K023874

NOV 2 0 2003

510(k) Summary

Prepared on August 20, 2003

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

Trade Names:		System 100 and System 100 Ultrafiltration Catheter	
Manufacturer:		Chf Solutions, Inc., Suite 170 - 7601 Northland Drive, Brooklyn Park, MN 55428	
Official Contact:		Amy Peterson Vice President, RA/QA/CR	Telephone: 763-463-4620 Fax: 763-463-4606
Device Generic Name:		High permeability hemodialysis system and short-term/non-implanted blood access device.	
Classification:		<u>System 100 - Accessory</u> • Class: II (21 CFR 876.5860) • Panel: Gastroenterology-Urology • Product code: KDI	<u>Non-implanted Blood Access Device</u> • Class: II (21 CFR 876.5540 (b)(2)) • Panel: Gastroenterology-Urology • Product code: MPB
Predicate Devices:		• CHF Solutions, System 100 (K013733, K023224, K024124) • Prisma (K981681)	• *med*Comp®, Schon XL Soft-line Double Lumen Catheter /Duo-Flow™ (K974236)
Device Description:		The System 100 Ultrafiltration Catheters are part of the fluid pathway and intended for blood withdrawal and infusion when repeat venous access over a period of ≤ 30 days is medically desired. Common medical practice is to exchange the catheter every seven days to minimize infection. The CVC catheter is percutaneously introduced into the subclavian vein or the internal jugular vein with the distal tip ending in the mid to lower superior vena cava. The proximal end with the proprietary connectors resides outside the body connecting to the withdrawal and infusion blood lines of the UF500 blood circuits which engages the System 100 pump console for ultrafiltration in patients with fluid overloaded. The catheter extension (A1513) may also be used to connect other commercially available CVC of the appropriate flow rate to the System 100 UF500 blood filter circuits.	
Indication for Use:		The System 100 is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload. The System 100 UF Catheter is indicted for attaining short-term (less than 30 days) percutaneous vascular access of the central circulatory system for ultrafiltration with the System 100.	
Safety & Performance:		The UF catheter and primary predicate device are similar in materials of construction and identical for packaging and sterilization. The UF catheter is provided sterile and nonpyrogenic. Bench tests demonstrate the UF catheter is compatible with the System 100. Other CVC with an acceptable flow rate would also be compatible with the System 100. Use of a CVC is expected to be performed in hospital environments where CVC use is common.	
Conclusion:		Based on the similar intended use, patient population, technology characteristics including well understood CVC medical risks, and performance as access with bench testing the catheter 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

NOV 2 0 2003

Ms. Amy Peterson (Official Correspondent)
Vice-President RA/QA/CR
CHF Solutions, Incorporated
Suite170-7601 Northland Drive
BROOKLYN PARK MN 55428

Re: K023874
Trade/Device Name: System 100 Ultrafiltration Catheter and System 100 for Use with Central Venous Access
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: 78 KDI
Dated: August 20, 2003
Received: August 22, 2003

Dear Ms. Peterson:

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 (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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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
(Page 1 of 1)

510(k) Number (if know): __K023874_____

Device Name: System 100 and System 100 Ultrafiltration Catheter

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

In association with central venous access:

1) The System 100 is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload.

2) The dual lumen ultrafiltration catheter [A1537] is indicated for use in attaining short-term (less than 30 days) percutaneous vascular access of the central circulatory system for ultrafiltration with the System 100.

   (INSERTION SITES) The dual lumen ultrafiltration catheter may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion sites include subclavian or femoral veins as required. Use should be limited to areas within the hospital where patients with a central venous catheter are routinely managed.

3) The catheter extension [A1513] may also be used to connect commercially available CVC of the appropriate flow rate to the System 100 UF500 blood filter circuits.

4) The System 100 S-100 console [A1100] may be used when either peripheral or central venous access is employed.

5) The UF 500 circuit [A1500 and A1550] may be used when either peripheral or central venous access is employed.

(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)

David R. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023874