OCT 25 2002

K023224

510(k) Summary

Product Name: Infusion Catheter Extension, Model 1513

Common Name: Catheter Extension / Accessory

Submitter's Name: 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

Summary Preparation Date: September 9, 2002

This summary is provide in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission.

The System 100 cleared under K013733 was classified as a high permeability hemodialysis system, 876.5860 which includes accessories. The extension catheter is considered an accessory and is substantially equivalent to that contained in the original clearance.

Class: II	Product code: KDI
Panel: Gastroenterology –Urology	Classification: 876.5860

The device has identical materials of construction, packaging and sterilization. It is provided sterile and the fluid pathway is nonpyrogenic. The intended use is to connect the System 100 circuit outflow line to the access catheter for filtered blood return into the patient. Two changes are reflected in this submission for an alternate catheter extension and do not change the intended use.

1) One of the two proprietary connectors was replaced with a standard male luer connector.
2) Labeling was updated to allow use of the alternate extension catheter on the outflow side of the System 100, UF 500 extracorporeal filter circuit.

Bench testing was performed on a variety of access catheters with specified dimensional characteristics for lumen diameter and length. Data generated demonstrated access catheters meeting or falling with these dimensional criteria result in flow rates acceptable for use with the System 100. The acceptable dimensional characteristics have been incorporated into the directions for use leaflet.

This product is substantially equivalent to the predicate device and considered acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2002

Ms. Amy Peterson
Official Correspondent and
Vice President, RA/QA/CR
CHF Solutions, Inc.
Suite 170
7601 Northland Drive
BROOKLYN PARK MN 55428

Re: K023224
Trade/Device Name: Infusion Catheter Extension, Model A1513
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: September 26, 2002
Received: September 27, 2002

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 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:

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" (21 CFR Part 807.97). 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

510(k) Number (if know): K023224

Device Name:
Infusion Catheter Extension Set with Securement Device & Male Luer, Model A1513

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

For use with System 100.
Extension set male connector is specifically designed to secure the extension set to the Statock securement device. Connect luer extension fitting directly to the infusion catheter hub only.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023224

CHF Solutions, Inc.