June 1, 2022

Fresenius Kabi AG
℅ Keith Dunn
Director Regulatory Affairs
Fresenius Kabi LLC, USA
3 Corporate Dr Suite 300
Lake Zurich, Illinois 60047

Re: K212445
Trade/Device Name: **free***flex*®+ Transfer Adapter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: April 29, 2022
Received: May 2, 2022

Dear Keith Dunn:

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
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)*
K212445

Device Name
freeflex®+ Transfer Adapter

Indications for Use *(Describe)*
The freeflex®+ Transfer Adapter is indicated for reconstituting and/or admixing a drug in a vial with a 20mm closure and the transfer of the drug into the freeflex®+ IV Bag prior to administration to the patient. The device may be used for pediatric (newborn to 21 years) and adult populations.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K212445 - 510(k) SUMMARY

1. Submitter Information

Name: Fresenius Kabi AG

Address: Else-Kröner-Str. 1
61352 Bad Homburg

Contact Person: Keith Dunn
Director, Regulatory Affairs
Fresenius Kabi USA, LLC
Three Corporate Drive, 2nd Floor
Lake Zurich, IL 60047 USA

Telephone Number: (224) 817-2430
Fax Number: (847) 550 2960
E-mail: keith.dunn@fresenius-kabi.com
Date Prepared: April 21, 2022

Secondary Contact Person: Jason Ma
Sr. Manager, Regulatory Affairs
Fresenius Kabi USA, LLC
Three Corporate Drive, 2nd Floor
Lake Zurich, IL 60047 USA

Telephone Number: 224-817-4100
Fax Number: 847 550 2960
E-mail: Jason.ma01@fresenius-kabi.com

2. Device Name and Classification

Device Trade Name: free*flex*®+ Transfer Adapter
Common Name: IV Fluid Transfer Set
Classification Name: 21 CFR 880.5440 Intravascular administration set
Regulatory Class: II
Product Code: LHI
510(k) Number: K212445

3. Predicate Device

Device Trade Name: Vial2Bag Advanced™ 20mm Admixture Device
Common Name: IV Fluid Transfer Set
Classification Name: 21 CFR 880.5440 Intravascular administration set

Regulatory Class: II
Product Code: LHI
510(k) Number: K201415

4. Device Description

The **free***flex*®+ Transfer Adapter is a single use, fluid transfer device that allows for the reconstitution and transfer of powdered or liquid drugs from drug vials into the **free***flex*®+ IV Bag (NDA BN070012) through the IV bag medication port. The device consists of a body, male Luer lock and a safety ring. The device is provided as a sterile, non-pyrogenicproduct.

The device is intended to be used with standard drug vials with a seal diameter of 20mm, with an elastomeric membrane. The device does not contain any medicinal substances and there are no additional accessories needed or provided with the **free***flex*®+ Transfer Adapter for the device to meet its intended purpose.

5. Principle of Operation

The **free***flex*®+ Transfer Adapter is operated by manual manipulation. Initially, the vial opening that the transfer adaptor will connect to is disinfected with 70% isopropyl alcohol. Next the **free***flex*®+transfer adaptor is removed from the package. The protective cap is removed from the **free***flex*®+ IV bag injection port and the injection port is disinfected with 70% isopropyl alcohol. The **free***flex*®+transfer adaptor is connected to the injection port, then attached to the drug vial. Fluid is transferred manually from the IV bag to the drug vial to reconstitute/dilute drug powder/liquid prior to being transferred back to the IV bag. Once the drug is transferred to the IV bag the transfer adapter is removed from the IV bag and discarded. Finally, the **free***flex*®+IV bag injection port is capped with a protective cap.

6. Indication for Use/ Intended Use

Indication for Use:

The **free***flex*®+ Transfer Adapter is indicated for reconstituting and/or admixing a drug in a vial with a 20mm closure and the transfer of the drug into the **free***flex*®+ IV Bag prior to administration to the patient. The device may be used for pediatric (newborn to 21 years) and adult populations.

7. Substantial Equivalence

Intended Use/Indication for Use—Discussion of Differences

The subject and predicate devices have the same intended use. The indication for use of the subject and predicate device are equivalent and do not create a new intended use.

- The indication for use for the subject device is limited to vials with a 20mm

closure.
- The subject device is only indicated for use with the **free***flex*®+ IV Bag.
- The predicate device does not indicate the patient population for which it may be used.

Physical Characteristics

The subject and predicate devices share the following physical characteristics:

- Flanges on the device provide secure attachment to the drug vial.
- A spike pierces the IV bag and drug vial for fluid transfer, providing a needle-free connection.

Technological Characteristics—Discussion of Differences

1. The predicate device is designed to attach to the administration port of a standard IV bag, size 50, 100 or 250 mL while the subject device is designed to attach only to the **free***flex*®+ IV Bag sizes 50, 100, 250, 500, or 1000 mL using the medication port.

2. The predicate device allows connection of an external IV administration set using an IV port with a twist off feature while the subject device, **free***flex*®+ Transfer Adapter, does not connect to an external administration set.

3. The predicate device allows connection of the Vial2Bag Advanced™ 20mm Admixture Device directly into the administration path while the subject device connects to the medication port of the IV Bag, which is not part of the administration path.

4. The predicate device allows connection to 20mm device (or smaller). The proposed device is designed for use with vials with 20mm opening only.

5. The main body of both devices is made of polycarbonate. The subject device has an additional component made of polypropylene (nut) that is not fluid contacting

Conclusion on Substantial Equivalence

The **free***flex*®+ Transfer Adapter has the same intended use and equivalent indication for use as the predicate device. The subject device has similar technological characteristics to the predicate, and the descriptive and performance information provided within this premarket notification demonstrates that:

- any differences do not raise different questions of safety and effectiveness compared to the predicate device; and
- the proposed device is at least as safe and effective as the legally marketed predicate device.

Based on the comparison of the intended use and the technological characteristics, the subject device is substantially equivalent to the currently marketed predicate Vial2Bag Advanced™ 20mm Admixture Device.

8. Comparison of the Technological Characteristics with the Predicate Device

The technological characteristics of the subject device, **free***flex*®+ Transfer Adapter, are substantially equivalent to those of the predicate device, Vial2Bag Advanced™ 20mm Admixture Device, in regard to the following technological characteristics:

- Principle of operation and conditions of use of the subject device are equivalent to those of the predicate device.
- Material composition of the subject device is equivalent to that of the predicate device in that both devices are made from plastics used in medical devices of this type. Material composition of the proposed device does not raise new questions of safety and effectiveness, as demonstrated by performance testing and biocompatibility evaluation.
- Physical specifications of the subject device are equivalent to those of the predicate device. The freeflex®+ Transfer Adapter does not raise new questions of safety and effectiveness, as demonstrated by performance testing.
- Design features and interfaces are equivalent in that both devices connect to a drug vial and IV bag and allow for fluid transfer between the drug vial and IV bag. The subject device is limited for use with the **free***flex*®+ IV Bag only. Performance verification of the subject device does not raise new questions of safety and effectiveness.
- Sterilization method and SAL level are identical between the subject andpredicate device.

A comparison between the predicate device and the subject device is provided in Table 1.

Table 1: Summary of Substantial Equivalence Comparison

Areas for Comparison	Subject Device K212445	Predicate Device K201415	Comparison
Product Code and Regulation	LHI 21 CFR 880.5440	LHI 21 CFR 880.5440	Same
Classification	Class II (non-exempt)	Class II (non-exempt)	Same
Review Panel	General Hospital	General Hospital	Same
Type of Use	Prescription use only	Prescription use only	Same
Conditions of Use	Single use only	Single use only	Same
Sterilization Method	Ethylene oxide	Ethylene oxide	Same
Indication for Use	The **free***flex*®+ Transfer Adapter is indicated for reconstituting and/or admixing a drug in a vial with a 20mm closure and the transfer of the drug into the **free***flex*®+ IV Bag prior to administration to the patient. The device may be used for pediatric (newborn to 21 years) and adult populations.	The Vial2Bag Advanced™ 20mm Admixture Device is indicated to serve as a connection between a 50, 100, or 250ml IV bag, vial with 20mm closure, and an external IV administration set. The integrated Vial Adapter makes it possible to reconstitute and/or admix drugs prior to administration to the patient.	Similar The differences are minimal and do not impact the risk to patient or user. Both devices have the same intended use for the reconstitution and transfer of drug content from the vial into the IV bag. The predicate is indicated for use with any standard IV bag whereas the **free***flex*®+ Transfer Adapter is for use only the **free***flex*®+ IV Bags.
Operation Principle	Manual	Manual	Same

Areas for Comparison	Subject Device K212445	Predicate Device K201415	Comparison
Design	The **free***flex*®+ Transfer Adapter is made of plastic materials and is a single use, sterile, non-pyrogenic transfer adapter device that connects to a 20mm seal diameter drug vial. The spike of the transfer device pierces the seal of the drug vial and allows for the reconstitution/dilution and transfer of drugs to a 50, 100, 250, 500 or 1000 mL **free***flex*®+ IV bag. Fluid is transferredfrom the IV bag to the drug vial by a manual process to reconstitute/dilute the drug prior to being transferred back to the IV bag. Once the drug is transferred to the IV bag the transfer adapter is removed from the IV bag and discarded.	The Vial2Bag Advanced™ 20mm Admixture Device is a single use, fluid transfer device that allows for the reconstitution and transfer of fluids from drug vials into the IV bag containing infusion solution, through the IV bag administration port. The device consists of the body, Protector, IV Port, and an integrated vial adapter. The Vial2Bag connects the IV bag and IV set and creates a fluid path. The Vial2Bag Advanced 20 mm Admixture Device's integrated vial adapter connects to the body of the Vial2Bag and to a 20mm (or smaller) seal diameter drug vial. The vial adapter spike pierces the seal of the drug vial. Fluid from the IV bag is transferred into the drug vial by a manual process to reconstitute/dilute the drug. Once reconstituted/diluted the drug solution is transferred to the IV bag. The vial adapter can remain attached to the Vial2Bag during drug delivery or alternatively be removed and discarded. The device works with standard 50, 100, 250mL IV bags.	Different The difference is minimal and does not impact the risk to patient or user. The Vial2Bag is a system which contains a vial adapter which is attached to the Vial2Bag system when reconstituting/admixing the drug and transferring it to the IV bag. The vial adapter can stay attached to the Vial2Bag device during drug delivery to the patient or be removed from the Vial2Bag device and discarded. The **free***flex*®+ Transfer Adapter is only the adapter. It is attached to the IV bag and drug vial. The drug is reconstituted/admixed and then once the drug has been transferred to the IV bag the **free***flex*®+ Transfer Adapter is removed from the IV bag and discarded.
Materials	Body: Polycarbonate Nut: Polycarbonate Safety Ring: Polypropylene	Body: Polycarbonate Option for siliconized spike Vented adapter has PTFE 0.2 micron air filter	Different The difference is minimal and does not impact the risk to patient or user. The main body of both devices is made of

Areas for Comparison	Subject Device K212445	Predicate Device K201415	Comparison
			polycarbonate. The subject device has an additional component made of polypropylene (nut) that is not fluid contacting
Biocompatibility	- Hemolysis - Cytotoxicity - Irritation - Skin Sensitization - Acute Systemic Toxicity - Chemical Characterization - Pyrogenicity - Particulate Testing	- Hemolysis - Cytotoxicity - Irritation - Skin Sensitization - Acute Systemic Toxicity - Sub-chronic Toxicity - Pyrogenicity - Particulate Testing	Similar The difference is not affecting the determination of an unacceptable adverse biological response. The subject device has additional evidence in chemical characterization whereas the predicate device was tested on sub-chronic toxicity. However, the sub-chronic toxicity testing is not required because the subject device is removed from the IV Bag after a few minutes and does not remain attached.
Drug Form	Powdered or liquid	Powdered or liquid	Same
Vial Size	20 mm	20 mm (or smaller)	Similar The difference is minimal and does not impact the risk to patient or user. The predicate device may be used with smaller size drug vials
Bag System	**free***flex*® + IV Bag	Standard IV Bag	Different The difference is minimal and does not impact the risk to patient or user. The predicate device may be used with any standard IV bag while the subject device mayonly be used with the **free***flex*® + IV Bag
Bag Size	50, 100, 250, 500, 1000 mL	50, 100, 250mL	Similar The difference is minimal and does not impact the risk to patient or user. The **free***flex*®+ Transfer Adapter can connect toadditional

Areas for Comparison	Subject Device K212445	Predicate Device K201415	Comparison
			sizes of IV bags compared to the predicate.
Performance Testing	USP<788> ISO22413 ISO80369-20 ISO11607-1 Internal Test Methods for mechanical and performance characteristics.	ISO 8536-4 Internal Test Methods for mechanical and performance characteristics.	Different For particulate testing the subject device followed USP<788> versus ISO8536-4 for the predicate. For other performance tests the subject device followed FDA recognized standards including ISO22413, ISO80369-20, ISO11607-1, as well as in house test methods versus in house test methods were followed for the predicate device.

9. Performance Testing—Bench

Functional performance bench testing was conducted to demonstrate that the **free***flex*®+ Transfer Adapter performs as intended. No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

The following performance testing was conducted to support the substantial equivalence determination (Table 2):

Table 2: Performance Testing: Subject Device

ISO 22413:2013 Transfer sets for pharmaceutical preparations	Fragmentation
USP <788> Particulate Matter in Injections Test method 1	Particulate Testing
ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	Luer Connector Leakage Stress Cracking Resistance Testing
ISO 11607-1 (2019-02) Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems	Sterile Barrier Systems Validation
Internal device performance test methods	• Visual Inspection • Penetration Force • Force to Remove Safety Ring • Separation under Tensile Force • Residual Volume in Adapter-Vial-System

9. Biocompatibility Testing

Following the FDA Guidance: "Use of International Standard ISO 10993-1, Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process", the tests selected were for prolonged externally communicating devices. The following biocompatibility tests were successfully conducted on the **free***flex*®+ Transfer Adapter:

- Hemolysis
- Cytotoxicity
- Irritation
- Skin Sensitization
- Acute Systemic Toxicity
- Chemical Characterization
- Material Mediated Pyrogenicity
- Particulate Testing

10. Sterilization Validation

Sterilization was achieved by ethylene oxide and meets the requirements of DIN EN 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. The ethylene oxide sterilization method achieves a Sterilization Assurance Level (SAL) of 10^{-6}.

11. Conclusion

The **free***flex*®+ Transfer Adapter, has met all established acceptance criteria for performance testing and design verification testing. Results of functional performance and biocompatibility testing conducted with the **free***flex*®+ Transfer Adapter, demonstratethat the subject device supports a substantial equivalence determination to the predicate device, Vial2Bag Advanced™ 20mm Admixture Device (K201415), as described in Section 7.