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

Re: K210707
Trade/Device Name: OnGuard®2 Chemfort™ Closed Administration (CADM)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: August 19, 2021
Received: August 24, 2021

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,

For Payal Patel
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)*
K210707

Device Name
OnGuard®2 Chemfort™ Closed Administration (CADM)

Indications for Use *(Describe)*
The OnGuard®2 Chemfort™ Closed Administration 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.

OnGuard®2 Chemfort™ Closed Administration 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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K210707 510(k) SUMMARY

Preparation Date:	**September 23, 2021**
Submitter Name	Simplivia Healthcare LTD. North Industrial Zone Kiryat Shmona, 1101801 Israel
Contact Person:	Shay Shaham VP QA / RA
Telephone Number:	(972) 4 6908826
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Trade Name:	OnGuard®2 Chemfort™ Closed Administration (CADM)
Common Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
Regulation Name:	Intravascular Administration Set
Regulation Number:	21CFR 880.5440
Product Code:	ONB
Device Class:	Class II
Predicate Device:	K192866, Chemfort™ Closed System Transfer Device (CSTD)

Device Description:

The OnGuard®2 Chemfort™ Closed Administration (CADM) devices allow drug transfer to the IV bag and drug administration to the patient. The use of elastomeric seals in CADM prevents hazardous drugs contamination of healthcare professionals, the patient and the environment.

The OnGuard®2 Chemfort™ Closed Administration contains four devices that connect between infusion containers and primary sets:

- Bag Adaptor Chemfort™ Port (BACP)
- Closed Y Inline Set (Y-Set)
- Closed IV Secondary Set (Secondary)
- Closed Adaptor Spike Port (CASP)

CADM devices are an addition to the cleared Chemfort™ system (K192866). CADM provides closed system protection during the following procedures:

1) Drug transfer to a container (e.g. IV bag) through the Chemfort™ Syringe Adaptor (K192866) and CADM Bag Adaptor Chemfort™ Port (BACP).
2) Drug administration, with one of the CADM sets after it is attached to the BACP and creates a closed system.

The main differences and *unique features* between the subject device and the predicate:

- In the Chemfort™ system (K192866) the infusion set's spike is connected to an IV bag via the Chemfort™ Bag Adaptor SP's (BASP) tail. This is a one-time connection which remains sealed during the entire administration procedure (and after). The CADM set's Syringe Adaptor component allows the healthcare professional to *have the option for safe disconnection of the patient's IV set after the drug was administrated, and then re-connecting it to a new IV bag* containing saline or a new drug for administration via a new CADM BACP device, while keeping the closed system.
- The CADM BACP (K210707) device consists of a distal Chemfort™ port which serves as both the drug transfer to the IV bag path and the infusion outflow path (drug administration), while the predicate device Chemfort™ BASP (K192866) has a Chemfort™ port for drug transfer and a separate path for drug administration.

Each of the OnGuard®2 Chemfort™ Closed Administration devices are available separately.

Intended Use / Indications for Use

Characteristics	**Subject Device- K210707** OnGuard®2 Chemfort™ Closed Administration (CADM)	**Predicate Device- K192866** Chemfort™ Closed System Transfer Device (CSTD)
Indication for Use	The OnGuard®2 Chemfort™ Closed Administration 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. OnGuard®2 Chemfort™ Closed Administration 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, 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.
Prescription Only or Over the Counter	Prescription Only	Prescription Only

Discussions of differences in Indications for Use statement

There are only editorial differences to the indications for use statement between the predicate and the subject device which do not change the indications.

Summary of Technological Characteristics

The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

	Proposed Device- K210707 **OnGuard®2 Chemfort™ Closed Administration**	**Predicate Device- K192866** **Chemfort™ Closed System Transfer Device (CSTD)**	**Equivalence to predicate**
Indications for use	The OnGuard®2 Chemfort™ Closed Administration 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. OnGuard®2 Chemfort™ Closed Administration 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, 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.	Different - the difference is in the product name Chemfort™ System versus OnGuard®2 Chemfort™ Closed Administration and an addition of "is a single use, sterile"
Target users	Pharmacists or other healthcare professionals	Pharmacists or other healthcare professionals	Same
Environment of use	Hospitals, compounding centres and clinics	Hospitals, compounding centres and clinics	Same
Components	Bag Adaptor Chemfort™ Port (BACP) Closed Y Inline Set (Y Set) Closed Adaptor Spike Port (CASP) Closed Secondary IV Set (Secondary)	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	Different device (CADM will be added to the Chemfort™ System)
Spike & body design	The BACP spike itself and the spike body (finger placement) design are based on the Bag Adaptor SP (BASP) design cleared under K192866		Same
Chemfort™ Port location	BACP- the Chemfort™ port is located in the distal part of the device	BASP- the Chemfort™ port is located in the middle of the device	Different – see comment 1
Drug delivery to bag	Through BACP Chemfort™ port	Through BASP Chemfort™ port	Same
Drug administration to patient	Through BACP Chemfort™ port and the connected CADM IV set	Through BASP tail, located in the distal part of the device and the connected IV set	Different – See comment 2
Residual volume	BACP residual volume is < 0.01% of 1 L saline bag	BACP residual volume is < 0.01% of 1 L saline bag	Same
Interaction with other devices	For most uses, the OnGuard®2 Chemfort™ Closed Administration devices will connect to an IV solution container and a primary	For most uses, the Vial Adaptor will connect to a vial, the Syringe Adaptor will connect to a syringe, the Luer Lock Adaptor will connect to a	Similar connections to Chemfort™ System's devices

	Proposed Device- K210707 **OnGuard®2 Chemfort™ Closed Administration**	**Predicate Device- K192866** **Chemfort™ Closed System Transfer Device (CSTD)**	**Equivalence to predicate**
	administration set. A connection also can be made with: - Syringe Adaptor (SA) (K192866) - Syringe Adaptor Lock (SAL) (K192866)	needless injection site, the Bag Adaptor SP will connect to an IV solution container and a primary administration set. A connection also can be made with - Syringe Adaptor (K192866) - Syringe Adaptor Lock (K192866)	
Re-use capability	All devices can be used up to 10 times, but once connected to a non-Chemfort™ device (such as IV bag) they can't be disconnected	All devices can be used up to 10 times, but once connected to a non-Chemfort™ device (such as drug vial) they can't be disconnected	Same
Principles of Operation	Multi-component system, devices are intended to be used as a system, manually manipulated	Multi-component system, devices are intended to be used as a system, manually manipulated	Same
Interaction with patient	No direct interaction - interaction with the patient is achieved by the passage of IV fluids through the central tubing of the administration set	No direct interaction - interaction with the patient is achieved by the passage of IV fluids through the central tubing of the administration set	Same
Interconnecting features	Mechanical snap connections	Mechanical snap connections	Same
Technology	All of the devices are sealed with resealing septum. When devices are joined together the two septums are pressed and then pierced by needle (from the Chemfort™ system's SA or SAL device), thus creating a secured fluid path.	All of the devices are sealed with resealing septum. When devices are joined together the two septums are pressed and then pierced by needle (from the Chemfort™ system's SA or SAL device), thus creating a secured fluid path.	Same
Safety features	Needle tip protector Septum to septum contact Spike cap	0.2 micron venting membrane Charcoal cloth Needle tip protector Septum to septum contact Spike cap	Similar- Needle tip protector Septum to septum contact Spike cap
Sterilization method	Ethylene Oxide validated cycle SAL 10^{-6}	Ethylene Oxide validated cycle SAL 10^{-6}	Same
Biocompatibility	All parts that are in contact with patient comply with the requirements of ISO 10993-1	All parts that are in contact with patient comply with the requirements of ISO 10993-1	Same
Shelf life	3 years	3 years	Same
Prescription use	Rx only	Rx only	Same

	Proposed Device- K210707 OnGuard®2 Chemfort™ Closed Administration	**Predicate Device- K192866 Chemfort™ Closed System Transfer Device (CSTD)**	**Equivalence to predicate**
Meets the NIOSH and ISOPP definition of a CSTD	Yes	Yes	Same

Discussions of differences in technological characteristics

Comment 1- The physical location of the predicate device's Chemfort™ port is different than that of the proposed device. The port of the Bag Adaptor SP (K192866) is located in the middle of the device body, in the distal part there is a tail to connect to an IV set, whereas in the proposed device, Bag Adaptor CP (K210707), the port is located in the distal part of the device.

Tests conducted to evaluate the difference: air & fluid tightness, bidirectional flow.

Comment 2- In the predicate device, Bag Adaptor SP (K192866), drug administration is performed by connecting an IV set to the tail, located in the distal part of the device. In the proposed device, Bag Adaptor CP (K210707), the Chemfort™ port also serves for drug administration by connecting one of CADM sets to the port located in the distal part BACP.

Tests conducted to evaluate the difference: tests according to ISO 8536-4, specifically; leakage, tensile strength, and flow rate.

Performance Data

Simplivia Healthcare conducted several performance tests to demonstrate that the OnGuard®2 Chemfort™ Closed Administration devices comply with the following standards and that they function as intended.

- ISO 8536-4:2010, Infusion equipment for medical use —Part 4: Infusion sets for single use, gravity feed.
    - Tests conducted to ensure compliance with the standard: leakage, tensile strength, closure piercing device, flow rate, tubing, drip chamber & drip tube, flow regulator & protective cap.
- ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.
    - Tests conducted to ensure compliance with the standard: positive pressure liquid leakage, sub-atmospheric pressure air leakage, stress cracking, resistance to separation from axial load, resistance to separation from unscrewing & resistance to overriding.
- USP <788> Particulate Matter in Injections
    - Particulate matter testing was conducted in accordance USP <788> and met the USP acceptance criteria.
- ISO 14971:2007, Medical devices- Application of risk management to medical devices

Biocompatibility

In accordance with ISO 10993-1, the CADM devices are classified as: Blood path, indirect, Contact Duration: Prolonged (24hrs to 30days). The following testing was conducted:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous reactivity
- Acute systemic toxicity
- Material mediated pyrogenicity
- Subacute/subchronic toxicity
- Hemolysis

Sterility, Shipping and Shelf-Life

- The OnGuard®2 Chemfort™ Closed Administration devices are supplied sterile for single-use. The devices are sterilized by Ethylene Oxide (EtO) gas to achieve a sterility assurance level (SAL) of at least 10^{-6}. The process underwent a full sterilization validation according to the 'overkill' (half cycle) approach.
- Residuals of Ethylene Oxide (EtO) and Ethylene Chlorhydrine (ECH) were tested after aeration and were found to comply with the requirements of ISO 10993-7:2008 for prolonged exposure devices (Category B).
- The bacterial endotoxins test (LAL) was performed using the kinetic turbidimetric methods for 10 samples (in pool) and was found to be less than 20 EU per device.
- A shelf life of three years has been established using the FDA recognized standard ASTM F1980-16 "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices", by exposing sterilized samples of CADM devices to accelerated aging equivalent to 3 years. Following the accelerated aging performance, functional and packaging integrity tests were performed. All tests passed according to the predetermined acceptance criteria.
- Package integrity testing, after environmental conditioning and simulated transportation in accordance with ISTA 3A, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.

  Sterile Barrier Packaging Testing was performed on the proposed device and were found to be in compliance according to the following standards:
  - Seal strength ASTM F88/F88-15
  - Dye penetration ASTM F1929-15

Conclusions

Simplivia Healthcare's OnGuard®2 Chemfort™ Closed Administration has the same intended use, indications for use, similar technological characteristics and principles of operation as its predicate device, K192866. Performance data demonstrated that the OnGuard®2 Chemfort™ Closed

Administration is as safe and effective as its predicate and does not raise any new safety and effectiveness issues. Thus, Simplivia Healthcare's OnGuard®2 Chemfort™ Closed Administration is substantially equivalent to its predicate device, K192866.