September 6, 2024

SFM Medical Devices GmbH
Olaf Broemsen
Head of Development & Regulatory
Brueckenstrasse 5
Waechtersbach Hessen, 63607
Germany

Re: K241976
Trade/Device Name: nextaro® va, 15mm, 5µm
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI
Dated: August 9, 2024
Received: August 9, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*
K241976

Device Name
nextaro® va, 15mm, 5µm

Indications for Use *(Describe)*
The nextaro® va, 15mm, 5µm 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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K241976 - 510K SUMMARY

Submitter:	sfm medical devices GmbH Brueckenstrasse 5 Waechtersbach Hessen GERMANY 63607
Contact Person:	Dr. Olaf Brömsen Head of Development & Regulatory Phone: +49 (6053) 805-224 E-Mail: olaf.broemsen@sfm.de
US Agent:	Phil Triolo Phone: 801-699-9846 Facsimile: 801-328-2399
Date Prepared:	July 05, 2024
Device: **510k number:**	nextaro® va, 15mm, 5µm K241976
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® va (K183187), sfm medical devices GmbH

Indications for Use:	The nextaro® va, 15mm, 5µm is indicated for the transfer and mixing of drugs contained in vials.
Device Description:	The nextaro® va, 15mm, 5µm is a sterile packaged vial adapter for single withdrawal of drug solutions with a single-use syringe via Luer adapter from drug vials or for one-time injection of a low-particle and sterile solution with immediate withdrawal of the prepared drug solution with a single-use syringe via Luer adapter from drug vials.

Technological Characteristics:

The nextaro® va has a plastic spike which is used to perforate the seal of a vial and a female luer adapter for connecting a standard syringe with male luer lock.
The fluid transfer assembly is designed with an in-line filter to ensure that any particulates (fragments of vial seals, undissolved pharmaceutical) remain in the vial.
To be used as intended, the nextaro® va is attached to a vial and the spike perforates the rubber stopper of the vial. After attachment to the drug vial, a low-particle, sterile solvent can be transferred into the drug vial with a syringe via the female luer and mixed and/or the drug solution can be drawn up with the single-use syringe.

Substantial Equivalence Comparison:

Areas for Comparison	Predicate Device nextaro® va K183187	Proposed Device nextaro® va, 15mm, 5µm	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
Design Features			
Vial size the product is to be used with	20 mm	15 mm	Different, see Discussion of Differences
Packaging size	Dimensioned for 20mm vial adapter	Dimensioned for 15mm vial adapter	Different, see Discussion of Differences

Areas for Comparison	Predicate Device nextaro® va K183187	Proposed Device nextaro® va, 15mm, 5µm	Comparison
Has vial adapter / vial access component	Yes	Yes	Same
Uses vacuum pressure	No	No	Same
In-line liquid filter	Yes	Yes	Same
Filter type	Mesh filter, Mesh size 15 µm nominal	Membrane filter, Pore size 5µm nominal	Different, see Discussion of Differences
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 evaluation	Pass	Pass	Same
Shelf Life	5 years	5 years	Same
Principles of Operation			
Manually operated	Yes	Yes	Same
Mechanically connected to a drug vial	Yes	Yes	Same
Transfer solvent manually using a syringe plunger rod	Yes	Yes	Same
Mixing / Drug reconstitution achieved through manual agitation of vial while connected to device	Yes	Yes	Same

Areas for Comparison	Predicate Device nextaro® va K183187	Proposed Device nextaro® va, 15mm, 5µm	Comparison
Mixed drug is manually aspirated into a syringe barrel using the syringe plunger rod	Yes	Yes	Same
Single Use	Yes	Yes	Same
Materials			
Transfer device	Polypropylene	Polypropylene	Same
In-line Filter	Polyethylene terephthalate	Acrylic copolymer matrix on non-woven nylon support	Different, see Discussion of Differences
Packaging	Blister Pack: PETG Lid: Tyvek	Blister Pack: PETG Lid: Tyvek	Same

Discussion of Differences

Vial size the product is to be used with	The predicate device is designed for vials with a diameter of 20 mm and the proposed device is designed for vials with a diameter of 15 mm. The basic design remains unchanged and has only been adapted to the size of the vials to be used.
Packaging size	The packaging dimensions have been changed from the currently marketed 20mm Vial Adapter to accommodate a 15mm Vial Adapter. The packaging material is the same. Packaging testing has been shown that the packaging of the subject and the predicate device are substantially equivalent.
Filter type and filter material	The subject and the predicate device 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 proposed device has an alternative material for the in-line filter. The filter in the predicate device is made of woven polyethylene terephthalate (mesh filter), while the filter in the subject device is made of an acrylic copolymer matrix on non-woven nylon support (membrane filter). A retention rate of ≥80 % of particles with a size of ≥ 20 µm was confirmed for the predicate device and for the subject device, so that both devices meet the requirements of ISO 8536-4. The performance of the filters (retention) of the subject and predicate devices has been shown to be substantially equivalent. The biocompatibility tests show that the subject device is biocompatible and can be regarded as substantially equivalent regarding biocompatibility.

Performance Testing

The modifications to the proposed device were evaluated and a risk assessment has been performed. The following non-clinical tests were conducted on the proposed device, nextaro® va, 15mm, 5µm, to ensure that potential risks associated with the modification were mitigated to acceptable levels.

Test name	Testing Standard
Biocompatibility assessment	ISO 10993-1
Chemical Characterization (Leachables/Extractables)	ISO 10993-18
Cytotoxicity (Extraction with DMEM – FBS)	ISO 10993-5
Skin Sensitization – Maximization (Polar and Nonpolar Extract)	ISO 10993-10
Intracutaneous Reactivity (Irritation)	ISO 10993-10
Acute Systemic Toxicity	ISO 10993-11
Materials Mediated Pyrogenicity	ISO 10993-11 (tested according to USP <151>)
Hemocompatibility (Hemolysis - Extract)	ISO 10993-4 (tested according to ASTM F756)
EO Residues	ISO 10993-7
Reducing (oxidizable) ingredients	ISO 8536-4
Titration acidity or alkalinity	ISO 8536-4
Residue on Evaporation	ISO 8536-4
UV absorption of the extract	ISO 8536-4
Detection of metal ions	ISO 8536-4
Particulate contamination	ISO 8536-4 and USP <788>
Filter Retention Rate	ISO 8536-4
Leakage / Tightness of the system	ISO 8536-4 / ISO 22413
Tensile strength	ISO 8536-4 / ISO 22413
Penetration Force	ISO 22413 (using a test procedure outlined in Annex B of ISO 8536-2)
Fragmentation Test	ISO 22413
Verification of the design specification for Transfer devices with housing	ISO 22413
Luer connector testing	ISO 80369-7 (test methods according to ISO 80369-20)

Test name	Testing Standard
Retention Force	Internal performance standard
Transfer performance (practical transfer and residual volume)	Internal performance standard
Conformity of the packaging / packaging process validation (packaging integrity testing):	ISO 11607-1 / ISO 11607-2
- seal width	DIN EN 868-5
- peel feature	DIN EN 868-5
- seal strength	DIN EN 868-5
- dye penetration	ASTM F1929
- transport test	ASTM D4169
- bubble test	ASTM F2096
- visual inspection	ASTM F1886/1886M
- burst testing	ASTM F2054/F2054M

Testing verified that all acceptance criteria were met.

Summary / Conclusion

The nextaro® va and nextaro® va, 15mm, 5µm have equivalent indications, principles of operation and technological characteristics. The only technical differences are: (1) the modified geometry / dimensions of the device (adapted to vials with a diameter of 15mm), (2) the adapted packaging design and (3) the material of the filter.

Testing demonstrates that the differences do not present any new concerns of safety or effectiveness. The modifications made to the subject device, nextaro® va, 15mm, 5µm, do not affect the intended use of the device nor do they alter its fundamental scientific technology compared to the predicate device, the nextaro® va. Thus, the nextaro® va, 15mm, 5µm is substantially equivalent to the predicate device, nextaro® va.