March 15, 2019

sfm medical devices GmbH
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K183187
Trade/Device Name: nextaro® Transfer System, nextaro® va
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI
Dated: February 18, 2019
Received: February 21, 2019

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sapana Patel -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183187

Device Name
The nextaro® Transfer System and nextaro® va

Indications for Use *(Describe)*
The nextaro® Transfer System and nextaro® va is indicated for the transfer and mixing of drugs contained in vials.

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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510K SUMMARY
K183187

Submitter's Name and Address	sfm medical devices GmbH Brueckenstrasse 5 Waechtersbach Hessen GERMANY 63607
Manufacturer	sfm medical devices GmbH Brueckenstrasse 5 Waechtersbach Hessen GERMANY 63607
Contact Person:	Phil Triolo Phone: 801-699-9846 Facsimile: 801-328-2399
Date Prepared:	March 14, 2019
Device:	nextaro® Transfer System and nextaro® va
FDA Product Code:	LHI
Class:	II
Common or Usual Name:	I.V. Fluid Transfer Set
Regulation Description:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Legally Marketed Predicate:	Mix2Vial® Transfer Device (K031861) West Pharmaceutical Services, Inc.
Reason for Submission:	New Device
Device Description:	The nextaro® Transfer System and nextaro® va is indicated for the transfer and mixing of drugs contained in vials. The nextaro® Transfer System and nextaro® va is practically one system with two variants which are to be used independently.

Technological Characteristics:

The ***nextaro® Transfer System*** consists of two components already assembled (screwed together) in the delivery condition. Each of the components has a plastic spike which is used to perforate the seals of a solvent vial, or lyophilizated pharmaceutical vial, respectively. The components have a male and female Luer adapter to create an air-tight inner media-carrying system with open ends for fluid transfer. Both components are equipped with a filter element to prevent particles (fragments of vial seals, undissolved pharmaceutical) from being administered into the patient's circulatory system.

To be used as intended, the spike of the blue ("upper") part of the nextaro® Transfer System is used to perforate the seal of the solvent vial. The assembly is flipped vertically and the spike of the white ("lower") part of the device is used to perforate the seal of the pharmaceutical vial. The solvent transfer process starts immediately due to the vacuum in the pharmaceutical vial.

After solvent transfer and reconstitution of the pharmaceutical by gentle swirling, the blue component of the device is removed from the white part by unscrewing, a standard syringe with a male Luer is attached to the exposed female Luer of the device to aspirate the ready-to-use solution.

The ***nextaro® va*** is a standalone device. Basically, it is the lower part of the nextaro® Transfer System, but without the thread which the latter has to connect the upper part. After connecting the nextaro® va to a pharmaceutical vial by pushing it downwards, a solvent can be transferred by a syringe via the female Luer. After solvent transfer and reconstitution of the pharmaceutical by gentle swirling, a standard syringe with a male Luer is attached to the female Luer of the device to aspirate the ready-to-use solution.

Indications for Use:

The nextaro® Transfer System and nextaro® va is indicated for the transfer and mixing of drugs contained in vials.

Substantial Equivalence Comparison:

Areas for Comparison	Predicate Device Mix2Vial K031861	Proposed Device nextaro® Transfer System	Proposed Device nextaro® va	Comparison
Indications for Use				
Intended use or indications	Intended for transferring and mixing drugs contained in two vials	Indicated for the transfer and mixing of drugs contained in vials	Indicated for the transfer and mixing of drugs contained in vials	See Discussion of Differences
Regulatory Information				
Device Classification Name	Set I.V. Fluid Transfer	Set I.V. Fluid Transfer	Set I.V. Fluid Transfer	Equivalent
Regulation Number	880.5440	880.5440	880.5440	Equivalent
Regulation Description	Intravascular Administration Set	Intravascular Administration Set	Intravascular Administration Set	Equivalent
Product Code	LHI	LHI	LHI	Equivalent

Areas for Comparison	Predicate Device Mix2Vial K031861	Proposed Device nextaro® Transfer System	Proposed Device nextaro® va	Comparison
Regulatory Medical Specialty	General Hospital	General Hospital	General Hospital	Equivalent
Device Class	2	2	2	Equivalent
GMP Exempt	No	No	No	Equivalent
Design Features				
Uses vacuum pressure	Yes	Yes	No	See Discussion of Differences
Vial size the product is to be used with	20 mm / 14 mm	20 mm	20 mm	Equivalent to 20 mm model
Vial adapter / vial access component	Yes	Yes	Yes	Equivalent
In-line liquid filter	Yes	Yes	Yes	Equivalent
Mesh opening	15 µm	11 µm	11 µm	See Discussion of Differences
Open area	9 %	5 %	5 %	See Discussion of Differences
Female Luer adapter for connection to syringes	Yes	Yes	Yes	Equivalent
Luer adapter and vial adapter are integrated in one component	Yes	Yes	Yes	Equivalent
Needleless access to vial	Yes	Yes	Yes	Equivalent
Sterile, biocompatible fluid path	Yes	Yes	Yes	Equivalent
Manufactured by plastic injection molding	Yes	Yes	Yes	Equivalent
Single use, sterile	Yes	Yes	Yes	Equivalent
Sterilization	Gamma / EtO	EtO	EtO	Equivalent to one of the methods (EtO)
Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	SAL 10^{-6}	Equivalent
Biocompatibility	Pass	Pass	Pass	Equivalent
Shelf Life	> 3 years	5 years	5 years	Equivalent
Principles of Operation				
Manually operated	Yes	Yes	Yes	Equivalent
Mechanically connected to a drug vial	Yes	Yes	Yes	Equivalent
Transfers solvent manually using a syringe plunger rod	No	No	Yes	similar
Drug reconstitution through manual agitation of vial while connected to device	Yes	Yes	Yes	Equivalent
Mixed drug is manually aspirated into a syringe barrel using the syringe plunger rod	Yes	Yes	Yes	Equivalent

Areas for Comparison	Predicate Device Mix2Vial K031861	Proposed Device nextaro® Transfer System	Proposed Device nextaro® va	Comparison
Single Use	Yes	Yes	Yes	Equivalent
Materials				
Transfer device	Polycarbonate	Polypropylene, TPE	Polypropylene	Similar
In-line Filter	Polyethylene terephthalate	Polyethylene terephthalate	Polyethylene terephthalate	Equivalent
Packaging	Blister Pack: PETG Lid: Tyvek	Blister Pack: PETG Lid: Tyvek	Blister Pack: PETG Lid: Tyvek	Equivalent

Discussion of Differences

Difference in Indications: While the indications for use for the nextaro® Transfer System and nextaro® va are worded slightly different than that of the predicate device, both the subject devices and predicate device are used for the same purpose: The transfer of solvents into a drug vial / the aspiration of the ready-to-use solution of the dissolved pharmaceuticals which are contained in vials. The nextaro® Transfer System is intended to be used with *two* vials (solvent and pharmaceutical agent vial) just as is the predicate device, while the nextaro® va is intended to be used with *one* vial (pharmaceutical agent vial; the solvent transferred into pharmaceutical agent vial by a syringe with male Luer adapter filled with solvent). There is no critical difference in the intended therapeutic use of the subject and predicate devices.

Uses Vacuum Pressure: The nextaro® Transfer System, the nextaro® va and the Mix2Vial all are used to transfer solvent into a vial which contains a freeze-dried pharmaceutical agent (lyophilizate). All of the devices use pressure to transfer the solvent: In the case of the nextaro® Transfer System, the devices use the negative pressure within the pharmaceutical agent vial to transfer the solvent from the solvent vial which was connected to the device beforehand, just as is the case with the predicate device. The nextaro® va also uses pressure to transfer the solvent, but due to the design of the nextaro® va, the solvent must be applied by means of a syringe. However, the direction of the solvent flow is the same for all predicate and subject devices.

There is no critical difference in the use of vacuum pressure or manual pressure (to the plunger of the syringe) to transfer the solvent. The solvent transfer methods of the subject and predicate devices can be regarded as equivalent.

Filter Elements: The nextaro® Transfer System, the nextaro® va and the Mix2Vial all are equipped with filter elements, to retain fragments which could be punched out during perforation of the vial seals from being transferred or aspirated into the ready-to-use solution. The same applies for undissolved pharmaceutical agent particles.

The filter mesh used in the nextaro® and nextaro® va are capable to retain particles of $\geq$ 15 µm size. A retention rate of > 95 % of particles sized $\geq$ 15 µm has been confirmed by testing. The performance of the filters (retention) of the subject and predicate devices has been shown to be substantially equivalent.

Shelf life: The predicate device has a shelf-life of > 3 years while the subject devices have a shelf-life of 5 years. The packaging materials are equivalent. The subject devices are substantially equivalent with regard to their shelf-life. This does not raise different questions of safety or effectiveness

Materials: Both the predicate and the nextaro® devices are made of biocompatible thermoplastic polymer materials. Although the basic materials for the manufacturing of the devices is not the same, the performance tests show that the subject devices are substantially equivalent regarding the performance of the devices. Both the subject device and predicate use the same filter material (PET). The biocompatibility tests show that the subject devices are biocompatible and can therefore be regarded as substantially equivalent in regard to biocompatibility.

Testing

The following tests were conducted to demonstrate that the nextaro® Transfer System and nextaro® va perform as intended.

Standard	Test Performed
ISO 22413	• Fragmentation • Penetration Force • Piercing • Verification of Design Specifications for Transfer Devices with Housing
ISO 594-2	• Male Conical Fitting / Luer Connector
ISO 8536-4	• Flow Rate of Infusion Fluid • Fluid Filter (Retention Rate) • Leakage (Aging/ Submersion Test) • Metal Ions • Particulate Contamination • Penetration Force • Reduction of Oxidizable Matter • Residue on Evaporation • Tensile Strength • Titration Acidity or Alkalinity • UV Absorption of Extract Solution

Standard	Test Performed
ISO 11607 ASTM D3078 ASTM F 1886 ASTM F 1929-12 ASTM F 1980-07 ASTM F 2054-07, EN 868-5 ISTA 2A	• Sterile Barrier and Packaging Systems • Bubble Emissions • Integrity of Seals • Seal Leakage • Accelerated Aging • Seal Strength • Transport Testing
USP <85> , USP <161>	• Bacterial Endotoxin
N/A	• Roll Inhibition (to design specification) • Transfer performance for residual volume (to design specification) • Opening torque (to design specification)

Biocompatibility

Tests were conducted to show that the nextaro® Transfer System and the nextaro® va were evaluated for biocompatibility in accordance with ISO 10993-1. Filter particulate testing was also conducted (see above table).

Material Mediated Pyrogenicity
LAL Testing

Sterility

The sterility of the nextaro® Transfer System and nextaro® va were validated in accordance with 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 maximum levels of ethylene oxide (EtO) and ethylene chlorohydrin (ECH) residuals remaining on the products were within the guidelines for limited and tolerable contact limit devices according to ISO 10993-7:2008.

Summary / Conclusion

The evaluation of the proposed nextaro® devices has demonstrated through performance testing to be substantially equivalent to the predicate device. Based on the device type, indications, intended use, technological characteristics, physical characteristics, the nextaro® Transfer Device and nextaro® va are substantially equivalent to the predicate device.