August 5, 2025

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

Re: K251411
Trade/Device Name: Chemfort Female Luer Lock Adaptor
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: May 5, 2025
Received: May 7, 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,

David Wolloscheck -S

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)*
K251411

Device Name
Chemfort® Female Luer Lock Adaptor

Indications for Use *(Describe)*
Chemfort® 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 administration and preparation, thus 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.**

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

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# CHEMFORT® FEMALE LUER LOCK ADAPTOR 510(K) SUMMARY

| | |
|---|---|
| **Preparation Date:** | **August 05, 2025** |
| **Device name:** | Chemfort® Female Luer Lock Adaptor |
| **Type of 510(k) submission:** | Traditional |
| **Date of Submission:** | May 07, 2025 |
| **Applicant's name:** | Simplivia Healthcare LTD.<br>North Industrial Zone<br>Kiryat Shmona, 1101801<br>Israel |
| **Phone:**<br>**Fax:** | (972) 4 6908826<br>(972) 74 7652161 |
| **FDA Registration Number** | 9611423 |
| **Contact Person:** | Shay Shaham<br>VP QA / RA |
| **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 |
| **Predicate Device:** | Chemfort® Adaptors (K192866) |

**Intended Use / Indications for Use**

Chemfort® 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 administration and preparation, thus 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.

**Device Description**

The Chemfort® Closed System Transfer Device (CSTD) is developed by Simplivia Healthcare Ltd. The system is used by pharmacists, nurses or other healthcare professionals to prepare drugs, including cytotoxic drugs, and allow the safe reconstitution of powder and liquid drugs transfer for infusion containers (infusion bags, semi-rigid bottles, and collapsible plastic containers), injection, or administration. It is supplied sterile with a sterility assurance level (SAL) of $10^{-6}$.

The Chemfort® Female Luer Lock Adaptor is part of the Chemfort® system of devices. The Chemfort® Female Luer Lock Adaptor is intended for the safe drug transfer from one syringe to another and allows closed access via Chemfort® devices to any standard male Luer connection (see below in more details).

1. Syringe to Syringe connection:
   The Chemfort® Female Luer Lock Adaptor is connected to the Chemfort® Luer Lock Adaptor. The Chemfort® Luer Lock Adaptor port is connected to an empty / saline containing syringe (syringe "A"), equipped with a Chemfort® Syringe Adaptor or Chemfort® Syringe Adaptor Lock. A drug containing syringe (syringe "B"), equipped with a Chemfort® Syringe Adaptor or Chemfort® Syringe Adaptor Lock is connected to the Chemfort® Female Luer Lock Adaptor. This assembly of devices allows drug transfer from one syringe "A" to the other, syringe "B", for drug dilution (if syringe "A" contains saline) or drug dosage (if syringe "A" is empty). This procedure allows safe drug transfer from one syringe to another. The drug in Syringe "A" can then be injected to an intravenous (IV) bag through the Chemfort® spike or in a bolus through another Chemfort® Luer Lock Adaptor connected to a Y-site on an IV set.
   Note that this procedure also involves the Chemfort® Vial Adaptor to allow to withdraw the drug from the drug vial to syringe "B".
2. Connection to IV sets:
   The Chemfort® Female Luer Lock Adaptor is connected to an IV set through the luer lock connection (proximal end or infusion line). The Chemfort® port can then connect to one of the Chemfort® Closed Administration (CADM) IV sets. This setup transfers an open IV set connection to a closed connection.
   The Chemfort® Female Luer Lock Adaptor can be in contact with concentrated or diluted drugs.
   The Chemfort® Female Luer Lock Adaptor is a single-use device intended for use on adults, children and infants.

**Summary of Technological Characteristics:**

The following table (**Table 1**) compares the Chemfort® Female Luer Lock Adaptor to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

**Table 1. Proposed Device and Predicate Device Comparation**

| **Category** | **Proposed Device Chemfort® Female Luer Lock Adaptor** | **Predicate Device Chemfort Adaptors (K192866)** | **Equivalence to predicate** |
|---|---|---|---|
| **Device Class** | Class II | Class II | Same |
| **Classification Panel** | General Hospital | General Hospital | Same |
| **Product Code** | ONB | ONB | Same |
| **Regulation Description** | Intravascular Administration Set | Intravascular Administration Set | Same |
| **Regulation No.** | 21 C.F.R. §880.5440 | 21 C.F.R. §880.5440 | Same |
| **Indications for use** | Chemfort® 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 administration and preparation, thus minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs.<br>Chemfort® prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 7 days. | 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.<br>Chemfort® prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 7 days. | Same |
| **Components** | Part of Chemfort®, a multi-components system | Part of Chemfort®, a multi-components system | Same |
| **Interaction with other devices** | The distal end connects to any male luer connection.<br>The proximal end connects to Chemfort® Syringe Adaptor / Syringe Adaptor Lock. | Luer Lock Adaptor: the distal end connects to any female luer connection.<br>The proximal end connects to Chemfort® Syringe Adaptor / Syringe Adaptor Lock. | Different – the devices differ in the Luer connection. Performance testing in compliance to ISO 80369-7:2021 demonstrates |

| Category | Proposed Device Chemfort® Female Luer Lock Adaptor | Predicate Device Chemfort Adaptors (K192866) | Equivalence to predicate |
|---|---|---|---|
| | | | the difference will not raise any new or different questions of safety and effectiveness. |
| **Re-use capability** | Distal end: to maintain the closed system, the Female Luer Lock Adaptor should not be disconnected from the luer end. Proximal end: The Chemfort® port of the Female Luer Lock Adaptor can be connected and disconnected from the Syringe Adaptor port up to 10 times. | Distal end: to maintain the closed system, the Female Luer Lock Adaptor should not be disconnected from the luer end. Proximal end: The Chemfort® port of the Luer Lock Adaptor can be connected and disconnected from the Syringe Adaptor port up to 10 times. | Same |
| **Principles of Operation** | Multi-component system, components are intended to be used as a system, manually manipulated. | Multi-component system, components are intended to be used as a system, manually manipulated. | Same |
| **Interaction with patient** | No direct interaction- device interaction with the patient is achieved through the passage of fluids through Chemfort® devices. | No direct interaction- device interaction with the patient is achieved through the passage of fluids through Chemfort® devices. | Same |
| **Interconnecting features** | • Mechanical snap connections.<br>• Luer connection | • Mechanical snap connections.<br>• Luer connection | Same |
| **Safety features** | Septum to septum contact | Septum to septum contact | Same |
| **Target users** | Nurses, pharmacists or other healthcare professionals. | Nurses, pharmacists or other healthcare professionals. | Same |
| **Technology** | All of the Chemfort® devices ports are sealed with resealing Septum. When Syringe Adaptor and Chemfort® port are joined, the two septums are pressed together and then pierced by a needle (from the Syringe Adaptor or Syringe Adaptor Lock), thus creating a secured fluid path. | All of the Chemfort® devices ports are sealed with resealing Septum. When Syringe Adaptor and Chemfort® port are joined, the two septums are pressed together and then pierced by a needle (from the Syringe Adaptor or Syringe Adaptor Lock), thus creating a secured fluid path. | Same |
| **Environment of use** | Hospitals, compounding centers and clinics | Hospitals, compounding centers and clinics | Same |
| **Sterilization method** | Ethylene Oxide validated cycle SAL $10^{-6}$ | Ethylene Oxide validated cycle SAL $10^{-6}$ | Same |

| Category | Proposed Device Chemfort® Female Luer Lock Adaptor | Predicate Device Chemfort Adaptors (K192866) | Equivalence to predicate |
|---|---|---|---|
| **Biocompatibility** | All of the device parts that are in contact with patient comply with the requirements of ISO 10993-1 | All of the device's parts that are in contact with patient comply with the requirements of ISO 10993-1 | Same |
| **Raw Material in the fluid path** | Polypropylene and Polyisoprene | Chemfort Vial Adaptor- Polypropylene and Polyisoprene | Same |
| **Prescription use** | Rx only | Rx only | Same |

**Performance Data**

Simplivia conducted several performance tests to demonstrate that the Chemfort® Female Luer Lock Adaptor is safe and effective throughout it's intended shelf life (3 years) and that it functions as intended, according to its specifications, in a safe and effective manner, see in the Table 2 the main tests performed.

**Table 2. Performance testis and their applicable standards**

| Test name | Description | Results | Standard |
|---|---|---|---|
| Particulate Analysis | Chemfort® Female Luer Lock Adaptor fluid path was examined for particles | Pass | USP <788>, Particulate Matter in Injections, Method 1- Light Obscuration Particle Count Test. |
| Bidirectional flow | The ability of the device to deliver liquid throughout the system was verified. | Pass | Internal procedure |
| Assembly's Connection | Evaluation of the connection force between Chemfort® Syringe Adaptor and Chemfort® Female Luer Lock Adaptor ports. | Pass | Internal procedure |
| Air Tightness | This test demonstrated that there is no leakage between the Chemfort®'s Female Luer Lock Adaptor and the Chemfort® Syringe Adaptor ports connection. | Pass | Internal procedure |
| Fluid Leakage | Ensure that the Chemfort® Female Luer Lock Adaptor's luer connector. | Pass | Internal procedure |
| Luer test | The luer lock connection complies with ISO 80369-20 | Pass | ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications |

Other relevant standards:

- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications
- ISO 10993-1:2018, Biological Evaluation of Medical Devices. Part 1: Evaluation and testing within a risk management process.
- ISO 10993-4:2017, Biological Evaluation of Medical Devices. Part 4: Selection of tests for interactions with blood.
- ISO 10993-5:2009, Biological Evaluation of Medical Devices. Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-7:2008/Amd 1:2019, Biological Evaluation of Medical Devices. Part 7: Ethylene oxide sterilization residuals.
- ISO 10993-10:2021, Biological Evaluation of Medical Devices. Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2017, Biological Evaluation of Medical Devices. Part 11: Tests for systemic toxicity.
- ISO 10993-18:2020, Biological Evaluation of Medical Devices. Part 18: Chemical characterization of medical device materials within a risk management process.
- ISO 11135:2014 + Amd.1:2018, Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO 11607-1:2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
- ISO 14971:2019 –Medical devices—Application of risk management to medical devices
- USP <85>, Bacterial Endotoxins Test.
- USP <161>, Transfusion and Infusion Assemblies and Similar Medical Devices.

**Substantial Equivalence**

Simplivia Healthcare's Chemfort® Female Luer Lock Adaptor has similar indications for use, raw material and similar technological characteristics and principles of operation as the predicate device, K192866. Performance data demonstrated that the Chemfort® Female Luer Lock Adaptor is as safe and as effective as its predicate and does not raise any new safety and effectiveness issues. Thus, Simplivia Healthcare's Chemfort® Female Luer Lock Adaptor is substantially equivalent to its predicate device, K192866.