DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 6, 2016

PharmaC, LLC
% Sigi Caron
Medtech Consultants, Inc.
20370 Skyhawk Lane
Topanga, California 90290

Re: K161800
Trade/Device Name: OnSite-IV™
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: November 7, 2016
Received: November 8, 2016

Dear Sigi Caron:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang
-S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161800

Device Name
OnSite-IV™

Indications for Use *(Describe)*
The OnSite-IV™ is a single use sterile device for the preparation and / or transfer of drugs from a standard pharmaceutical vial into an elastomeric pump or IV bag.

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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510(K) SUMMARY – K161800

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DATE PREPARED	December 6, 2016
APPLICANT	PharmaC, LLC. 6655 North Vista Lane Jackson, WY 83001 Tel: (307) 690-3648
OFFICIAL CORRESPONDENT	Sigi Caron Vice President, Regulatory and Clinical Affairs, PharmaC, LLC. Principal, MedTech Consultants, Inc. 20370 Skyhawk Lane Topanga, CA 90290 sigi@medtechconsultants.com Tel: (310) 455-3473 Fax: (888) 295-1535
TRADE NAME	OnSite-IV™
COMMON NAME	Vial Adapter / Reconstitution Device
DEVICE CLASSIFICATION	Regulation Number - 21 CFR §880.5440 Regulation Name - Intravascular administration set Product Code LHI, Class-II
PREDICATE DEVICE	E-Z-Link – K133097 IV Fluid Transfer Pin - K925401

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The OnSite-IV™ device is a sterile, single use device that, through the use of an integrated vial spike, facilitates creation of a sterile fluid path to transfer liquid from the syringe body to a standard pharmaceutical vial with a 20 mm cap containing a drug, in order to mix or reconstitute the drug and aspirate and transfer the prepared drug back into the syringe body for delivery into an IV bag or elastomeric pump. The device is intended to be used by health care professionals (HCPs) such as physicians, nurses and pharmacists in a clinical setting.

INDICATIONS FOR USE:

The OnSite-IV™ is a single use sterile device indicated for the preparation and / or transfer of drugs from a standard pharmaceutical vial into an elastomeric pump or IV bag.

SUBSTANTIALLY EQUIVALENT TO:

The OnSite-IV™ device is substantially equivalent in intended use and technological features to the E-Z Link device (K133097) and the IV Fluid Transfer Pin (K925401).

TECHNICAL CHARACTERISTICS:

The design and handling characteristics of the OnSite-IV are based on a standard injection syringe. The OnSite-IV consists of three main components: Syringe Barrel, Stopper, and Plunger with integrated vial spike (IV Fluid Transfer Pin - K925401). The Syringe Barrel has an elliptical shape with a Luer lock connector and is printed with graduation markers to indicate volume. The Syringe Barrel also has an arrow marker to indicate rotational position. The Stopper is an elastomeric sealing material that has an elliptical shape to prevent rotation within the Syringe Barrel. Rotation of the Stopper is prevented to allow the stopper to act as a valve. The Stopper has a fluid pathway and features that create a valve at the interface between the Plunger and Stopper. The Plunger has an internal fluid pathway along its length and an arrow marker to indicate rotational position. The integrated vial spike on the Plunger utilizes a bacterial retentive air-venting filter.

The OnSite-IV™ device shares the same design features as the predicate devices and does not introduce any new technological characteristics. The indications for use are similar. Both are intended for use to mix drugs in a standard pharmaceutical vial and to transfer the prepared drug back into the syringe. The OnSite-IV™ is used to transfer prepared drug into an IV bag or an elastomeric pump. This additional capability does not impact the performance of the OnSite-IV™. The following table compares the feature of the proposed device and its predicates.

ELEMENT	ONSITE-IV™	E-Z-LINK K133097	IV FLUID TRANSFER PIN K925401
Indications for Use	The OnSite-IV™ is a sterile, single use device indicated for the preparation and / or transfer of drugs from a standard pharmaceutical vial into an elastomeric pump or IV bag.	Single use, sterile device for preparation or drugs in a standard vial using liquid from a standard luer syringe to transfer the prepared drug back into the syringe for delivery.	Vented with security clip for preparing and dispensing diluent from standard 20 mm rubber-stoppered vials
Design Features			
Has vial adapter / vial access component	yes	yes	yes
Has a syringe component	yes	yes	No syringe component

ELEMENT	ONSITE-IV™	E-Z-LINK K133097	IV FLUID TRANSFER PIN K925401
Syringe and vial adapter integrated into one component	yes	No, 2 component system	No. Only vial adapter
Needleless access to vial	yes	No, contains plastic and stainless steel cannulas	yes
Sterile, biocompatible fluid path	yes	yes	yes
Assembled from plastic injection molded components	yes	yes	yes
Single use, sterile	yes	yes	yes
Principles of Operation			
Manually operated	yes	yes	yes
• mechanically connected to a drug vial	yes	yes	yes
• transfers liquid manually using a syringe plunger rod	yes	yes	No. Not supplied with syringe
• mixing / drug reconstitution achieved through manual agitation of the vial while connected to device	yes	yes	yes
• mixed drug is manually aspirated back into the syringe barrel using the syringe plunger rod	yes	yes	No. Not supplied with syringe

SUMMARY OF NONCLINICAL TESTING:

Design verification & validation testing was conducted per FDA recognized standards and additional device specific performance requirements. Testing per ISO 7886-1:1993 - Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use included:

- Limits for Acidity or Alkalinity
- Limits for Extractable Metals
- Tolerance on Graduated Capacity

- Dead Space
- Liquid Leakage at Syringe Piston under Compression
- Air Leakage at Syringe Piston under Compression
- Air Leakage past Syringe Piston during Aspiration
- Fiducial Line
- Fit of Piston in Barrel

Sterilization of the device was validated in accordance with the VD_{max}^{25} method described by ANSI/AAMI/ISO 11137-2:2013 to establish a 10^{-6} sterility assurance level (SAL).

Biocompatibility testing was conducted based on the nature and duration of contact, the construction of the device, and both the ISO 10993-1 recommendations and the FDA Guidance for Use of ISO10993-1:

- Cytotoxicity Study using the ISO Elution Method (ISO 10993-5)
- Maximization Sensitization (ISO 10993-10)
- Intracutaneous Reactivity Irritation Test in Rabbits (ISO 10993 Part 10)
- Acute Systemic Toxicity Test in Mice (ISO 10993-11)
- Hemolysis, Extract Method (ASTM F 756)
- Hemolysis, Direct Method (ASTM F 756)
- Materials Mediated Pyrogen Test in Rabbits (ISO 10993-11, USP <151>)

Additional performance testing of the device included:

- Luer Connection Performance (ISO 594-1, ISO 594-2)
- Particulate Matter (USP <788>)
- Performance of the Bacterial Retentive Filter (ASTM F2101)

Further performance-based testing to internal requirements was also conducted after sterilization, simulated transportation conditioning and accelerated aging:

- Visual Inspection
- Device Retained Volume After Use
- Drug Mixing
- Force to Operate Valve
- Graduated Marking Durability

All features provided for the OnSite-IV™ have been verified to operate as specified. Testing confirms that the OnSite-IV™ can be used according to its intended use and in an equivalent manner to the predicate devices.

CONCLUSIONS - BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The OnSite-IV™ is substantially equivalent to the listed predicate devices (E-Z Link device, K133097 and IV Fluid Transfer Pin - K925401) with respect to its indications for use (intended use) and technical characteristics. The differences between the E-Z Link and the OnSite-IV™ are that the E-Z link uses plastic and stainless steel cannulas to access the drug vial, and the syringe and adapter are provided as separate components. The OnSite-IV™, on the other hand, utilizes an integrated universal vial spike adapter (one integrated device, not two components). Testing per FDA recognized consensus standards, other standards and device specific bench testing demonstrate that the OnSite-IV™ functions as intended in the specific use conditions. The information and data provided in this 510(k) submission identifies that the subject device is substantially equivalent to the predicate devices.