May 10, 2024

Fresenius Medical Care Renal Therapies Group, LLC
Timothy Groves
Regulatory Affairs - Senior Lead
920 Winter Street
Waltham, MA 02451

Re: K233950
Trade/Device Name: pureFLOW 402 (F00012067); pureFLOW 406 (F00012068); pureFLOW 401 (F00012069); pureFLOW 400 (F00012070)
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: KPO
Dated: April12, 2024
Received: April 12, 2024

Dear Timothy Groves:

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
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
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Center for Devices and Radiological Healthh

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.

Submission Number *(if known)*

K233950

Device Name

pureFLOW 402 (F00012067);
pureFLOW 406 (F00012068);
pureFLOW 401 (F00012069);
pureFLOW 400 (F00012070)

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.

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1. 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.

1.1. 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:	15 December 2023

1.2. Device Name

Trade Names:	pureFLOW 402 (F00012067); pureFLOW 406 (F00012068); pureFLOW 401 (F00012069); pureFLOW 400 (F00012070)
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

1.3. Legally Marketed Predicate Device

The legally marketed predicate device for the proposed pureFLOW dialysis solutions manufactured in Guadalajara, Mexico is the pureFLOW dialysis solutions manufactured from St. Wendel, Germany (K233159). This device is not currently subject to a design-related recall.

1.4. Device Description

1.4.1. Device Identification

1.4.1.1. 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, sodium bicarbonate, and glucose. The pureFLOW dialysis 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 400 series Products

Part Number	Description
F00012067	pureFLOW 402 (0 mEq/L K^+)
F00012070	pureFLOW 400 (2 mEq/L K^+)
F00012068	pureFLOW 406 (3 mEql/L K^+)
F00012069	pureFLOW 401 (4 mEq/L K^+)

1.4.2. Device Characteristics

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

1.4.3. Environment of Use

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

1.4.4. 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 pureFLOW 400 series solutions contain calcium are used for treatment modalities using heparin anticoagulation.

1.4.5. 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* (04 September 2020).

Each bag is equipped with an HF-connector, a luer-lock connector, and an injection port. The pureFLOW bags are composed of the materials listed in Table 2.

Table 2: 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

Table 2: pureFLOW Bag Materials

Component	Material
	Thermoplastic Elastomer
HF Connector with Cap	Polycarbonate
	Silicone
Overwrap	Polyolefin/Elastomer

1.4.6. Key Performance Specifications/Characteristics

The key performance specifications of pureFLOW solutions are outlined in Table 3.

Table 3: Key Performance Specifications

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

1.5. 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.

1.6. Indications for Use

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

1.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the pureFLOW solutions are substantially equivalent to those of the predicate pureFLOW solutions (K233159):

- Intended Use
- Design
- Principle of Operation

- Performance Specifications

1.8. Performance Data

The container closure system of the proposed pureFLOW solutions is identical to the predicate pureFLOW solutions manufactured in St. Wendel, Germany (K233159), with the exception of the bag film material (additional layer of PVOH), a new injection port (septum) material, and modified eyelet holes. Therefore, functional performance testing submitted in K233159 is being leveraged to support the proposed pureFLOW container closure system. Testing conducted to support the determination of substantial equivalence is summarized in Table 4.

Table 4: 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
Injection Port	Determine the integrity and penetration force of the septum and injection port
Temperature and Pressure Resistance	Demonstrate that the performance of the bag meets specification for temperature and pressure resistance
Gas Barrier	Evaluate the integrity of the bag as a CO_2 barrier

1.8.1. Biocompatibility Testing

Biocompatibility testing was conducted to evaluate the material changes 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"* (08 September 2023). 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.

1.8.2. Human Factors Validation Testing

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

1.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

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

1.8.4. Software Verification and Validation Testing

Not applicable. The pureFLOW solutions do not contain software.

1.8.5. Animal Studies

No animal studies were performed.

1.8.6. Clinical Studies

No clinical studies were performed.

1.9. 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.