November 3, 2021

Sol-Millennium Medical Group
Jim Barley
Director RA
315 Shawnee North Drive, Suite 100
Suwanne, Georgia 30024

Re: K202732
Trade/Device Name: SOL-CARE IV Bag Safety Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: October 7, 2021
Received: October 8, 2021

Dear Jim Barley:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202732

Device Name
SOL-CARE IV Bag Safety Connector

Indications for Use *(Describe)*
The SOL-CARE IV Bag Safety Connector is designed for drug administration to I.V. bag without using sharp hypodermic needle attached to a drug pre-filled syringe. It incorporates a shielded needle to allow safe access through the injection port of I.V. 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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SOL-MILLENNIUM®
Building a healthier tomorrow

510(k) Summary K202732

Date Prepared: November 2, 2021

A. Submitter Information

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Secondary Contact Person: James Barley
Director of RA
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B. Device Information

- Trade or Proprietary Name: SOL-CARE IV Bag Safety Connector
- Common Name: I.V. Fluid Transfer Set
- Regulation Name: Intravascular administration set
- Regulation Number: 21 CFR 880.5440
- Classification: Class II
- Establishment Registration Number - 3014312726
- Panel: General Hospital
- Product codes: LHI

C. Predicate device

- Predicate: K083851 Inviro Medical Blunt fill Needle

D. Device Description

SOL-CARE IV Bag Safety Connector HYP001

The device provides a simple, cost-effective solution to an everyday problem - how to make drug additions to an IV bag without using an exposed hypodermic needle attached to a drug-filled syringe. It incorporates a shielded needle to allow safe access through the 'rubber bung' on the INJECTION tail of an IV bag.

Catalog Number

Following is a listing of model numbers and product descriptions included in thissubmission:

Sol-Care Hypotec REF Catalog Numbers and Description	
REF/Catalog #	**Description**
HYP001	SOL-CARE IV Bag Safety Connector

E. Statement of Indications for Use

SOL-CARE IV Bag Safety Connector (HYP001)

The SOL-CARE IV Bag Safety Connector is designed for drug administration to I.V. bag without using sharp hypodermic needle attached to a drug pre-filled syringe. It incorporates a shielded needle to allow safe access through the injection port of I.V. bag.

F. Comparison of Technological Characteristics:

The SOL-CARE IV Bag Safety Connector is substantially equivalent to the InviroMedical Blunt Fill Needle.

The following table compares the physical, mechanical, biological and chemical specifications of the SOL-CARE IV Bag Safety Connector to the Inviro Medical Blunt Fill Needle.

ELEMENT OF COMPARISON	Inviro Medical Blunt Fill Needle (Predicate Device)	SOL-CARE IV Bag Safety Connector	Comments
Classification Name	Set, I.V. Fluid Transfer	Intravascular Administration Set	SE
Product Code	LHI	LHI	SE
510(k) #	K083851	K202732	N/A
Regulation Number	21CFR 880.5440	21CFR 880.5440	SE
Indications For Use	The Inviro Blunt and Inviro Blunt w/EZ Wings Cannulas are used in conjunction with a syringe as an additive device for aspiration from multi-dose medicine vials or injection into I.V. Systems and pre-	The SOL-CARE IV Bag Safety Connector is designed for drug administration to I.V. bag without using sharp hypodermic needle attached to a drug pre-filled syringe. It incorporates a shielded needle to allow safe access through the injection port of I.V. bag.	SE

	slit septums covering injection sites.		
principle of operation	Facilitate the transfer of medication from the medicine vial into a syringe, then inject the medication into an I.V. System.	Facilitate the transfer of medication from the syringe into the I'V. System.	SE
needle length	1-1/2"	1-1/2" and 2"	Different
needle gauge	18 gauge	18 gauge	SE
needle tip configuration	Blunt – 45 degree tip angle	Blunt – 45 degree tip angle	SE
lubricant	Silicone oil	Silicone oil	SE
reuse durability	No	No	SE
hub/needle bond strength	Per ISO 7886	Per ISO 7886	SE
Needle enclosed within Tube Holder	No	Yes	Different
biocompatibility	Per ISO 10993-1	Per ISO 10993-1	SE
Sterile	Yes	Yes	SE
Packaging	Silicone oil	Silicone oil	SE
materials	Needle Hub-Polypropylene, Needle – SUS 304, Glue – Epoxy and Cap - ABS	Needle Hub-Polypropylene, Needle – SUS 304, Glue – Epoxy, Tube Holder - Polypropylene	Different
labeling	Per 21 CFR 801	Per 21 CFR 801	SE

Discussion

The main differences between the SOL-CARE IV Bag Safety Connector and the predicate device, Inviro Medical Blunt Fill Needle include:

1. Indications for Use – The intended use of the SOL-CARE IV Bag Safety Connector is to inject medication into an I.V. Bag while the intended use of the Inviro Medical Blunt Fill Needle is to transfer medication from the medicine vial into a syringe and then inject that medication into a I.V. Bag. The indications for use of the proposed device are a subset compared to the predicate device indications for use. Both devices are used by the same type of healthcare professionals under the same conditions of use. Both devices have an identical principle of operation as well as mechanism of action. The differences in wording in the indications for use statements do not introduce new questions regarding safety or effectiveness due to their similarities in purpose, function and conditions of use.
2. Length of needle – The length of the Inviro Medical Blunt Fill Needle is 1.5 inches while the needle lengths for the SOL-CARE IV Bag Safety Connector are 1.5" and 2". The summary of testing below using FDA recognized standards shows additional tests conducted to address the differences in length of the needle. Performance testing demonstrated that the differences in length do not raise any questions of safety and effectiveness.
3. Needle enclosed within a Tube Holder – The Sol-Care I.V. Bag Connector has the BluntFill Needle enclosed within a Tube Holder while the Blunt Fill Needle alone does not have a Tube Holder. The summary of testing below using FDA recognized standards shows additional tests conducted to address the differences in length of the needle. Performance testing demonstrated that the differences in length do not raise any questions of safety and effectiveness.
4. Materials - The subject device includes some different materials in comparison to the predicate device. The biocompatibility and performance testing shows that differences in materials of construction do not raise any questions of safety or effectiveness. The list of test below shows the applicable biocompatibility tests for the Hypotec 001.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The SOL-CARE IV Bag Safety Connector met the appropriate requirements contained in thefollowing standards:

1. EN ISO 7864:2016, Sterile hypodermic needles for single use-Requirements and test methods.
2. EN ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcareapplications – Parts for intravascular or hypodermic applications.
3. EN ISO 9626:2016, Stainless Steel needle tubing for the manufacture of medical devices – Requirements and test methods
4. ISO 11607-1-2:2017, Packaging for terminally sterilized medical devices, Parts 1 and 2.
5. ISO 11135:2014, Sterilization of health care products – Ethylene oxide - Requirementsfor development, validation and routine control of a sterilization process for medical devices.
6. ISO 10993-1:2018, Biological evaluation of medical devices Part 1:Evaluation and testing

Summary of Testing:

The tests below are according ISO 7864 except as indicated with the relevant standard adjacent to the testing name.

- Cleanliness
- Defects of Needle
- Defects of needle point
- Lubricant
- Needle Gauge
- Needle Stiffness
- Needle Resistance to Breakage
- Bond Between Needle hub and Needle
- Patency of Lumen
- Distance from Needle tip to Protector Tube
- Connection Strength Between Protection tube and Needle Hub
- Penetration Force
- Luer connection testing per ISO 80369-7 and ISO 80369-20
- Flow Rate
- Priming Volume
- Particulate Contamination (ISO 8536-4:2019)
- Limits for acidity or alkalinity (For Needle)
- Limits of Extractable Metals (For Needle)
- Needle Resistance to Corrosion ISO 9626:2016
- Reducing Substance ISO 8536-4:2010
- Metal Ions ISO 8536-4:2010
- Titration Acidity or Alkalinity ISO 8536-4:2010
- Residue on Evaporation ISO 8536-4:2010
- UV Absorption of extract Solution ISO 8536-4:2010

Sterilization andPackaging Test according to ISO 11607

- Sterilization (EO/ECH residue) ISO 10993-7 :2008
- Appearance (visual check)
- Dimension (dimensional measurement)
- Printing (visual check)
- Tearing Force
- Clean Peel
- Dye Penetration
- UDI Identification
- Sticker readability and integrity (Visual)

Biological Test according ISO 10093

- Cytotoxicity (Tested to ISO 10993-5:2009)
- Sensitization (Tested to ISO 10993-10:2010)
- Irritation of Intracutaneous Reactivity (Tested to ISO 10993-10:2010)
- Acute Systemic Toxicity (Tested to ISO 10993-11:2006)

- Material Mediated Pyrogenicity (Tested to ISO 10993-11:2006)
- Hemocompatibility (ISO 10993-4:2017)
- Partial Thromboplastin (PTT) ISO 10993-4:2017
- Platelet Count ISO 10993-4:2017
- Haematology ISO 10993-4:2017

H. Discussion of Clinical Tests:

N/A

I. Conclusions Demonstrating Safety, Effectiveness and Performance:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The proposed devices, SOL-CARE IV Bag Safety Connector have been determined to be substantially equivalent to the predicate device, Inviro Medical Blunt Fill Needle that received marketing clearance on May 15, 2009 under 510(k) number K083851 with respect to the indications for use and technological characteristics.