April 16, 2024

sfm medical devices GmbH
Olaf Broemsen
Head of Development & Regulatory
Brueckenstrasse 5
Waechtersbach, 63607
Germany

Re: K240748
Trade/Device Name: nextaro® v, 20/20
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI,
Dated: March 11, 2024
Received: March 19, 2024

Dear Olaf Broemsen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240748

Device Name
nextaro® v, 20/20

Indications for Use *(Describe)*
The nextaro® v, 20/20 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.

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

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510K SUMMARY

Submitter:	sfm medical devices GmbH Brueckenstrasse 5 Waechtersbach Hessen GERMANY 63607
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US Agent:	Phil Triolo Phone: 801-699-9846 Facsimile: 801-328-2399
Date Prepared:	March 11, 2024
Device: **510(k) number:**	nextaro® v, 20/20 K240748
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:	nextaro® Transfer System (K183187), sfm medical devices GmbH
Indications for Use:	The nextaro® v, 20/20 is indicated for the transfer and mixing of drugs contained in vials.
Device Description:	The nextaro® v, 20/20 is a sterile-packaged transfer device with ventilation on solvent side with built-in particle filter (15µm nominal) installed on solvent and drug side and a female Luer-Lock adapter for the connection of a single-use syringe for a low-particle withdrawal of the prepared drug solution.

Technological Characteristics:

The nextaro® v, 20/20 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 at the spikes.

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® v, 20/20 is used to perforate the seal of the solvent vial. The assembly is flipped vertically and the spike of the white ("bottom") 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.

The spike of the upper part has two lumens. One lumen allows air to enter the solvent vial so that ventilation takes place during the transfer. The other lumen ensures that the solvent is transferred to 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 prepared solution.

Substantial Equivalence Comparison:

Areas for Comparison	**Predicate Device nextaro® transfer system K183187**	**Proposed Device nextaro® v, 20/20**	**Comparison**
Indications for Use			
Intended use or indications	Indicated for the transfer and mixing of drugs contained in vials	Indicated for the transfer and mixing of drugs contained in vials	Same
Regulatory Information			
Device Classification Name	Set I.V. Fluid Transfer	Set I.V. Fluid Transfer	Same
Regulation Number	880.5440	880.5440	Same
Regulation Description	Intravascular Administration Set	Intravascular Administration Set	Same
Product Code	LHI	LHI	Same
Regulatory Medical Specialty	General Hospital	General Hospital	Same
Device Class	2	2	Same
GMP Exempt	No	No	Same

Areas for Comparison	Predicate Device nextaro® transfer system K183187	Proposed Device nextaro® v, 20/20	Comparison
Design Features			
Vial size the product is to be used with	20 mm (water side) 20 mm (drug side)	20 mm (water side) 20 mm (drug side)	Same
Has vial adapter / vial access component	Yes	Yes	Same
Uses vacuum pressure	Yes	Yes	Same
Air inlet at water side	No	Yes	Different See Discussion of Differences
In-line liquid filter	Yes	Yes	Same
Mesh opening	11 µm	11 µm	Same
Female Luer adapter for connection to syringes	Yes	Yes	Same
Luer adapter and vial adapter are integrated in one component	Yes	Yes	Same
Needleless access to vial	Yes	Yes	Same
Sterile, biocompatible fluid path	Yes	Yes	Same
Manufactured by plastic injection molding	Yes	Yes	Same
Single use, sterile	Yes	Yes	Same
Sterilization	EtO	EtO	Same
Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	Same
Biocompatibility	Pass	Pass	Same
Shelf Life	5 years	5 years	Same
Principles of Operation			
Manually operated	Yes	Yes	Same
Mechanically connected to a drug and solvent vial	Yes	Yes	Same
Drug reconstitution achieved through manual agitation of vial while connected to device	Yes	Yes	Same
Mixed drug is manually aspirated into a syringe barrel using the syringe plunger rod	Yes	Yes	Same

Areas for Comparison	Predicate Device nextaro® transfer system K183187	Proposed Device nextaro® v, 20/20	Comparison
Single Use	Yes	Yes	Same
Materials			
Transfer device	Polypropylene	Polypropylene	Same
In-line Filter	Polyethylene terephthalate	Polyethylene terephthalate	Same
Packaging	Blister Pack: PETG Lid: Tyvek	Blister Pack: PETG Lid: Tyvek	Same

Discussion of Differences

Air inlet at water side	The proposed device has a different spike design with an air inlet at the water side (upper part). The air inlet on the water side enables the transfer of pharmaceuticals into low pressure vials.

Performance Testing

The modification to the proposed device was evaluated and a risk assessment has been performed. The following non-clinical tests were conducted on the proposed device, nextaro® v, 20/20, to ensure that potential risks associated with the modification were mitigated to acceptable levels.

Test name	Testing Standard
Penetration force	ISO 22413 (using a test procedure outlined in Annex B of ISO 8536-2)
Fragmentation	ISO 22413
Transfer performance (practical transfer and residual volume)	Internal performance standard
Verification of the design specification for Transfer devices with housing	ISO 22413

Testing verified that all acceptance criteria were met.

Summary / Conclusion

The nextaro® Transfer System and nextaro® v, 20/20, have the same indications, principles of operation, and technological characteristics, such as performance, materials, design, sterilization, biocompatibility, and packaging. The only technological difference is the spike design on the water side (upper part). Testing demonstrates that the difference does not present any new concerns of safety or effectiveness. The modifications made to the subject device, nextaro® v, 20/20, do not affect the intended use of the device, nor do they alter its fundamental scientific technology compared to the predicate device, the

nextaro® Transfer System. Thus, the nextaro® v, 20/20 is substantially equivalent to the predicate, nextaro® Transfer System.