February 25, 2021

Simplivia Healthcare Ltd.
Shay Shaham
VP Qa/ra
North Industrial Zone
Kiryat Shmona, 1011801
Israel

Re: K201142
Trade/Device Name: TEVADAPTOR Bag Adaptor LL, TEVADAPTOR Bag Adaptor LL with ULTRASITE, TEVADAPTOR Bag Adaptor SP with ULTRASITE, TEVADAPTOR IV Secondary Safety Set with ULTRASITE, TEVADAPTOR IV Secondary Safety set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB, FPA
Dated: January 19, 2021
Received: January 25, 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
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201142

Device Name
I.V. Administration Set: TEVADAPTOR Bag Adaptor LL; TEVADAPTOR Bag Adaptor LL with ULTRASITE; TEVADAPTOR Bag Adaptor SP with ULTRASITE; TEVADAPTOR IV Secondary Safety Set with ULTRASITE; TEVADAPTOR IV Secondary Safety

Indications for Use *(Describe)*
Tevadaptor® 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.

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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K201142 510(k) Summary

Name: Simplivia Healthcare Ltd.
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Fax (972)4-8921665

Contact Person: Shay Shaham
VP QA & RA
Simplivia Healthcare Ltd.
Tel. (972)52-831-3378
Fax (972)4-8921665

Date Prepared: February 21, 2021

Name of Device: Intravascular Administration Set:
TEVADAPTOR Bag Adaptor LL
TEVADAPTOR Bag Adaptor LL with ULTRASITE
TEVADAPTOR Bag Adaptor SP with ULTRASITE
TEVADAPTOR IV Secondary Safety Set with ULTRASITE
TEVADAPTOR IV Secondary Safety

Common Name: Closed Drug Reconstitution and Transfer System

Classification: **Product Code:** ONB (primary), FPA (secondary)
Regulation No: 21 C.F.R. §880. 5440
Class: II
Regulation name: Intravascular administration set
Classification Panel: General Hospital

Predicate Device: I.V. Administration Set (K121269)

Reference Device: Chemfort™ Closed System Transfer Device (CSTD) (K192866)

Intended Use / Indications for Use

Tevadaptor® 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.

Device Description

The I.V. Administration Set is single use, sterile, non-pyrogenic device used to administer intravenous solutions and/or drugs solutions from a container to a patient's vascular system.

The I.V. Administration set is comprised of various components such as: Spike, tubing, clamp, ULTRASITE® needless injection site (Y-site), 'twist-off' and Luer connection.

The I.V. Administration set is part of the Tevadaptor® closed system transfer device (CSTD) and is intended to interact with Tevadaptor® and/or Chemfort™ system's Syringe Adaptor (SA), Syringe Adaptor Lock (SAL) and Luer Lock Adaptor (LLA) components that were cleared under K192866. The Tevadaptor® and Chemfort™ CSTD are intended to protect the healthcare professional, the patient and the environment during preparation, reconstitution, compounding and administration of hazardous drugs in the form of liquid, vapor or aerosol.

The Tevadaptor® and/or Chemfort™ SA connects to the Tevadaptor® port located on the I.V. Administration set's Spike component. After the connection is made, a fluid path is opened which allows to inject of the drug to the patient's IV bag. The Tevadaptor® and/or Chemfort™ LLA connects to any female luer connection located on the I.V. Administration set to create a Tevadaptor® port connection that enables the Tevadaptor® and/or Chemfort™ SA to administer the drug directly to the patient.

The purpose of this submission is to add five new designs of I.V. Administration Sets to the Tevadaptor® and/or Chemfort™ Closed System Transfer Device (CSTD) that was cleared for sale in the US under K192866, the descriptions of the added sets, subject of this submission:

- Tevadaptor® IV Secondary Safety Set with ULTRASITE®
- Tevadaptor® IV Secondary Safety Set
- Tevadaptor® Bag Adaptor LL
- Tevadaptor® Bag Adaptor LL with ULTRASITE®
- Tevadaptor® Bag Adaptor SP with ULTRASITE®

All of the components used in the five new I.V. Administration Sets were previously used in the predicate device cleared under K121269, except for the Spike component which has been redesigned in comparison to the predicate's Spike component that was cleared under K121269. The redesigned Spike component is substantially equivalent to the reference device, Chemfort™ Bag Adaptor SP's Spike component, which was cleared under K192866. The Spike component of both the IV Administration Set and of the reference device are identical in terms of design and raw material.

Summary of Technological Characteristics Including Modifications to the Device:

The following table compares the I.V. Administration sets 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.

Item	Predicate Device: Simplivia Healthcare Ltd. IV Administration Set (K121269)	Proposed Device: Simplivia Healthcare Ltd. IV Administration Set (K201142)	Equivalence to predicate
Product Code	FPA	ONB (primary) FPA (secondary)	K201142 sets were tested according to NIOSH and proved to be a CSTD
Regulation Number	880.5440	880.5440	Same
Indications for use	The I.V. Administration Set is a single use, sterile I.V. set for administration of fluids from a container to a patient's vascular system.	Tevadaptor® 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.	Since K201142 sets are under the ONB code, the intended use includes the following: The sets mechanically prohibit 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.
Components	Spike, drip chamber, tubing, flow regulator, clamp, ULTRASITE® Y injection site, Luer connection	Spike, drip chamber, tubing, flow regulator, clamp, ULTRASITE® Y injection site, Luer connection, twist-off	Similar
Sterilization	Ethylene Oxide validated cycle SAL 10^{-6}	Ethylene Oxide validated cycle SAL 10^{-6}	Same
Biocompatibility	Biocompatible	Biocompatible	Same
Interconnecting features	Mechanical snap connections, Luer lock connection, spike	Mechanical snap connections, Luer lock connection, spike	Same
Interaction with patient	No direct interaction - this is a secondary set	No direct interaction - this is a secondary set	Same
Indirect interaction with patient	Indirect interaction with the patient is achieved through the passage of IV fluids through the central tubing of the administration set	Indirect interaction with the patient is achieved through the passage of IV fluids through the central tubing of the administration set	Same

Item	Predicate Device: Simplivia Healthcare Ltd. IV Administration Set (K121269)	Proposed Device: Simplivia Healthcare Ltd. IV Administration Set (K201142)	Equivalence to predicate
Interaction with other devices	For most uses, this secondary administration set will connect to an IV solution container and a primary administration set. Other connections may be made through specific components of the set, such as the Spike Port and the ULTRASITE® Y injection site. while using the following Chemfort™ or Tevadaptor™ components: - Syringe Adaptor (K192866) - Syringe Adaptor Lock (K192866) - Luer Lock Adaptor (K192866)	For most uses, this secondary administration set will connect to an IV solution container and a primary administration set. Other connections may be made through specific components of the set, such as the Spike Port and the ULTRASITE® Y injection site, while using the following Chemfort™ or Tevadaptor™ components: - Syringe Adaptor (K192866) - Syringe Adaptor Lock (K192866) - Luer Lock Adaptor (K192866)	Same
Intended Shelf life	3 years	3 years	Same
Meets the NIOSH and ISOPP definition of a CSTD	N/A (the first draft protocol was issued in 2015)	Yes	The first draft protocol was issued after predicate 510(k)

Performance Data

Simplivia conducted several performance tests to demonstrate that the modified I.V. Administration sets comply with the following standards and that they function as intended.

- ISO 10993-1:2009, 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, Biological Evaluation of Medical Devices. Part 7: Ethylene oxide sterilization residuals.
- ISO 10993-10:2010, 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 10993-18:2005, Biological Evaluation of Medical Devices. Part 18: Chemical characterization of medical device materials within a risk management process.
- ISO 11135:2014, 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 8536-4:2010, Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed.
- ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.
- ISO 14971:2007 – Medical devices Medical devices — Application of risk management to medical devices

Substantial Equivalence

Simplivia Healthcare's modified I.V. Administration sets have the same intended use and principles of operation as its predicate device, K121269. Performance data demonstrate that the modified I.V. Administration sets are as safe and effective as their predicate device and do not raise any new safety and effectiveness issues. Thus, Simplivia Healthcare's modified I.V. Administration Sets are substantially equivalent to their predicate device, K121269.