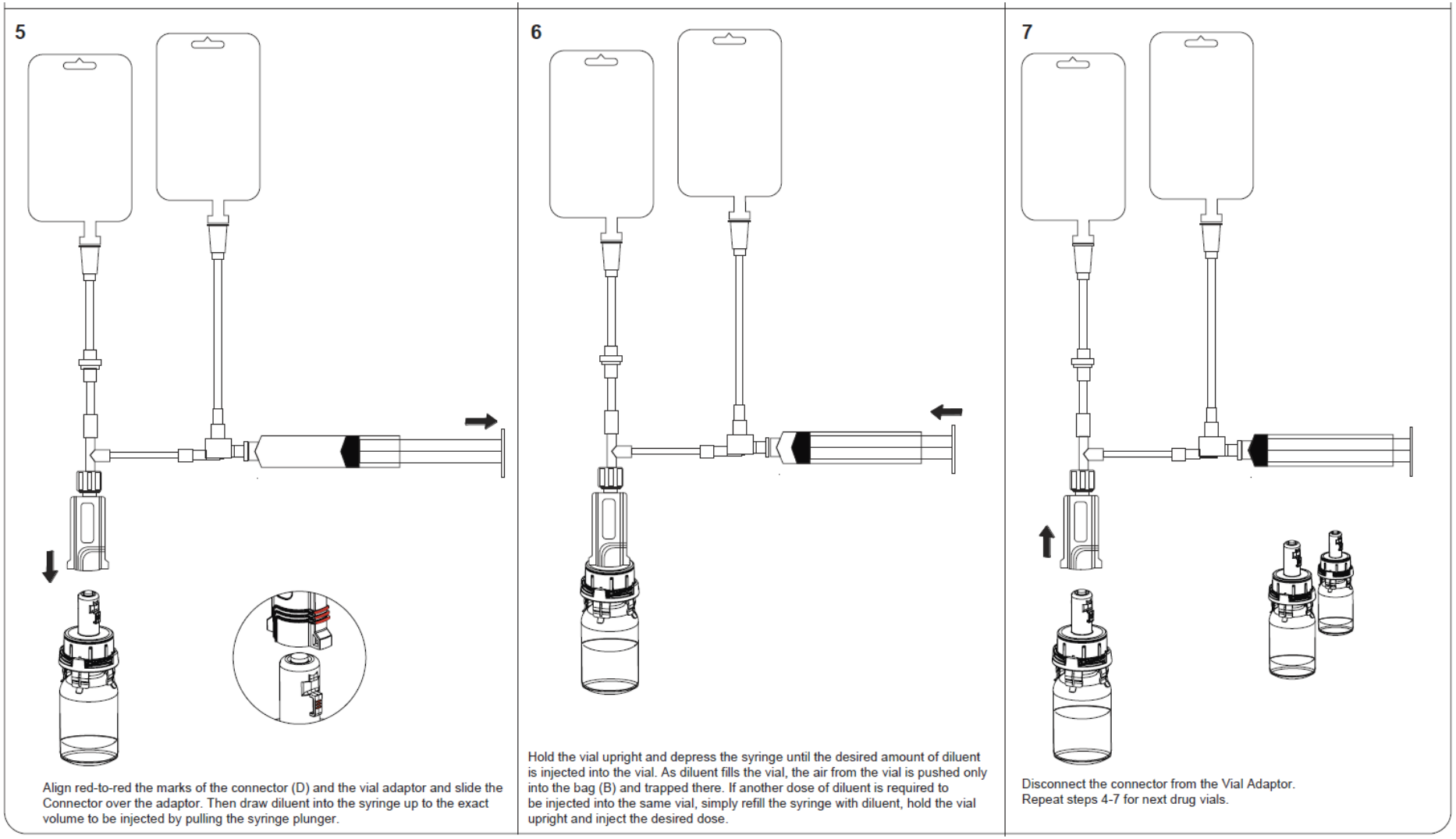
Equashield Closed System drug Transfer Device (CSTD) IFU



Align red-to-red the marks of the connector (D) and the vial adaptor and slide the Connector over the adaptor. Then draw diluent into the syringe up to the exact volume to be injected by pulling the syringe plunger.

Hold the vial upright and depress the syringe until the desired amount of diluent is injected into the vial. As diluent fills the vial, the air from the vial is pushed only into the bag (B) and trapped there. If another dose of diluent is required to be injected into the same vial, simply refill the syringe with diluent, hold the vial upright and inject the desired dose.

Disconnect the connector from the Vial Adaptor. Repeat steps 4-7 for next drug vials.

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Equashield Closed System drug Transfer Device (CSTD) IFU

Ordering and Catalogue Information Chart:

Name	***Model #***	***Description***	***Sizes***
Vial Adaptor	VA-13 VA-13/2 VA-20 VA-20/2 VA-20C VA-20C/2 VA-28 VA-28/2	Adaptor to the medication vial	13mm, 20mm, 28mm vial neck sizes
Syringe Unit	SU-1 SU-1/2 SU-3 SU-3/2 SU-5 SU-5/2 SU-10 SU-10/2 SU-20 SU-20/2 SU-30 SU-30/2 SU-35 SU-35/2 SU-60 SU-60/2 SU-EZ60 SU-EZ60/2	Piston syringe	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 35ml, 60ml
Spike Adaptor	SA-1	Adaptor to inject into the infusion bag	Single size
	SA-W	Adaptor withdraw from infusion bag	
Luer Lock Adaptor	LL-1	Adaptor to a female luer lock port	
Male Luer Lock Connector	MC-1	Adaptor to female luer lock port of an IV tubing	
Female Luer Lock connector	FC-1	Adaptor to male luer lock port	
Protective Plug	PP-1	Plug that protects against foreign objects openings during transport	
Y-Site Tubing	LL-1Y	Luer Lock Adaptor with Y-Site Tubing	
Secondary Tubing	SA-1S	Spike Adaptor-1 with Secondary Tubing Accessory and a drip chamber	
Reconstitution Tubing	LL-1R	For reconstitution	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records released Under FOIA Request #2016-385; Released by CDRH on 04-28-2016

Equashield Closed System drug Transfer Device (CSTD) IFU

Instructions for Use

Precautions:

- This device should only be used under the supervision of a Pharmacist or Health Care Professional and after having read these instructions carefully!
- CAUTION: U.S. law restricts this device to sale by or on the order of a Pharmacist or Health Care Professional
- This device is not intended to be used with blood or blood products.
- Not to be used with high-pressure infusion systems.
- Prevention of microbial ingress has been substantiated to a time period of 7 days. Equashield does not extend the sterility and use date of the drug beyond manufacturer recommendations. Please refer to individual drug labeling or USP compounding guidelines for beyond use dating of a drug.
- Multiple reconnection of components has been substantiated up to 10 times.
- Caution this device contains components made from ABS and polycarbonate and is not intended to be used with drugs containing DMA in concentrations greater than 33%.
- Caution: "This device is not intended to be a substitute for drug reconstitution which requires ISO class 5 environment admixing or the use of a Biological Safety Cabinet (BSC) or laminar flow hood".
- Caution: When using the reconstitution set, the standard syringe is not to be disconnected and reconnected during the reconstitution of multiple vials.

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.

Symbols:

	Do not re-use (single use)		Do not re-sterilize
	Expiration date		Do not use if package is damaged
LOT	Lot Number		Dispose of used materials safely, according to your local regulations
REF	Catalog Number		Consult Instructions for use
STERILE EO	Sterilized using ethylene oxide		The device is not made with DEHP
	Manufacturer		The device is not made with natural rubber latex

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Equashield Closed System drug Transfer Device (CSTD) IFU

Device Description: Equashield is not an IV Administration Set, it 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 plasticizers or 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.

Shelf Life: This device has a shelf life of 2 years from the manufacturing date. Please ensure the Expiration Date on the product label has not been exceeded before using this product.

Components:
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 1), 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:
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.

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.

Reconstitution Tubing –consists of a T connector permanently attached to a conical connector. The tubing is very similar to the Y-Connector Tubing which extends from the main IV bag through a check valve, in a similar manner the other end of the T travels from the pressure equalization bag through a check valve into the T-connector. Just like the Y-Tubing splits two fluid paths the Reconstitution Tubing also splits two fluid paths.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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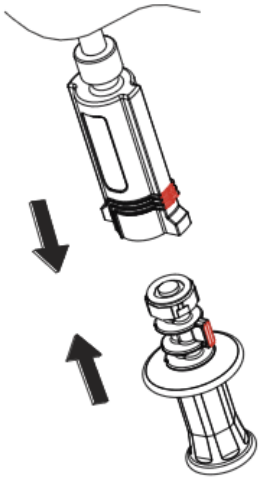
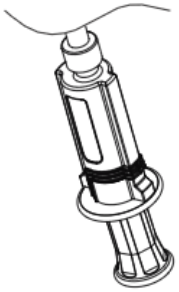
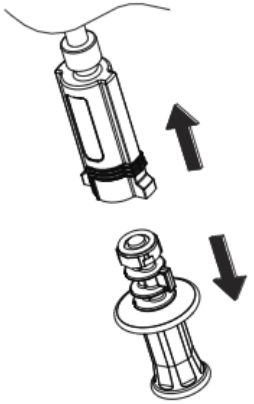
Equashield Closed System drug Transfer Device (CSTD) IFU

Directions for Use:

Protective Plug REF: PP-1	
Closed System Plug for additional mechanical protection for EQUASHIELD's connectors.	EQUASHIELD Closed System Connector.

Connection of the Protective Plug	1  Align the red orientation marks and slide the Protective Plug into any EQUASHIELD connector.	2  Done.	3  Pull to disconnect.

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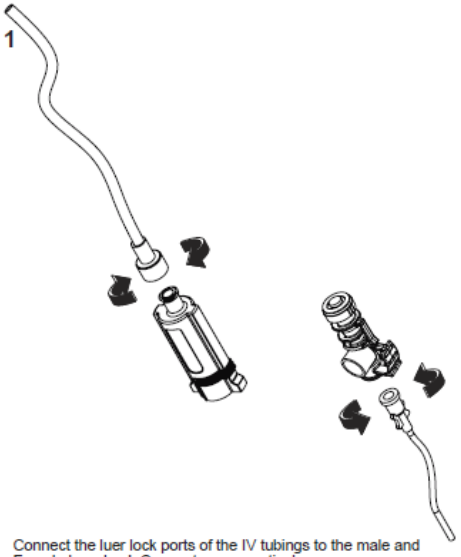
Equashield Closed System drug Transfer Device (CSTD)

IFU

Female Luer Lock Connector	Male Luer Lock Connector	Luer Lock Adaptor
REF: FC-1	REF: MC-1	REF: LL-1
Closed System female Connector for connection of two IV tubing segments.	Closed System male Connector for connection of two IV tubing segments.	Closed system Adaptor for connection of two IV tubing set segments or for injection into Luer Lock port.

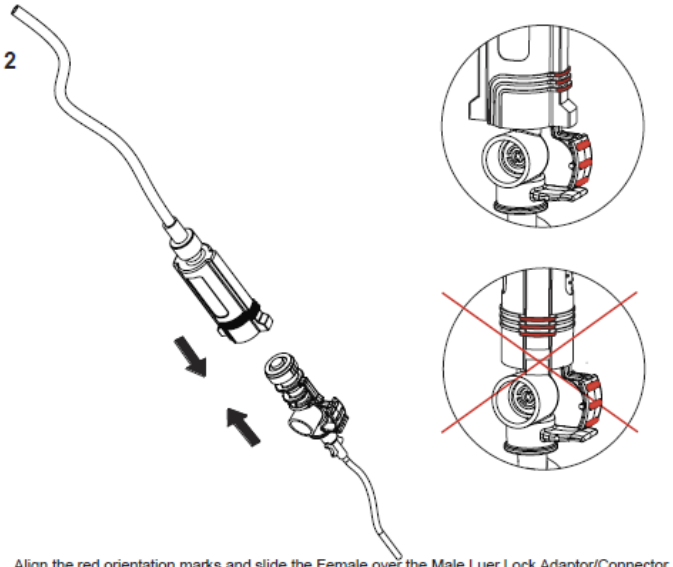
Connection of two IV tubing segments

1



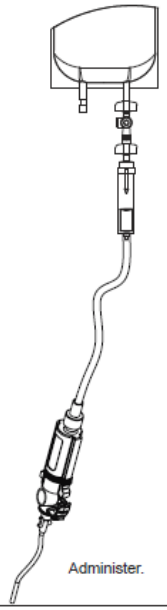
Connect the luer lock ports of the IV tubings to the male and Female Luer Lock Connectors respectively.

2



Align the red orientation marks and slide the Female over the Male Luer Lock Adaptor/Connector. **Do not twist or rotate during or after connection.**

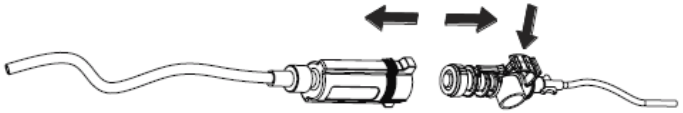
3



Administer.

4

Push the lever to disconnect.



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Equashield Closed System drug Transfer Device (CSTD)

IFU

Syringe Unit	Vial Adaptor	Spike Adaptor	Spike Adaptor-W	Luer Lock Adaptor
REF: SU-3; SU-5; SU-10; SU-20; SU-30; SU-35; SU-60;	REF: VA-13; VA-20; VA-20C; VA-28;	REF: SA-1;	REF: SA-W	REF: LL-1
Closed system Syringe Unit for drug transfer.	Vial Adaptor for closed system vial access.	Closed system Spike Adaptor for injection into infusion bag and for infusion administration.	Spike Adaptor for Withdrawal of diluent from a bag.	Closed system Adaptor for injection into Luer Lock port.

Transfer from vial to Syringe Unit

1. Click the Vial Adaptor on the vial and remove the protective cap.
2. Align the red orientation marks and slide the Syringe Unit over the adaptor. **Do not twist or rotate during or after connection.**
3. Invert and withdraw the liquid. **Never inject into the vial when in upside down position.**
4. Pull the Syringe Unit from the Vial Adaptor.

Drug reconstitution and transfer

1. Click Vial Adaptor on the vial and remove the protective cap.
2. Align the red orientation marks and slide the Syringe Unit pre-filled with diluent over the adaptor. **Do not twist or rotate during or after the connection.**
3. Inject the diluent into the vial.
4. Invert and withdraw the diluted drug. **Never inject into the vial in upside down position.**
5. Pull the Syringe Unit from the Vial Adaptor.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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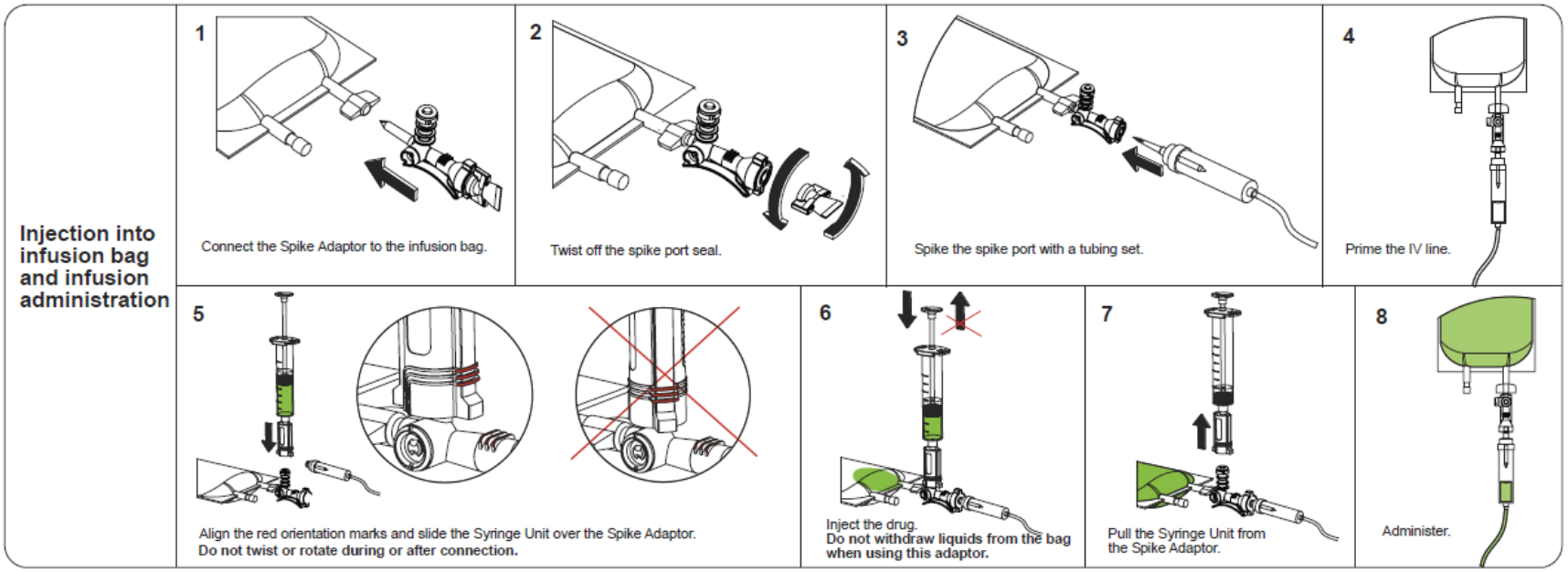
Equashield Closed System drug Transfer Device (CSTD)

IFU



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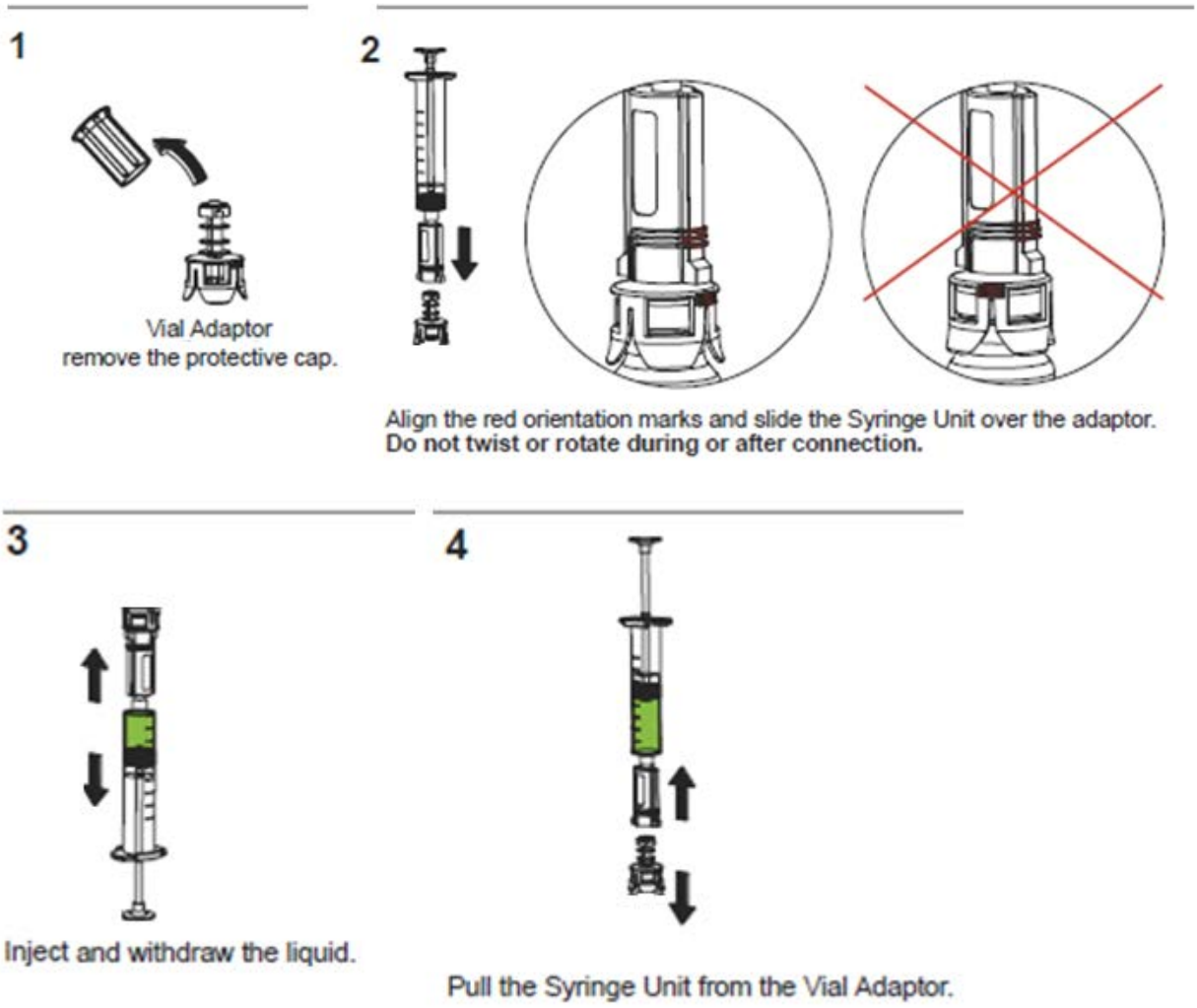
Equashield Closed System drug Transfer Device (CSTD) IFU

Instructions for Use of Vial Adaptor:



Reconstitution Set intended to be used for reconstituting Powdered Drugs. Directions for Using Reconstitution Tubing on Next page:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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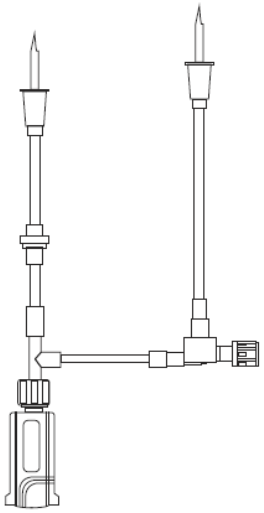
Equashield Closed System drug Transfer Device (CSTD) IFU

Reconstitution Tubing

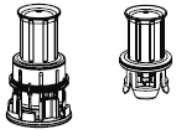
REF: LL-1R

Tubing set for closed system reconstitution of drugs in their vials.



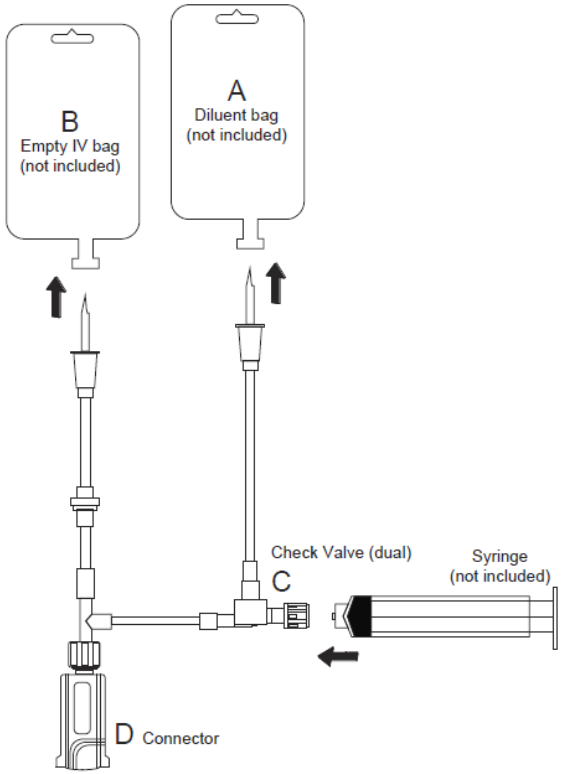
Vial Adaptor

REF: VA-13/2; VA-20/2; VA-20C/2; VA-28/2; VA-13; VA-20; VA-20C; VA-28;



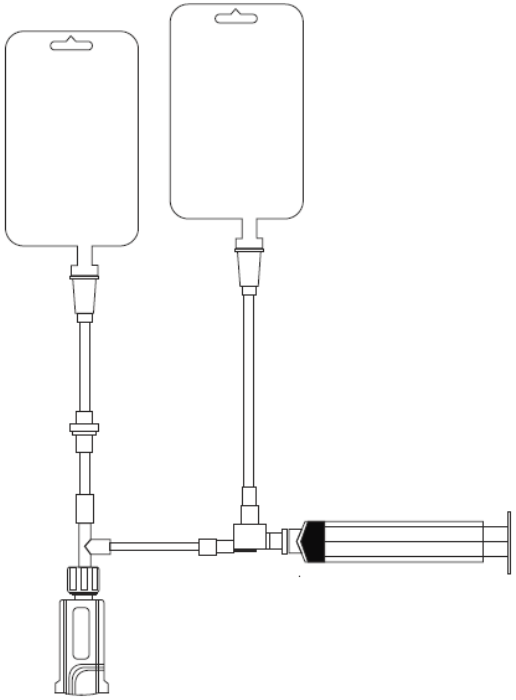
Vial Adaptor for closed system vial access.
The special Vial Adaptor VA-20C shall only be used with extra thick vial rubber stoppers.

1



Spike the diluent bag (A) by the liquid path. Spike the empty IV bag (B) by the second spike. This will be used to capture air to equalize pressure and collect waste diluent. Connect any standard luer lock syringe to the Check Valve's luer lock port (C). This syringe can be used in next steps to prime the set.

2



Hang or place the diluent bag (A) higher than rest of the system components. The bag (B) can be placed anywhere.

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Equashield Closed System drug Transfer Device (CSTD) IFU

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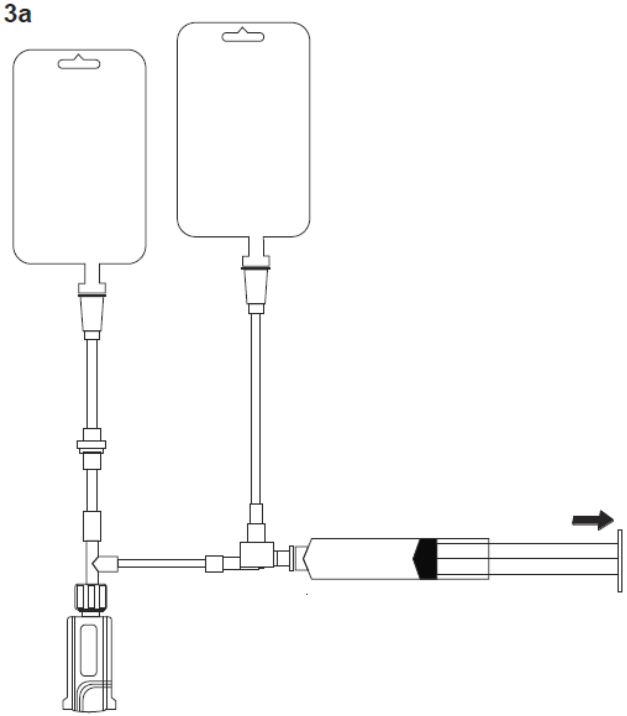	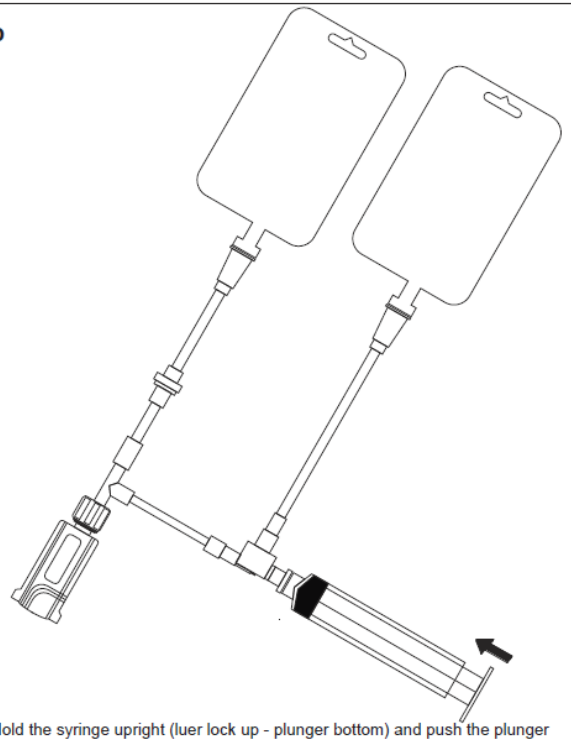	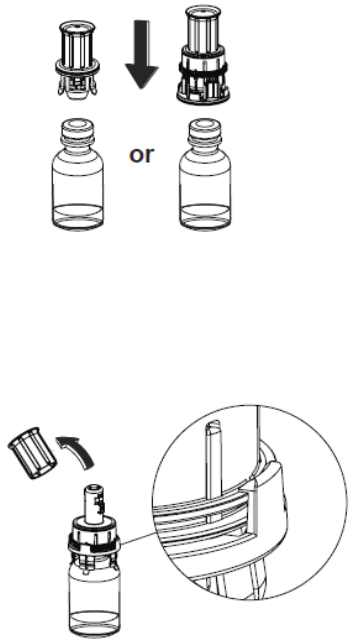
Prime the tubing set by drawing at least 15 ml of diluent from the diluent bag into the syringe by pulling the syringe plunger.	Hold the syringe upright (luer lock up - plunger bottom) and push the plunger until syringe is empty. The Dual Check valve (C) ensures that this action pushes the air bubbles from the syringe and primes the whole set. In this step diluent flows only into the empty bag (B) and nothing into bag (a).	Click the Vial Adaptor firmly onto the drug vial and ensure snapping of all 4 locking elements. Remove the protective cap. Disinfect the access port septum before each repeated connection by wiping the septum over a minimum period of 5 seconds with a sterile 70% isopropyl alcohol prep pad.

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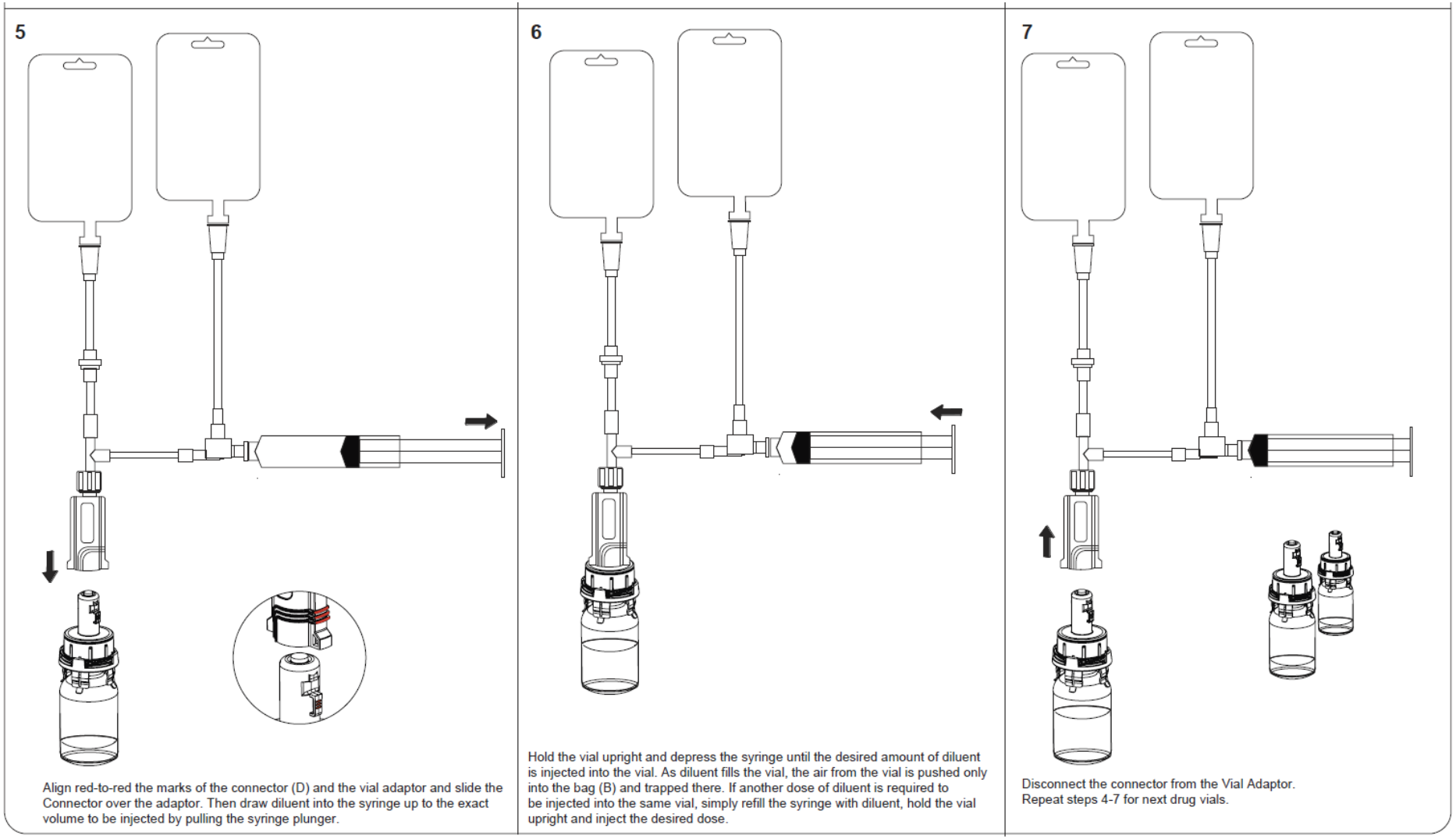

Align red-to-red the marks of the connector (D) and the vial adaptor and slide the Connector over the adaptor. Then draw diluent into the syringe up to the exact volume to be injected by pulling the syringe plunger.

Hold the vial upright and depress the syringe until the desired amount of diluent is injected into the vial. As diluent fills the vial, the air from the vial is pushed only into the bag (B) and trapped there. If another dose of diluent is required to be injected into the same vial, simply refill the syringe with diluent, hold the vial upright and inject the desired dose.

Disconnect the connector from the Vial Adaptor. Repeat steps 4-7 for next drug vials.

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Equashield Closed System drug Transfer Device (CSTD) IFU

Ordering and Catalogue Information Chart:

Name	***Model #***	***Description***	***Sizes***
Vial Adaptor	VA-13 VA-13/2 VA-20 VA-20/2 VA-20C VA-20C/2 VA-28 VA-28/2	Adaptor to the medication vial	13mm, 20mm, 28mm vial neck sizes
Syringe Unit	SU-1 SU-1/2 SU-3 SU-3/2 SU-5 SU-5/2 SU-10 SU-10/2 SU-20 SU-20/2 SU-30 SU-30/2 SU-35 SU-35/2 SU-60 SU-60/2 SU-EZ60 SU-EZ60/2	Piston syringe	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 35ml, 60ml
Spike Adaptor	SA-1	Adaptor to inject into the infusion bag	Single size
	SA-W	Adaptor withdraw from infusion bag	
Luer Lock Adaptor	LL-1	Adaptor to a female luer lock port	
Male Luer Lock Connector	MC-1	Adaptor to female luer lock port of an IV tubing	
Female Luer Lock connector	FC-1	Adaptor to male luer lock port	
Protective Plug	PP-1	Plug that protects against foreign objects openings during transport	
Y-Site Tubing	LL-1Y	Luer Lock Adaptor with Y-Site Tubing	
Secondary Tubing	SA-1S	Spike Adaptor-1 with Secondary Tubing Accessory and a drip chamber	
Reconstitution Tubing	LL-1R	For reconstitution	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EQUASHIELD®

Closed System for Drug Transfer.

Reconstitution Tubing **REF: LL-1R**

Device is not made with natural rubber latex, or DEHP.

CE 0483

STERILE EO

Rx Only

Gravity feed only

Free from Pyrogens

This device is to be used by or on the instruction of a physician or a licensed practitioner

EQUASHIELD Medical Ltd. POB 12, Tefen Industrial Park 24959, Israel

LOT:XX-XXXXX
EXP:XX/XXXX

PEEL ▶ OPEN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Thrid Party Testing

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(b)(4) Thrid Party Testing

(b)(4) Thrid Party Testing

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Performance Test (b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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