October 21, 2025

Simplivia Healthcare Ltd.
Shay Shaham
VP QA/RA
North Industrial Zone, Eli Horovitz 1
P.O. Box 888
Kiryat Shmona, 1101801
Israel

Re: K253033
Trade/Device Name: Chemfort® 28-day 20 mm Vial Adaptor and 13 mm Convertor
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: September 21, 2025
Received: September 22, 2025

Dear Shay Shaham:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colleen J. Lawrimore -S

Colleen Lawrimore, Ph.D.
For David Wolloscheck, Ph.D.
Assistant 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253033

Device Name
Chemfort® 28-day 20 mm Vial Adaptor and 13 mm Convertor

Indications for Use *(Describe)*
Chemfort® 28-day 20 mm Vial Adaptor is a single use, sterile 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, thus minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs.

Chemfort® 28-day 20 mm Vial Adaptor prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 28 days or 10 activations.

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY - K253033

Chemfort® 28-day 20 mm Vial Adaptor and 13 mm Convertor

Trade name:	Chemfort® 28-day 20 mm Vial Adaptor and 13 mm Convertor
Type of 510(k) submission:	Special
Date of Preparation:	20 October 2025
Owner and Submitter:	Simplivia Healthcare LTD. North Industrial Zone, Eli Horovitz 1 P.O. Box 888 Kiryat Shmona, 1101801 Israel
Phone: **Fax:**	(972) 4 6908826 (972) 74 7652161
Contact Person:	Shay Shaham, VP QA/RA, Simplivia Healthcare Ltd.
Product Code:	ONB
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set
Classification Panel:	General Hospital
Common Name:	Closed antineoplastic and hazardous drug reconstitution and transfer system (CSTD)
Device Class:	Class II
Indications for Use:	Chemfort® 28-day 20 mm Vial Adaptor is a single use, sterile 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, thus minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs. Chemfort® 28-day 20 mm Vial Adaptor prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 28 days or 10 activations.
Predicate Device: 510(k) Sponsor: 510(k) Number:	Chemfort® Closed System Transfer Device (CSTD) Simplivia Healthcare LTD K192866

Clearance Date:	7 May 2020
Product Code:	ONB
Regulation Name:	Intravascular administration set
Regulation Number:	21 CFR 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.

The components of the predicate 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 Indications for Use statement for the predicate CSTD system cleared under K192866 is:

> *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.*

In addition, the labeling for the predicate device includes the precautionary 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 introduces a new version of the 20mm Vial Adaptor to the Chemfort® CSTD system, called the Chemfort® 28-day 20 mm Vial Adaptor, as a range extension. This new Vial Adaptor differs from the predicate Vial Adaptor only with respect to the usage time limitation, which is extended from 7 to 28 days, but with the same limit of 10 activations. This change is reflected in the Indications for Use statement and the device labeling, as follows (changes bolded and underlined):

Indications for Use:
*Chemfort® **28-day** 20 mm Vial Adaptor is a **single use, sterile** 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, thus minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs.*

*Chemfort® 28-day 20 mm Vial Adaptor prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to **28** days **or 10 activations**.*

Precautionary statement in labeling:
*The ability to prevent microbial ingress for up to **28** 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.*

Substantial Equivalence Discussion:
While the subject device differs from the predicate device in relation to the usage time limit, in all other respects, the subject device is identical to the 20 mm Vial Adaptor cleared as part of the predicate Chemfort® Closed System Transfer Device under K192886. These identical device characteristics are detailed in the following predicate device comparison table.

Comparison of Technological Characteristics			
Item	**Subject device:** Chemfort® 28-day 20 mm Vial Adaptor and 13 mm Convertor	**Predicate device:** Chemfort® Closed System Drug Transfer Device (CSTD)	**Equivalence to Predicate**
Indications for use	Chemfort® 28-day 20 mm Vial Adaptor is a single use, sterile 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, thus minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs. Chemfort® 28-day 20 mm Vial Adaptor prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 28 days or 10 activations.	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.	Different; The indications for use are identical except for the maximum duration of use. Change supported by bench testing as described below. Specification of single use, sterile has been added for the subject device. However, this modification does not change the intended use of the device.

Comparison of Technological Characteristics			
Item	**Subject device:** Chemfort® 28-day 20 mm Vial Adaptor and 13 mm Convertor	**Predicate device:** Chemfort® Closed System Drug Transfer Device (CSTD)	**Equivalence to Predicate**
Components	28-day 20 mm Vial Adaptor with 13 mm Vial Converter	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	The Vial Adaptor component of the predicate is physically identical to the subject device. The 13 mm Converter has not changed.
Vial venting/ microbial barrier	Vial venting through 0.2 micron microbial membrane barrier	Vial venting through 0.2 micron microbial membrane barrier	Identical
Prevents escape of drug or vapor concentration	Yes	Yes	Identical
Closed drug transfer mechanism	Elastomeric membrane	Elastomeric membrane	Identical
Interconnecting features	Mechanical snap connections, with elastomeric membrane	Mechanical snap connections, with elastomeric membrane	Identical
Activation mechanism	Push-together connection with clip locks	Push-together connection with clip locks	Identical
Vial Adaptor Safety features	0.2 micron venting membrane Charcoal cloth Septum to septum contact	0.2 micron venting membrane Charcoal cloth Septum to septum contact	Identical
Direct interaction with patient	No direct interaction	No direct interaction	Identical
Indirect interaction with patient	Indirect interaction with the patient is achieved through the passage of IV fluids through the fluid path of the applicable components	Indirect interaction with the patient is achieved through the passage of IV fluids through the fluid path of the applicable components	Identical
Interaction with other devices	Normal use would involve connection of subject device to the Chemfort® Syringe Adaptor component	Normal use would involve interconnection of Chemfort® device components, including Vial Adaptor to Syringe Adaptor	The Vial Adaptors Interaction with other devices is identical.
Connection to external syringe	Via Syringe Adaptor	Vial Adaptor connects to external syringe through Syringe Adaptor	Identical
Sterilization	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Identical
Vial Adaptor Materials	Thermoplastics, silicone rubber, membrane and charcoal fabric	Thermoplastics, silicone rubber, membrane and charcoal fabric	Identical
Biocompatibility	In accordance with ISO 10993 series and FDA guidance	In accordance with ISO 10993 series and FDA guidance	Identical
Shelf life	3 years	3 years	Identical
Prescription use	Rx only	Rx only	Identical

Comparison of Technological Characteristics			
Item	**Subject device:** Chemfort® 28-day 20 mm Vial Adaptor and 13 mm Convertor	**Predicate device:** Chemfort® Closed System Drug Transfer Device (CSTD)	**Equivalence to Predicate**
Meets the NIOSH and ISOPP definition of a CSTD	Yes	Yes	Identical
Color coding	Yes, Cap component is colored using identical pigment previously cleared for use in Chemfort® components	No	Different; As the pigment was part of a previous clearance, this difference does not raise new/different questions of safety and effectiveness.
Usage limitation	28 days or 10 activations	7 days or 10 activations	Different time limit

The difference in usage time limitation has been verified by bench testing using the same test protocols used for the predicate Vial Adaptor, including the following characteristics:

- Microbial ingress
- Bidirectional Flow
- Vapor Containment
- Disconnection Force from Drug Vial
- Air Tightness
- Fluid Tightness
- Particulate Matter

Substantial Equivalence Conclusion:
Chemfort® 28-day 20 mm Vial Adaptor has similar indications for use, Identical raw material, technological characteristics and principle of operation as the predicate device, the Chemfort® 20 mm Vial Adaptor included within cleared 510(k) submission K192866.

Simplivia has performed bench tests (see above) to ensure that the differences in usage time do not affect the device's safety and effectiveness. In addition, the exterior color of the 28-day 20 mm Vial Adaptor is unique to prevent mix-up with other Chemfort® Vial Adaptors.

The results of performance testing to the same protocols used for the predicate device demonstrate that the Chemfort® 28-day 20 mm Vial Adaptor is as safe and as effective as its predicate and does not raise any new questions of safety and effectiveness. Thus, Simplivia Healthcare's Chemfort® 28-day 20 mm Vial Adaptor is substantially equivalent to its predicate device, the Chemfort® 20 mm Vial Adaptor included within K192866.