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K050609

510(k) Summary
Prepared on August 11, 2005

This 510(k) Summary is submitted in accordance with 21 CFR 807.92.

Trade Names:	Aquadex™ System	
Manufacturer:	CHF Solutions, Inc., Suite 170 - 7601 Northland Drive, Brooklyn Park, MN 55428	
Official Contact:	Chris Scavotto Quality Assurance Manager	Telephone: 763-463-4621 Fax: 763-463-4606
Device Generic Name:	Aquadex FlexFlow™ System	
Classification:	High permeability dialysis systems - classified as Class II	
Predicate Devices:	Aquadex FlexFlow™ System (K040489)	PRISMA ™ CFM Systems (K981681)
Device Description:	The Aquadex FlexFlow™ System removes excess fluid from the patient in fluid overload by ultrafiltration of blood across a hollow-fiber hemofilter at the clinician selected rate. The system is comprised on a console mounted on a cart, proprietary software and accessories (venous access catheters, extensions and a blood pump circuit). Patient access is obtained via either peripheral or central venous veins.	
Indication for Use:	The Aquadex 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.	
Safety & Performance:	Bench testing was performed to validate the disposable product and software changes in support of the Indication for Use change. A subset of 60 patients with 89 extended use (>8hrs) UF500 circuits use were summarized from a post market on-label prospective study in support of the Indication for Use change. The data generated demonstrated the Aquadex™ System continues to be safe and effective through 24 hours of continuous use.	
Conclusion:	Based on the similar intended use, patient population, technology characteristics, and performance characteristics as assessed with bench testing and clinical data the Indication for Use has been shown to be safe and effective for its intended use. This product is substantially equivalent[1] and considered acceptable for the intended use.	

[1] This document uses the term "substantial equivalent" as intended in 21 CFR 807.87 and not as defined in Title 36 of the U.S. Code.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Chris Scavotto
Quality Assurance Manager
CHF Solutions, Inc.
Suite 170-7601 Northland Drive
BROOKLYN PARK MN 55428

Re: K050609
Trade/Device Name: Aquadex™ FlexFlow™ System
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: August 17, 2005
Received: August 18, 2005

Dear Mr. Scavotto:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT
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510(k) Number: K050609

Device Name: Aquadex FlexFlow™ System

FDA's Statement of the Indication for Use for Device:

The Aquadex 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.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use** ____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050609