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DEC 2 3 2003

510(k) Summary

Prepared on May 30, 2003

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

Trade Name: Dual-Lumen Extended Length Catheter (dELC)

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

Generic Name: Short-term/non-implanted blood access device

Classification:

System 100 - Accessory
- Class: II (21 CFR 876.5860)
- Panel: Gastroenterology-Urology
- Product code: KDI

Non-implanted Blood Access Device
- Class: II (21 CFR 876.5540 (b)(2))
- Panel: Gastroenterology-Urology
- Product code: MPB

Predicate Devices:
- CHF Solutions, System 100, Extended Length Catheter (K013733)
- B. Braun Accuguide® (K971999)
- *med*Comp® VASCU-PICC™ (K030270) and Duo-Flow™ (K974236)

Device Description: The dELC is a 6 French, polyurethane, dual lumen extended-length catheter. It is intended to provide short-term peripheral venous access to facilitate blood removal and return for the purposes of ultrafiltration. The catheter has a low profile, flexible hub with suture wings for securement to the skin. The dual lumen tubing in the proximal portion of the catheter shaft is a double-D configuration and is bonded to a single lumen tube for the distal portion. The blood is drawn up through the single lumen tubing, and infused back into the vessel through the short proximal section of the catheter shaft. The catheter will connect directly to the UF circuit of the System 100 to conduct blood to and from the patient for the purposes of ultrafiltration.

Indication for Use: The Dual Lumen ELC catheters are peripheral venous access catheters, inserted preferably in the basilic vein (arm) and antecubital region respectively, and specifically for use with the System 100.

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

Safety & Performance: The Dual-Lumen ELC and predicate devices are similar in materials of construction and identical for packaging and sterilization. The Dual-Lumen ELC is provided sterile and nonpyrogenic. Bench tests demonstrate the Dual-Lumen ELC is compatible with the System 100.

Conclusion: Based on the intended use, technology characteristics and bench testing, the new access catheter has been shown to be safe and effective for its intended use. This product is substantially equivalent[11] and considered acceptable for the intended use.

[11] 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

DEC 2 3 2003

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

Re: K031689
Trade/Device Name: System 100 Dual Lumen Extended Length Catheter (dELC)/ A1557
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 NQJ
Dated: September 24, 2003
Received: September 25, 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

510(k) Number (if know): ___K031689_____

Device Name: Dual Lumen Extended Length Catheter (dELC)

Indication For Use for device:

The Dual Lumen ELC catheters are peripheral venous access catheters, inserted preferably in the basilic vein (arm) and antecubital region respectively, and specifically for use with the System 100.

The catheter is not intended for the infusion of medications or fluids, for laboratory sampling, or other venous access needs.

The 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031689