

K070512

**Attachment C****510K Summary Safety and Effectiveness  
510(k) Summary (Prepared on February xx<sup>th</sup>, 2007)**

APR 27 2007

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

<b>Trade Names:</b>	Aquadex FlexFlow™ System (trademark pending)
<b>Manufacturer:</b>	CHF Solutions, Inc., Suite 170 - 7601 Northland Drive, Brooklyn Park, MN 55428
<b>Official Contact:</b>	Chris Scavotto                      Telephone: 763-463-4621 QA Director                              Fax: 763-463-4606
<b>Device Generic Name:</b>	Ultrafiltration (Aquapheresis) System
<b>Classification:</b>	High permeability dialysis systems - classified as Class II
<b>Predicate Devices:</b>	Aquadex FlexFlow System (K062922)
<b>Device Description:</b>	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.
<b>Indication for Use:</b>	The Aquadex FlexFlow™ System is indicated for: <ul style="list-style-type: none"> <li>• Temporary (up to 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and</li> <li>• Extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization.</li> </ul> All treatments must be administered by a health care provider, under physician prescription, both of whom having received training in extracorporeal therapies.
<b>Safety &amp; Performance:</b>	Regression testing was performed to verify and validate the software change and to generate data in support of the labeling change which incorporates a catheter compatibility chart using the principles of ISO 14971:2000 "Medical devices – Application of risk management to medical devices. Data generated demonstrated the Aquadex FlexFlow System continues to be safe and effective.
<b>Conclusion:</b>	Based on the similar intended use, patient population, technology characteristics, and performance as assessed



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Mr. Chris Scavotto  
Director of Quality Assurance  
CHF Solutions<sup>®</sup>, Inc.  
7601 Northland Drive, Suite 170  
BROOKLYN PARK MN 55428

APR 27 2007

Re: K070512  
Trade/Device Name: Aquadex FlexFlow<sup>™</sup> System  
Regulation Number: 21 CFR §876.5860  
Regulation Name: High permeability hemodialysis system  
Regulatory Class: II  
Product Code: KDI  
Dated: March 27, 2007  
Received: March 28, 2007

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.



*Protecting and Promoting Public Health*

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.

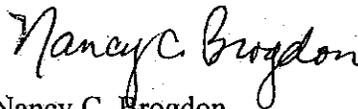
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT  
(Page 1 of 1)

510(k) Number (if known): K07 0512

Device Name: Aquadex FlexFlow™ System

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

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 health care 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  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K070512