August 2, 2024

Diality, Inc.
Amnon Talmor
Director, Regulatory Affairs
181 Technology Drive, Suite 150
Irvine, CA 92618

Re: K233798
Trade/Device Name: Moda-flx Hemodialysis System and Cartridge
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI, FIP, FJK
Dated: June 28, 2024
Received: July 1, 2024

Dear Amnon Talmor:

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
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)*

K233798

Device Name

Moda-flx Hemodialysis System and Cartridge

Indications for Use *(Describe)*

The Moda-flx Hemodialysis System™ is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute, post-acute, or chronic care facility. Treatments must be administered under a physician's prescription, by a trained person who is considered competent in the use of the device.

Treatment types available include: Intermittent Hemodialysis (IHD), Sustained Low Efficiency Dialysis (SLED/ SLEDD), and Prolonged Intermittent Renal Replacement Therapy (PIRRT).

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.

510(k) Summary

1. Submitter

Name:	Diality, Inc. 181 Technology Drive #150 Irvine, CA 92618
Primary Contact:	Clayton Poppe Chief Scientific Officer Diality, Inc. 1-949-916-5851
Submission Correspondent:	Amnon Talmor Regulatory Affairs Director Diality, Inc.
Submission Author:	Tori Anaya Regulatory Affairs Specialist Diality, Inc.
Date Prepared:	November 28, 2023

2. Device Classification

Trade/Proprietary Name:	Moda-flx Hemodialysis System and Cartridge
Common/Generic Name:	Hemodialysis delivery system and disposable cartridge with water purification system
Classification Names:	High permeability hemodialysis system (21 CFR § 876.5860) Water purification system for hemodialysis (21 CFR § 876.5665) Hemodialysis system and accessories (21 CFR § 876.5820)
Product Codes:	KDI; FIP; FJK
Regulatory Class:	II

3. Predicate and Reference Devices

Predicate Devices:

- Tablo Hemodialysis System (K223248)
- Tablo Cartridge (K210782)

Reference Devices:

- Fresenius 2008T BlueStar Hemodialysis Machine (K222952)
- Fresenius 2008K BlueStar Hemodialysis Machine (K150708)
- Prismaflex System 7.10 (131516)
- Aksys PHD Personal Hemodialysis Kits (K010131)

4. Indications for Use

The Moda-flx Hemodialysis System™ is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute, post-acute, or chronic care facility. Treatments must be administered under a physician's prescription, by a trained person who is considered competent in the use of the device.

Treatment types available include: Intermittent Hemodialysis (IHD), Sustained Low Efficiency Dialysis (SLED/ SLEDD), and Prolonged Intermittent Renal Replacement Therapy (PIRRT).

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™ is a transportable hemodialysis system that consists of three parts: Hemodialysis Delivery (HD) Device, Dialysate Generator (DG) Device, and a single use Moda-flx Hemodialysis System™ Cartridge that provides extracorporeal access during hemodialysis. The Moda-flx Hemodialysis System™ Cartridge is only compatible with the Moda-flx Hemodialysis System™. The system creates purified water from tap water; from this purified water and chemical concentrates, the system creates dialysate in real time. The chemicals used to create the dialysate are standard 45X concentrates.

Ultrafiltration is achieved by controlling the dialysate going in and coming out of the dialyzer independently, using pumps on the HD Device to control fluid flow from both the inlet and outlet of the dialyzer. An external bag of saline is used to provide solution infusions to combat hypotensive episodes. Saline is also used to prime the Moda-flx Hemodialysis System™ Cartridge prior to use.

Prescribed blood flow rate is generated by a peristaltic pump, while heparin is administered to prevent blood coagulation. All fluid pathways are disposable and easily installed and replaced. Once installed, the device will check the connections of the fluid pathways and the system will automatically prepare itself for treatment.

6. Comparison to Predicate Device

The fundamental technological characteristics are consistent between the subject and predicates devices, including:

- High permeability delivery system
- Concentrate proportioning
- Dialysate preparation, delivery, quality and conductivity monitoring
- Peristaltic blood pump
- Pinch valves
- Touch screen user interface
- Software controlled
- Device specific extracorporeal blood tubing
- Used with legally marketed dialyzers
- Ultrafiltration flow rate
- Alarms
- Water purification system

For the subject and predicate hemodialysis systems, differences include:

- Dialysate and blood flow rates
- Heparin pump
- Disinfection method
- Dialysate generation and ultrafiltration control
- Dialyzer integrity monitoring
- Venous pressure low limit
- Dialysate temperature range
- Fixed ratios
- Cart

For the blood tubing cartridge, differences include:

- Blood volume

7. Performance Data

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

- Biocompatibility testing
- Electrical safety and electromagnetic compatibility
- Software verification and validation testing
- Cybersecurity testing
- Reprocessing/disinfection testing
- Sterilization testing
- Shelf-life testing
- Bench performance testing, including clearance, transport and dialyzer integrity testing
- Usability testing
- Animal studies: no animal studies were required to support this submission.
- Clinical studies: no clinical studies were required to support this submission.

6. Conclusion

The results of design verification and validation testing of the Moda-flx Hemodialysis System™ demonstrate the substantial equivalence of the Moda-flx Hemodialysis System™ to the Tablo Hemodialysis System (K222952) and Tablo Cartridge (K210782).