February 24, 2020

CHF Solutions, Inc.
Dawn Li
Principal Regulatory Affairs Specialist
12988 Valley View Road
Eden Prairie, MN 55344

Re: K192756
Trade/Device Name: Aquadex FlexFlow System 2.0
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: January 22, 2020
Received: January 23, 2020

Dear Dawn Li:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Carolyn Y. Neuland, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192756

Device Name
Aquadex FlexFlow® System 2.0

Indications for Use *(Describe)*
The Aquadex FlexFlow® System is indicated for:

Continuous ultrafiltration therapy for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kilograms or more whose fluid overload is unresponsive to medical management, including diuretics.

All treatments must be administered by a healthcare provider, within an outpatient or inpatient clinical setting, under physician prescription, both of whom having received training in extracorporeal therapies.

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.

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510(k) Summary

Revised December 22, 2019

1. Submitter information/ 510(k) Holder

Submitter:	CHF Solutions, Inc.
Establishment Registration:	3007137787
Address:	12988 Valley View Rd Eden Prairie, MN 55344, U.S.A.
Contact Information:	Dawn Li Principal Regulatory Affairs Specialist (952) 715-6278 Dawn.li@chf-solutions.com

2. Device Information

Trade Name:	Aquadex FlexFlow® System 2.0
Common Name:	Fluid Removal System
Classification Name:	High Permeability Hemodialysis System
Product Code:	KDI
Regulation Number:	Class II, 21 CFR 876.5860

3. Predicate Device Information

Primary Predicate Device:	Aquadex FlexFlow System (K071854)
Secondary Predicate Device:	Prismaflex System (K171671)

4. Device Description

The Aquadex FlexFlow system comprises the following components:

- Aquadex FlexFlow console, microprocessor-controlled
- Blood Circuit Set with integral hemofilter, disposable
- Venous access catheter

The Aquadex FlexFlow console includes a blood pump, ultrafiltrate pump, control panel, weight scale, air detector, blood leak detector, electrical connectors for the circuit pressure sensors, and mechanical interfaces that hold the circuit in place. The console controls the rate at which the blood pump removes blood from the patient, and the clinician sets the

maximum rate at which the ultrafiltrate pump extracts ultrafiltrate from the blood. Patient access is obtained either peripherally or through the central venous veins. Blood is withdrawn from a vein and passes through a withdrawal pressure sensor before entering the blood pump tubing loop. The rotating rollers propel the blood through the tubing to the air detector, then into the hemofilter before being returned to the patient. The console screen displays information to help the clinician prime, set up, and operate the system. All system alarm limits are set by the console.

The Aquadex FlexFlow blood circuit is a preassembled, sterile (EtO), single-patient use set. There are two models of the blood circuit: A06162 and A06163. The blood circuit set A06162 consists of a filter, tubing, pressure sensors, connectors, pinch clamps, a priming spike, an ultrafiltrate connecting bag and data key. The blood circuit set A06163 has the same components, except that it also has an inline blood chamber for use in monitoring the patient's hematocrit (Hct) during therapy.

CHF Solutions Inc. offers a dual lumen extended length catheter (dELC) for use with the Aquadex FlexFlow System. The catheter is a peripheral venous access device with stainless steel coil reinforcement. The venous access catheter was not reviewed in K192756 as it was already cleared for safe and effective use under K041791 with no changes since the original clearance affecting its safety and effectiveness.

5. Indications for Use

The Aquadex FlexFlow® System is indicated for:

Continuous ultrafiltration therapy for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kilograms or more whose fluid overload is unresponsive to medical management, including diuretics.

All treatments must be administered by a healthcare provider, within an outpatient or inpatient clinical setting, under physician prescription, both of whom having received training in extracorporeal therapies.

6. Comparison of Technological Characteristics

There are no technological differences between the subject device and the primary predicate device (K071854). Both the subject and primary predicate devices remove excess fluid from the patient by ultrafiltration of blood across a hollow-fiber hemofilter at the clinician-selected ultrafiltration rate. They have identical control mechanisms, operating principles, energy type, sterilization, packaging and all other design features.

The Prismaflex is a software-controlled device that performs Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload and Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated. The technological characteristics of the Aquadex FlexFlow system are equivalent to the subset of the Prismaflex system (K171671) technology with the exception of the lower ultrafiltration rate, smaller extracorporeal volume, and lower extracorporeal blood flow rate. The technological differences between Aquadex and Prismaflex do not raise different questions of safety or effectiveness with regard to ultrafiltration in patients weighing 20 kilograms or more.

Comparison of technological and performance characteristics are provided in the table below:

Regulatory and Use Information				
	Aquadex System with Modified Intended Use *(subject device)*	**Aquadex System with Original Intended Use** *(primary predicate)*	**Prismaflex System** *(secondary predicate)*	**Comparison**
Manufacturer	CHF Solutions, Inc.	CHF Solutions, Inc.	Baxter Healthcare Corp.	Same as primary predicate.
510(k) Number	TBD	K071854	K171671	--
Regulatory Classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System	Dialyzer, High Permeability With Or Without Sealed Dialysate System	Dialyzer, High Permeability With Or Without Sealed Dialysate System	Same for all three products.
Product Code	KDI	KDI	KDI	
Regulation	876.5860, high permeability hemodialysis system	876.5860, high permeability hemodialysis system	876.5860, high permeability hemodialysis system	
Device Class	2	2	2	
Available Therapies	Aquapheresis (Ultrafiltration with Aquadex)	Aquapheresis (Ultrafiltration with Aquadex)	SCUF CVVH CVVHD CVVHDF TPE	Same as primary predicate. Prismaflex has more therapy modes than Aquadex; aquapheresis is comparable to the Prismaflex SCUF mode.
Anticoagulation	User-controllable as continuous or bolus	User-controllable as continuous or bolus	User-controllable as continuous or bolus	Same for all three products

Regulatory and Use Information				
	Aquadex System with Modified Intended Use *(subject device)*	**Aquadex System with Original Intended Use** *(primary predicate)*	**Prismaflex System** *(secondary predicate)*	**Comparison**
Intended Use	The Aquadex FlexFlow System is indicated for: Continuous ultrafiltration therapy for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kilograms or more whose fluid overload is unresponsive to medical management. All treatments must be administered within an inpatient or outpatient clinical setting by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies.	The Aquadex FlexFlow System is indicated for: • Temporary (up to 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and • Extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. All treatments must be administered by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies.	The Prismaflex control unit is intended for: • Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload. • Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated. All treatments administered via the Prismaflex control unit must be prescribed by a physician.	Compared to primary predicate: the subject device clarifies the type of ultrafiltration, the weight minimum, and an unresponsive to medical management clause. Compared to secondary predicate: Aquadex is only indicated for ultrafiltration. All three products are prescription use only.

Device Components and Accessories				
	Aquadex System with Modified Intended Use *(subject device)*	**Aquadex System with Original Intended Use** *(primary predicate)*	**Prismaflex System (SCUF Mode)** *(secondary predicate)*	**Comparison**
Dedicated Disposable Sets Available in U.S.	UF 500 Blood Circuit Set	UF 500 Blood Circuit Set	For CRRT (includes SCUF): M60/M100/M150, HF1000 & HF1400	Same as primary predicate.

Device Components and Accessories				
	Aquadex System with Modified Intended Use *(subject device)*	**Aquadex System with Original Intended Use** *(primary predicate)*	**Prismaflex System (SCUF Mode)** *(secondary predicate)*	**Comparison**
Pumps	Effluent Blood	Effluent Blood	PBP solution Replacement solution Dialysate solution Effluent Blood	Same as primary predicate. Aquadex has fewer pumps vs. Prismaflex because replacement solution and dialysate are not administered by Aquadex.
Scales	Effluent	Effluent	Dialysate Replacement Effluent Pre blood (PBP)	Same as primary predicate. Aquadex has fewer scales vs. Prismaflex because effluent is the only solution to be measured.
Device Specifications and Settings				
Blood Flow Rate Range	10-40 ml/min	10-40 ml/min	10-450 ml/min	Same as primary predicate. Aquadex has a lower maximum blood flow rate than Prismaflex.
Blood Flow Rate Accuracy	+15%/-20% of setting for withdrawal pressure (Pw) ≥ -250 mmHg	+15%/-20% of setting for withdrawal pressure (Pw) ≥ -250 mmHg	±10% of user set rate at nominal blood flow of 450 ml/min or the highest achievable blood flow at 37° C at an access pressure of -200 mmHg l pressure and without any PBP flow	Same as primary predicate. Aquadex Comparable to Prismaflex.
Effluent Pump Flow Rate	0 to 500 ml/hr	0 to 500 ml/hr	0 to 10000 ml/hr depending on the therapy	Same as primary predicate. Aquadex has a lower maximum effluent pump flow rate.
Patient Fluid Removal Performance Range	0 to 500 ml/hr	0 to 500 ml/hr	0 to 2000 ml/hr maximum for CRRT Increment: 10 ml/hr	Same as primary predicate. Aquadex has a lower maximum fluid removal rate.
Patient Fluid Removal Performance Range Accuracy	±10% of user set rate	±10% of user set rate	±10% of user set rate	Aquadex accuracy is statistically comparable Prismaflex.

7. Safety and Performance Data

Bench performance testing was performed on all three systems, Aquadex 1.0 (the primary predicate device), Aquadex 2.0 (the subject device), and Prismaflex® (the secondary predicate device) at the same therapy settings in order to derive a direct comparison of the fluid removal accuracies. Based on the accuracy calculations, the Aquadex FlexFlow System (1.0 and 2.0) met the design specifications and remained accurate within ±10% when comparing the displayed and actual ultrafiltration amount. The accuracy of the Aquadex FlexFlow System is comparable to the PrismaFlex System across all test scenarios.

In support of the clarified indication for use, CHF Solutions requested clinical data from a three-center retrospective study involving the use of Aquadex FlexFlow for pediatric patients and performed by investigators independent of the manufacturer. A total of 93 Aquadex blood circuits were used on 26 pediatric patients (21 years or younger) weighing 20 kilograms or more from 28 hospitalizations. More than half (57%) of the patients were female, and most patients were treated in the intensive care units, PICU (46%) and CICU (36%). The primary underlying disease for patients was cardiac disease at 39% or kidney disease at 29%.

None of the patients died during therapy with Aquadex (100% treatment course survival rate), and eight patients died after therapy but prior to hospital discharge (71% hospital survival rate). None of the deaths were related to the ultrafiltration device or procedure. No complications associated with treatment initiation were reported. Complications during therapy were infrequent, occurring in 11 cases (12% of circuits). Clot in the filter and hypotension during the treatment were the most common complications. In addition, no patient experienced a serious adverse event or device-related adverse event.

The Aquadex FlexFlow system was evaluated according to CHF procedures and performance testing protocols. The Aquadex FlexFlow system met all acceptance criteria. The performance testing demonstrates the Aquadex FlexFlow functions as intended. Below are high level summaries of testing used to demonstrate substantial equivalence along with FDA guidance documents and FDA recognized consensus standards.

- Biocompatibility testing to the most recent ISO 10993 requirements
- Electrical safety testing according to the most recent IEC 60601 standard
- Electromagnetic compatibility testing according to the most recent IEC 60601-1-2 standard
- Performance testing to IEC 60601-2-16 that confirms the device meets requirements for Essential Performance

- Software verification and validation testing in accordance with FDA's guidance "Guidance for the Content of Premarket Submission for Software Contained in Medical Device's"
- Performance testing to ISO 8637-1
- Human factors testing in accordance with IEC 62366-1, 62366-2 and FDA's Guidance "Applying Human Factors and Usability Engineering to Optimize Medical Device Design."

8. Conclusion

The technological differences between Aquadex FlexFlow and Prismaflex were evaluated in a risk analysis process compliant with ISO 14971 (2012), in which hazards were identified, design and process failure modes were identified and mitigated, and residual risks were assessed and judged acceptably low. The fluid removal accuracy was evaluated through performance testing, which showed no statistical difference between Aquadex and Prismaflex. The lower maximum settings for blood flow rate and effluent pump flow rate on the Aquadex FlexFlow system do not raise safety concerns and likely mitigate safety in smaller patients. Aquadex clinical performance demonstrate that the system is viable, safe, and well-tolerated therapy for patients with volume overload in pediatric patients weighing ≥20 kg.

In conclusion, the Aquadex FlexFlow system is substantially equivalent to both the predicate Aqudex FlexFlow system (K071854) and the Prismaflex System (K171671).