May 7, 2020

Simplivia Healthcare Ltd.
℅ Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consulting
Piazza Albania 10
Rome, 00153
ITALY

Re: K192866
Trade/Device Name: Chemfort™ Closed System Transfer Device (CSTD)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: April 2, 2020
Received: April 7, 2020

Dear Roger Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Tina Kiang, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192866

Device Name
Chemfort Closed System Transfer Device (CSTD)

Indications for Use *(Describe)*
Chemfort is a Closed System Transfer Device (CSTD) that mechanically prohibits the release of drugs, including antineoplastic and hazardous drugs, in vapor, aerosol or liquid form during preparation, reconstitution, compounding and administration, minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs.

Chemfort prevents the introduction of microbial and airborne contaminants into the drug or fluid path for 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary in accordance with 21 CFR 807.92(c)

Device Name:	Chemfort™ Closed System Transfer Device (CSTD)
Type of 510(k) submission:	Abbreviated
Date Prepared:	1 March 2020
510(k) Owner & Submitter	Simplivia Healthcare Ltd. North Industrial Zone P.O. Box 888 Kiryat Shmona Israel 1101801
Phone: **Fax:**	+972-4-6908830 +972-9-892-1659
FDA Registration Number:	9611423
510(k) Application Correspondent:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy Phone: +39 06 578 2665 Fax: +30 06 574 3786 Email: rgray@donawa.com
FDA Product Code:	ONB
FDA Regulation Number:	880.5440
FDA Regulation Name:	Intravascular administration set
Classification Panel:	General Hospital
Common Name:	Closed Drug Reconstitution and Transfer System
FDA Classification:	Class II
Indications for Use:	Chemfort™ is a Closed System Transfer Device (CSTD) that mechanically prohibits the release of drugs, including antineoplastic and hazardous drugs, in vapor, aerosol or liquid form during preparation, reconstitution, compounding and administration, minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs. Chemfort™ prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 7 days.

Predicate Device:
The predicate device selected for comparison with the Chemfort™ Closed System Transfer Device (CSTD) is:

Predicate Device Name: TEVADAPTOR® Closed Drug Reconstitution and Transfer System

510(k) Sponsor: Teva Medical
510(k) Number: K141448
Clearance Date: 23 January 2015
FDA Product Code: ONB
Regulation Name: Intravascular administration set
Regulation Number: 880.5440

Device Description:
The Chemfort™ Closed System Transfer Device (CSTD) is a system of components that allows the reconstitution of liquid or pre-dissolved powder drugs into infusion bags, flexible bottles or syringes. Single, partial or multiple vials can be used for each infusion solution container. The Chemfort™ CSTD prevents contamination of the user or the environment by the drug through the use of elastomeric seals and an active carbon filter. Sterility of the drug in the vial is maintained because any air entering the vial during pressure equalization enters through of a hydrophobic acrylic copolymer membrane with a pore size of 0.2 micron.

The components of the Chemfort™ CSTD system are:

- Vial Adaptor 20 mm with 13 mm Vial Converter
- Vial Adaptor 28 mm
- Vial Adaptor 32 mm
- Syringe Adaptor
- Syringe Adaptor Lock
- Luer Lock Adaptor
- Bag Adaptor SP

Each of the Chemfort™ system components is available separately.

The environment of use is unchanged from that of the predicate TEVADAPTOR® system cleared under K141448.

The device labeling includes the following statement: *"The ability to prevent microbial ingress for up to 7 days should not be interpreted as modifying, extending, or superseding manufacturer's labeling recommendations for the storage and expiration dating. Refer to drug manufacturer's recommendations and USP compounding guidelines for shelf life and sterility information."*

This submission for the Chemfort™ CSTD includes identification of changes in certain materials that are used in the predicate device in order to improve durability when used with drugs containing aggressive solvents, such as N'N' Dimethylacetamide. Design changes has also been made to the Vial Adaptor 20mm, Syringe Adaptor Hub, Luer Lock Adaptor, and Bag Adaptor SP.

Comparison with Predicate Device:
Table 1 provides a comparison of the Chemfort™ CSTD with the identified predicate device.

Table 1: Predicate device comparison

Item	Subject device: Chemfort™ CSTD	Predicate device: TEVADAPTOR®	Equivalence to Predicate
Device name	Chemfort™ Closed System Drug Transfer Device (CSTD)	TEVADAPTOR® Closed Drug Reconstitution and Transfer System	N/A
Manufacturer	Simplivia Healthcare, Israel	Teva Medical, Israel	N/A
510(k) number	K192866	K141448	N/A

Table 1: Predicate device comparison			
Item	**Subject device: Chemfort™ CSTD**	**Predicate device: TEVADAPTOR®**	**Equivalence to Predicate**
Product Code	ONB	ONB	Same
Reg No	880.5440	880.5440	Same
Indications for use	Chemfort™ is a Closed System Transfer Device (CSTD) that mechanically prohibits the release of drugs, including antineoplastic and hazardous drugs, in vapor, aerosol or liquid form during preparation, reconstitution, compounding and administration, minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs. Chemfort™ prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 7 days.	TEVADAPTOR® is a Closed System Drug Transfer Device (CSTD) that mechanically prohibits the release of the drug in vapor, aerosol or liquid form during preparation and administration, and prevents the introduction of microbial and airborne contaminants into the drug or fluid path, allowing the system to minimize exposure of individuals, healthcare personnel, and the environment to hazardous drugs.	Very similar
Components	Vial Adaptor 20 mm with 13 mm Vial Converter Vial Adaptor 28 mm Vial Adaptor 32 mm Syringe Adaptor Syringe Adaptor Lock Luer Lock Adaptor Bag Adaptor SP	Vial Adaptor 20 mm with 13 mm Vial Converter Vial Adaptor 28 mm No equivalent Syringe Adaptor Syringe Adaptor Lock (K170680) Luer Lock Adaptor Spike Port Adaptor	Equivalent - the devices differ in details, but the combination of components is intended to achieve an equivalent intended use.
Reuse capability	All components are for single use only	All components are for single use only	Same
Vial venting/ microbial barrier	Vial venting through 0.2 micron microbial membrane barrier	Vial venting through 0.2 micron microbial membrane barrier	Same
Prevents escape of drug or vapor concentration	Yes	Yes	Same
Closed drug transfer mechanism	Elastomeric double membrane	Elastomeric double membrane	Same
Interconnecting features	Mechanical snap connections, with elastomeric double membrane	Mechanical snap connections, with elastomeric double membrane	Same
Activation mechanism	Push-together connection with clip locks	Push-together connection with clip locks	Same
Safety features	0.2 micron venting membrane Charcoal cloth Needle tip protector Septum to septum contact	0.2 micron venting membrane Charcoal cloth Needle tip protector Septum to septum contact	Same
Direct interaction with patient	No direct interaction	No direct interaction	Same
Indirect interaction with patient	Indirect interaction with the patient is achieved through the passage of IV fluids through the central lumen of the applicable components	Indirect interaction with the patient is achieved through the passage of IV fluids through the central lumen of the applicable components	Same

Table 1: Predicate device comparison			
Item	**Subject device: Chemfort™ CSTD**	**Predicate device: TEVADAPTOR®**	**Equivalence to Predicate**
Interaction with other devices	Normal use would involve connection of device components with vial, syringe, IV line, IV bag - see following rows for further details	Normal use would involve connection of device components with vial, syringe, IV line, IV bag - see following rows for further details	Same
Connection to external syringe	Luer connections with permanent locking feature which prevents removal and remains protective through preparation, use and disposal	Luer connections with permanent locking feature which prevents removal and remains protective through preparation, use and disposal	Same
Connection to external standard IV line	Luer lock or spike port	Luer lock or spike port	Same
Connection to external standard IV bag	Spike	Spike	Same
Sterilization	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Same
Materials	Thermoplastics, silicone rubber and stainless steel: • Polypropylene RTP 199 X 143425 A NS, E-202384 White or PET Eastman Tritan Copolyester MX731 with white colorant EMD-202914; • PET Eastman Tritan Copolyester MX731; • PET Eastman Tritan Copolyester MX731 with orange colorant EC-481953 MB 4% PC TRANS.	Thermoplastics, silicone rubber and stainless steel: • ABS Polylac 757 White A79614B5; • Polycarbonate LEXAN 144R-112; • Polycarbonate LEXAN 144R-112 with orange colorant EC-481953 MB 4% PC TRANS.	Same Specific differences
Safety mechanism	Sleeve	Sleeve	Same
Power requirements	None	None	Same
Biocompatibility	In accordance with ISO 10993 and FDA guidance	In accordance with ISO 10993 and FDA guidance	Same
Prescription use	Rx only	Rx only	Same
Meets the NIOSH and ISOPP definition of a CSTD	Yes	Yes	Same

Substantial Equivalence Discussion

The Chemfort™ CSTD includes two new system components that were not included with the predicate device, these being the Vial Adaptor 32 mm and the Syringe Adaptor Lock. The introduction of these new system components raises no new issues of safety and/or effectiveness, because of their close similarity to components included in the predicate device. In addition, the Syringe Adaptor Lock was separately FDA-cleared under K170680.

Chemfort™ CSTD components that are the result of design and/or material changes from the predicate and reference devices have been subjected to successful bench, biocompatibility, shelf life and usability testing, in addition to sterilization validation, and there are no new questions of safety and/or effectiveness have been identified.

The introduction of the additional wording "*Chemfort prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 7 days"* in the indications for use statement has been verified by means of bench tests. The ability to prevent microbial ingress for up to 7 days should not be interpreted as modifying, extending, or superseding manufacturer's labeling recommendations for drug storage and expiration dating, however.

Non-Clinical Performance Testing:
Bench testing has been carried out on the Chemfort™ system components to demonstrate equivalence with the predicate device, including a number of tests at the end of the labeled 12-month shelf life:

- Disconnection force tests
- Assembly connection force tests
- Breakage of Syringe Adaptor Lock Luer retention teeth
- Bidirectional flow tests
- Air tightness tests
- Fluid tightness tests
- Residual volume tests
- Microbial ingress tests (7 days)
- Particulate matter tests per USP <788>
- Filter efficiency tests
- ISO 8536-4 & ISO 80369-7 tests, including:
    - Gauging test
    - Resistance for overriding
    - Unscrewing torque
    - Ease of assembly
    - Liquid leakage
    - Air leakage
    - Separation force of conical fitting assembly
    - Stress cracking
- Resistance to cytotoxic drugs
- Packaging integrity
    - Visual (ASTM F1886)
    - Peel (ASTM F88/F88M
    - Dye penetration (ASTM F1929)
    - Leakage (ASTM F2096)
    - Burst (ASTM F1140/F1140M)
- Seven-day filter exposure test
- Vapor containment
- Sterility validation (ISO 11135-1)
- ETO residuals (ISO 10993-7)
- Bacterial endotoxins (USP <85> and <161>)

Biocompatibility
Biocompatibility tests have been carried out on sterile components from the Chemfort™ system in accordance with ISO 10993 and FDA guidance, including:

- ISO 10993-5:2009: Cytotoxicity
- ISO 10993-10:2010: Sensitization, Irritation
- ISO 10993-11:2006: Acute Systemic Toxicity, Material Mediated Pyrogenicity
- ISO 10993-4: 2006: Hemocompatibility
- ISO 10993-18:2005, Chemical Characterization
- ISO 8536-4:2010: Chemical Tests
- Extractables and Leachables Tests

Substantial Equivalence Conclusion:
Based on the performance testing conducted on the subject device, the Chemfort™ CSTD, does not raise new types of safety and effectiveness questions. It is concluded that the Chemfort™ CSTD is substantially equivalent to the identified predicate device TEVADAPTOR®.