August 2, 2023

Simplivia Healthcare LTD.
Shay Shaham
VP QA/RA
North Industrial Zone
Kiryat Shmona, 1101801
Israel

Re: K231286
Trade/Device Name: Chemfort® Catheter Adaptor
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: May 3, 2023
Received: May 4, 2023

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 (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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K231286

Device Name
Chemfort® Catheter Adaptor

Indications for Use *(Describe)*
Chemfort® Catheter 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 administration, thus minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs.
Chemfort® Catheter Adaptor 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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K231286 510(K) SUMMARY

Preparation Date:	**July 31, 2023**
Device name:	Chemfort® Catheter Adaptor
Type of 510(k) submission:	Traditional
Date of Submission:	May 3, 2023
Applicant's name:	Simplivia Healthcare LTD. North Industrial Zone Kiryat Shmona, 1101801 Israel
Phone: **Fax:**	(972) 4 6908826 (972) 74 7652161
FDA Registration Number	9611423
Contact Person:	Shay Shaham VP QA / RA
FDA Product Code:	ONB
FDA Regulation Number:	21 CFR 880.5440
FDA Regulation Name:	Intravascular administration set
Classification Panel:	General Hospital
Common Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
FDA Classification:	Class II
Predicate Device:	Tevadaptor® Catheter Adaptor (K180489)

Indications for Use

Chemfort® Catheter 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 administration, thus minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs.
Chemfort® Catheter Adaptor prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 7 days.

Device Description

The Chemfort® Catheter Adaptor enables drug transfer to the catheter, thus allowing drug administration to the patient's urinary bladder. The use of elastomeric seals of the Chemfort® Catheter Adaptor prevents hazardous drug contamination of healthcare professionals, the patient, and the environment.

The Chemfort® Catheter Adaptor is an addition to the cleared Chemfort® system (K192866). The Catheter Adaptor provides closed system protection during the following procedures:

a) Drug transfer from a standard luer lock syringe to the Catheter Adaptor through the Chemfort® Syringe Adaptor (K192866).
b) Closed system drug administration to the urinary bladder, through a urinary catheter. The Catheter Adaptor fits a wide range of standard catheter sizes and converts an open catheter connection to a closed Chemfort® connection.

The Chemfort® Catheter Adaptor allows the healthcare professional to have the option for safe drug administration to the urinary catheter and safe disconnection of the Chemfort® Syringe Adaptor (K192866) from the patient's urinary catheter.

Summary of Technological Characteristics:

The following table (**Table 2**) compares the Chemfort® Catheter Adaptor to the predicate device 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, Refefance Device and Predicate Device Comparation

	Proposed Device Chemfort® Catheter Adaptor	**Predicate Device Tevadaptor® Catheter Adaptor (K180489)**	**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® Catheter 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 administration, thus minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs. Chemfort® Catheter Adaptor 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.	First part: Same meaning. Second part: Tevadaptor® was tested and proved to prevent contaminants from entering the drug or fluid path for up to 3 days, Chemfort® has been tested and approved for 7 days
Components	Part of Chemfort®, a multi-components system including Catheter Adaptor	Part of Tevadaptor®, a multi-components system including Catheter Adaptor	Same
Interaction with other devices	The distal end connects to the urinary catheter. The proximal end connects	The distal end connects to the urinary catheter. The proximal end connects	Same

	Proposed Device Chemfort® Catheter Adaptor	**Predicate Device Tevadaptor® Catheter Adaptor (K180489)**	**Equivalence to predicate**
	to Chemfort® Syringe Adaptor / Syringe Adaptor Lock.	to Tevadaptor® Syringe Adaptor / Syringe Adaptor Lock.	
Re-use capability	Distal end: to maintain the closed system, the Catheter Adaptor should not be disconnected from the urinary catheter. Proximal end: The Chemfort® port of the Catheter Adaptor can be connected and disconnected from the Syringe Adaptor port up to 10 times.	Distal end: to maintain the closed system, the Catheter Adaptor should not be disconnected from the urinary catheter. Proximal end: The Tevadaptor® port of the Catheter 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 the urinary catheter.	No direct interaction-device interaction with the patient is achieved through the passage of fluids through the urinary catheter.	Same
Interconnecting features	Mechanical snap connections.	Mechanical snap connections.	Same
Safety features	• Vented cap • Septum to septum contact	• Vented cap • Septum to septum contact	Same
Target users	Nurses or other healthcare professionals.	Nurses 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),	All of the Tevadaptor® devices ports are sealed with resealing Septum. When Syringe Adaptor and Tevadaptor® port are joined, the two septums are pressed together and then pierced by a needle (from the Syringe Adaptor or Syringe Adaptor Lock),	Same

	Proposed Device Chemfort® Catheter Adaptor	**Predicate Device Tevadaptor® Catheter Adaptor (K180489)**	**Equivalence to predicate**
	thus creating a secured fluid path.	thus creating a secured fluid path.	
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
Biocompatibility	All Catheter Adaptor parts that are in contact with patient comply with the requirements of ISO 10993-1	All Catheter Adaptor parts that are in contact with patient comply with the requirements of ISO 10993-1	Same
Prescription use	Rx only	Rx only	Same

Performance Data

Simplivia Healthcare conducted several performance tests to demonstrate that the Chemfort® Catheter Adaptor complies with the following standards and that it functions as intended.

- 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 Medical devices —Application of risk management to medical devices
- USP <85>, Bacterial Endotoxins Test.
- USP <161>, Transfusion and Infusion Assemblies and Similar Medical Devices.
- USP <788>, Particulate Matter in Injections

Substantial Equivalence

Simplivia Healthcare's Chemfort® Catheter Adaptor has similar indications for use, and similar technological characteristics and principles of operation as the predicate device, K180489. Performance data demonstrated that the Chemfort® Catheter 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® Catheter Adaptor is substantially equivalent to its predicate device, K180489.