June 28, 2024

Fresenius Medical Care Renal Therapies Group, LLC
Timothy Groves
RA Fellow - Regulatory Affairs North America
920 Winter Street
Waltham, Massachusetts 02451

Re: K233159
Trade/Device Name: pureFLOW 402, pureFLOW 400, pureFLOW 406, pureFLOW 401, pureFLOW 502, pureFLOW 504
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System And Accessories
Regulatory Class: Class II
Product Code: KPO

Dear Timothy Groves:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on December 1, 2023. Specifically, FDA is updating this SE Letter because FDA inadvertently indicated that the SE determination also included review and clearance of a predetermined change control plan (PCCP). However, your 510(k) submission did not include a PCCP, so FDA is providing this administrative correction. Please see the attached revised clearance letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Maura Rooney, OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices, (781) 462-8128 or Maura.Rooney@fda.hhs.gov.

Sincerely,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System and accessories
Regulatory Class: II
Product Code: KPO
Dated: September 27, 2023
Received: September 27, 2023

Dear Timothy Groves:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on December 1, 2023.

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,

Maura Rooney -S

Maura Rooney
Assistant Director
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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)*

K233159

Device Name
pureFLOW 402, pureFLOW 400, pureFLOW 406, pureFLOW 401, pureFLOW 502, pureFLOW 504

Indications for Use *(Describe)*
pureFLOW solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy

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."

5. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

5.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 460-1087
Fax:	(781) 699-9635
Contact Person:	Timothy Groves, Senior Lead
Preparation Date:	27 September 2023

5.2. Device Name

Trade Names:	pureFLOW
Common Name:	Dialysis Solutions for Continuous Renal Replacement Therapy (CRRT)
Regulation Name:	Hemodialysis System and Accessories
Regulatory Class:	Class II per 21 CFR § 876.5820
Product Code:	KPO
Product Code Name:	Dialysate Concentrate for Hemodialysis (Liquid or Powder)
FDA Review Panel:	Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

The legally marketed predicate device for the proposed pureFLOW dialysis solutions is the PrismaSATE dialysate (K162887). This device is not currently subject to a design-related recall.

The B.Braun Modified Duosol Bicarbonate Dialysate (K052393), NxStage Pureflow-B Dialysis Solutions (K053286), and Haemopharm Biofluids S.R.L's HMB32 Dialysis Solution (K212052) are used as reference devices.

5.4. Device Description

5.4.1. Device Identification

5.4.1.1. pureFLOW Dialysis Solutions

The pureFLOW solutions are single-use, sterile, ready-to-use dialysis solutions consisting of sodium chloride, potassium chloride, magnesium chloride, calcium chloride (400 series only), sodium bicarbonate, and glucose. The pureFLOW dialysis solutions containing calcium are available in four

(4) formulations which differ in potassium chloride concentration. A list of available calcium containing solutions is provided in Table 1.

Table 1: pureFLOW Products (400 series, calcium-containing)

Part Number	Description
F00011288	pureFLOW 402 (0 mEq/L K^+)
F00011367	pureFLOW 400 (2 mEq/L K^+)
F00011291	pureFLOW 406 (3 mEql/L K^+)
F00011292	pureFLOW 401 (4 mEq/L K^+)

The calcium-free pureFLOW dialysis solutions are available in two (2) formulations which differ in potassium chloride concentration. A list of available calcium-free solutions is provided in Table 2.

Table 2: pureFLOW Products (500 series, calcium-free)

Part Number	Description
F00010458	pureFLOW 502 (2 mEq/L K^+)
F00010459	pureFLOW 504 (4 mEq/L K^+)

5.4.2. Device Characteristics

pureFLOW solutions are single-use, steam sterilized dialysis solutions for use in Continuous Renal Replacement Therapy (CRRT).

5.4.3. Environment of Use

The pureFLOW solutions are used in acute care environments where CRRT is performed.

5.4.4. Brief Written Description of the Device

pureFLOW solutions are sterile dialysates for use in CRRT. The pureFLOW solutions are each provided in a 2-compartment bag. One compartment contains 4.75 L of a slightly alkaline bicarbonate solution and the other compartment contains 0.25 L of an acidic electrolyte, glucose solution. The 2 solutions are mixed before use by opening the peel seam between the compartments, yielding 5 L of a ready-to-use sterile solution. The dialysate bags are made of a gas barrier foil, a material manufactured without PVC, latex, or plasticizer. The calcium-containing pureFLOW 400 series solutions are used for treatment modalities using heparin anticoagulation while the calcium-free pureFLOW 500 series solutions are used for treatment modalities using regional citrate anticoagulation.

5.4.5. Materials of Use

The pureFLOW solutions are classified as externally communicating, blood path indirect, prolonged contact (>24 hours to 30 days) duration, Class II (Category B) devices in accordance with FDA guidance document *Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* (16 June 2016).

The pureFLOW 400 and 500 series solution container closure systems are constructed from identical materials, with the exception of colorants used in the HF-Connectors. Each bag is equipped with an HF-connector, a luer-lock connector, and an injection port. The HF-connectors of the pureFLOW 400 and 500 series container closure systems contain blue and yellow colorants, respectively. The pureFLOW bags are composed of the materials listed in Table 3.

Table 3: pureFLOW Bag Materials

Component	Material
Solution Bag	Multi-layer Gas Barrier Film
Connective Tubing	Polyolefin/Elastomer
Injection Port	Polypropylene
	Synthetic Rubber
Luer -Lock Connector with Cap	Polycarbonate
	Thermoplastic Elastomer
HF Connector with Cap	Polycarbonate
	Silicone
Overwrap	Polyolefin/Elastomer

5.4.6. Key Performance Specifications/Characteristics

The key performance specifications of pureFLOW solutions are outlined in Table 4.

Table 4: Key Performance Specifications

Chemical Component	Ionic Contribution (mEq/L, mixed)	
	pureFLOW 400 series	pureFLOW 500 series
Sodium (Na^+)	140	133
Potassium (K^+)	0, 2, 3, or 4	2 or 4
Magnesium (Mg^{2+})	1.0	1.5
Calcium (Ca^{2+})	3.0	0
Chloride (Cl^-)	109, 111, 112, or 113	116.5 or 118.5
Bicarbonate ($HCO3^-$)	35	20
Glucose	5.55	5.55

5.5. Intended Use

pureFLOW solutions are each intended to be used with commercially available CRRT systems as dialysate for the treatment of patients with acute renal failure.

5.6. Indications for Use

pureFLOW solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy.

5.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the pureFLOW solutions are substantially equivalent to those of the predicate PrismaSATE dialysate (K162887):

- Intended Use
- Design
- Principle of Operation
- Performance Specifications

5.8. Performance Data

Testing conducted to support the determination of substantial equivalence is summarized in Table 5.

Table 5: Performance Testing Summary

Test Conducted	Test Method Description
5 L Bag Hanging	Evaluate the stability of the eyelets (all 3 or a single one) over a period of 24 hrs when hanging on hooks
Shipping and Distribution	Demonstrate the integrity and robustness of the bag system packaging within the distribution environment
Primary Bag Welding	Evaluate the pull tension of foils, fixed seams of primary packaging, peel-stitched primary packaging, and peel-stitched secondary packaging
Tube Welding	Evaluate the pull force of tube welding/seals
HF-Connector and Luer Connector	• Evaluate torque for removing the protective cap from the female connector and the torque of male and female connector • Evaluate breaking strength of the cone of the HF-connector • Evaluate the leakage and tightness of the connectors • Evaluate the pull-out force of the connectors and injection ports
Injection Port	Determine the penetration force of the septum and injection port
Eyelet	Determine the pull force strength of the bag eyelet
Gas Barrier Measurement	Evaluate the integrity of the bag as a CO2 barrier
Sterility	Demonstrate that the solution is sterile
Luer-Lock Connector	Evaluate the tightness after stress crack resistance testing
Temperature and Pressure Resistance of Solution Bag	Determine the resistance of the bag towards temperature and pressure

5.8.1. Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993-1:2018 and FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (04 September 2020). The following endpoints were assessed to support the biological safety of the pureFLOW solutions container closure system:

- Chemical Characterization
- Cytotoxicity
- Sensitization
- Irritation
- Material Mediated Pyrogenicity
- Hemocompatibility
- Genotoxicity

A toxicological risk assessment was also performed.

5.8.2. Human Factors Validation Testing

The pureFLOW solutions were found to be safe and effective for their intended users, uses, and use environments.

5.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The pureFLOW solutions are not electrical mechanical devices.

5.8.4. Software Verification and Validation Testing

Not applicable. The pureFLOW solutions do not contain software.

5.8.5. Animal Studies

No animal studies were performed.

5.8.6. Clinical Studies

No clinical studies were performed.

5.9. Conclusion

The intended use, design, principle of operation, and performance specifications of the pureFLOW solutions are substantially equivalent to those of the predicate device. Differences between the pureFLOW solutions and the predicate do not raise new concerns with regard to safety or efficacy. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, pureFLOW solutions are safe and effective for their intended use.