December 20, 2024

Diality, Inc.
Clayton Poppe
Chief Scientific Officer
181 Technology Drive, Suite 150
Irvine, CA 92618

Re: K243607
Trade/Device Name: Moda-flx Hemodialysis System™ Cartridge (102121-001)
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: FJK
Dated: November 21, 2024
Received: November 21, 2024

Dear Clayton Poppe:

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,

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

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)*

K243607

Device Name

Moda-flx Hemodialysis System™ Cartridge (102121-001)

Indications for Use *(Describe)*

The Moda-flx Hemodialysis System™ Cartridge is a single use, disposable arterial and venous bloodline set, with dialysate tubing, intended to provide extracorporeal access during hemodialysis. The Moda-flx Hemodialysis System™ Cartridge is compatible only with the Moda-flx Hemodialysis System™.

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."

510(k) Summary

1. Submitter

Name:	Diality, Inc. 181 Technology Drive #150 Irvine, CA 92618
Submission Correspondent:	Clayton Poppe Chief Scientific Officer Diality, Inc.
Submission Author:	Clayton Poppe Chief Scientific Officer Diality, Inc.
Date Prepared:	November 21, 2024

2. Device Classification

Trade/Proprietary Name:	Moda-flx Hemodialysis System™ Cartridge (102121-001)
Common Name:	Blood Tubing Set
Classification Names:	Hemodialysis System and Accessories (21 CFR § 876.5820)
Product Codes:	FJK
Regulatory Class:	II

3. Predicate Device: K233798

4. Indications for Use

The Moda-flx Hemodialysis System™ Cartridge is a single use, disposable arterial and venous bloodline set, with dialysate tubing, intended to provide extracorporeal access during hemodialysis. The Moda-flx Hemodialysis System™ Cartridge is compatible only with the Moda-flx Hemodialysis System™.

5. Device Description

The Moda-flx Hemodialysis System™ Cartridge is a single use blood tubing set that provides extracorporeal access during hemodialysis and is only compatible with Moda-flx Hemodialysis System™.

6. Comparison to Predicate Device

The fundamental technological characteristics are consistent between the subject and predicates devices. The purpose of this Special 510(k) are modifications to the Moda-flx Hemodialysis System Cartridge.

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

- Mechanically Induced Hemolysis Testing
- Air Bolus Testing
- Continuous Air Infusion Testing
- Blood Flow Rate Testing
- Tensile Testing of Tubing Joints
- Pressure Leak Testing
- Simulated Use Testing

No animal or clinical studies were required to support this submission.

6. Conclusion

The results of design verification and validation testing for the subject device demonstrate the substantial equivalence of the subject device modifications to the predicate Moda-flx Hemodialysis System Cartridge (K233798).