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510(k) Summary for CHF Solutions' System 100

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
Submitter	CHF Solutions, Inc.
Contact Person	Dianna Thomsen King & Spalding 1730 Pennsylvannia Ave. Washington, D.C. 20006 Telephone: 202-626-5594 FAX: 202-626-3737
Date Prepared	November 9, 2001
Name	System 100
Classification Name	High permeability hemodialysis system
Device Classification	Classification: Class II Classification Panel: Gastroenterology Devices Regulation Number: 21 C.F.R. §876.5680
Predicate Devices	• PRISMA Continuous Fluid Management System (K981681; cleared 1998) • PRISMA M60 Set
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act.

510(k) Summary for CHF Solutions' System 100

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Device Description	System 100 consists of the: • S-100 console • UF 500 set • Venous access catheters • Catheter extension set • Needless flushing port • Catheter insertion kit
Indications for Use	System 100 is indicated for temorary (up to 8 hours) ultrafiltration treatment of patients with fluid overload.
Technological Characteristics	System 100 contains features and functions that were previously-cleared in PRISMA's device. Minor modifications were made to System 100 because the device is designed to only remove fluids (the predicate device removes fluids and solutes) and to incorporate current technology.
Non-clinical and Clinical Performance Data	CHF Solutions, Inc. performed non-clinical testing on System 100 to demonstrate that the device met its functional and performance specification. System 100 was subjected to extensive safety, software, and performance testing. Clinical data confirm that the device is safe and effective for its intended use.
Conclusion	System 100 is substantially equivalent to the currently cleared and marketed PRISMA system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 2002

CHF Solutions, Inc.
c/o Ms. Dianna Thomsen
King and Spalding
1730 Pennsylvania Avenue, N.W.
WASHINGTON DC 20006-4706

Re: K013733
Trade/Device Name: System 100 with UF 500 Set, Venous Access Catheters, Catheter Extension Set, and Catheter Insertion Kit
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: March 5, 2002
Received: March 5, 2002

Dear Ms. Thomsen:

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 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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in your catheter insetion kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. 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.

In addition, we have determined that your device kit contains povidone iodine swabsticks, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with these drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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,

for David A. Legan

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

510(k) Number: K013733

Device Name: System 100

Indications for Use:

System 100 is indicated for temporary (up to 8 hours) ultrafiltration treatment of patients with fluid overload.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013733