AUG 2 8 2000

Fluid Process Systems, Inc.

p. 1/4

August 15, 2000

Food and Drug Administration
9200 Corporate Blvd
Rockville, Md. 20850

RE: 510(k) Summary for K991495 per section 807.92(c)

Dear Sir or Madame:

Pursuit to section [807.92(a)(1)], we are submitting a 510(k) summary to complete our application

Trade Name: Exchange Carbon and Deionization Tanks for Hemodialysis per [807.02.(a)(2)]
Common Name: Exchange Deionization
Classification Name: Deionization for Hemodialysis, Class II (generic class) section # 78, Gastroenterology/Urology section 21 CFR 807.87.C

Submitted by:

Stephen C. Hambric
Vice President
Fluid Process Systems, Inc.
Phone: (915) 852-1007
Fax: (915) 852-1020

Exchange Deionization as a predicate device can be found in the legally marketed device submitted by the following companies: [807.92(a)(3)]

Aqua-Med Systems,Inc.
3607 Chapel Hill Road
McHenry, Il. 60050

R.D. Baker,DBA Dayton Water Services
1288 McCook Ave.
Dayton, Oh. 45404

K991495
p. 2/4

In Summary: [807.92(a)(4)]

Deionization has long been a standard to treat water used in hemodialysis. Because of the patient safety considerations, Deionization, as a freestanding system must include several types of safety precautions. We have addressed each issue in designing the complete system. A detailed description of each component is outlined below.

Technological Characteristics [807.92(a)(6)]

1. A carbon tank with an empty bed contact time sufficient to remove any chlorine and chloramines is placed in front of the deionization equipment. The deionization equipment consists of both separate bed and mixed bed tanks. The arrangement of the tanks is as follows:

Carbon Tank (used to remove chloramines and chlorines)
Cation Tank (used to remove positively charged particles)
Anion Tank (used to remove negatively charged particles)
Mixed Bed (used as a working polisher to cleanse the water)
Mixed Bed (used as a final polisher)

Other integral pieces of equipment are

The lines which flow the product. These must be free from TOC Leaching and bacteria. Special materials are used in the hoses to prevent the growth of bacteria. The hose runs are as short as possible to reduce the amount of "Hide Out" space for bacteria growth. An "ultraviolet Disaffection Unit" is placed in line to remove any remaining bacteria from the line. The "Ultraviolet Disaffection Unit" removes 99.9% of the bacteria that is present. The use of "Ultra-violet Rays" creates pyrogens or the destroyed bodies of the bacteria. These pyrogens are further removed by using a "Submicron Filter" which is normally sized at .05 micron. This Filter is capable of collecting most anything that escapes the deionization process and the "Ultraviolet Disaffection Unit". A Resistivity Monitor is placed at the inlet to the Hemodialysis Stream. This monitor measures the quality of the water coming from the deionization equipment. The monitor features an inline cell, which continually measures the quality of the water. It has both an audible and visual alarm to alert the operator to any alarm condition. The set point is adjustable but we recommend the setting at 2 megohms. This setting alerts the operator that the system is nearing exhaustion and steps are necessary to protect the patients.

AMMI/ANSI Standards are normally set at 1 megohm and the above setting allow the operator to react prior to an emergency. Prior to each patient shift, the operator must as a minimum, check for chloramines, chlorines, resistivity and flow. The "Ultraviolet Disaffection Unit", "Ultrafilter" and resistivity monitor should be checked for operation.

An operational log should be used to record each parameter prior to any patient shift. This log provides assurance that each test has been performed and all equipment has been checked prior to use.

By providing the equipment and safety factors described above, the most comprehensive steps have been used to insure that the water quality is safe for hemodialysis.

2. By sizing the tanks with sufficient capacity, we can provide the end
User with both the time and methodology to run the equipment as desired. The system is always supported by a mirror image, which can be placed n service in a matter of minutes.

3. Several checkpoints are included as precautions to insure that each patient shift is safe to perform hemodialysis. The safety factors are:
   a. Check the inlet water volume.
   b. Check for Chloramines and Chlorines after the carbon tank.
   c. Check the operation of the "Ultraviolet Disaffection Unit".
   d. Check the flow across the "Ultrafilter".
   e. Check the condition of the Resistivity Monitor and measure the water quality.

   These steps will insure that a safe and effective patient shift can be achieved.

4. The water produced by the exchange carbon and deionization tanks is intended to dilute the Dialysate used to cleanse blood during hemodialysis. The purity of the water helps to determines how effective the dialysis procedure is accomplished. The steps taken to protect the patient are there to insure the quality of the dialysis program. The standards used to measure the water quality are put in place to protect the patient.

5. All data submitted as part of this package was collected under normal operating clinical conditions. Copies of the test results originally submitted to the FDA are included with this summary.

6. Equipment was placed in normal operation during a non-patient shift and water was circulated through the equipment for a period of time. Test samples were taken from the through put of the deionization tanks using treated water and non-treated water. The determination for using non-treated water was to illustrate that under the most adverse conditions, the deionization equipment will produce water meeting AMMI/ANSI Standards.

7. In conclusion, the deionization tanks will produce the quality of water as defined by AMMI/ANSI Standards for use in hemodialysis applications. In our area, because well water has high TDS, a Reverse Osmosis System will not meet the one megohm quality limitation defined by AMMI. For this reason, our consensus of opinion is that deionization meets the standards more readily.

Respectfully Submitted,

Stephen C. Hambric
Fluid Process Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2000

Mr. Stephen C. Hambric
Vice President
Fluid Process Systems, Inc.
998A Peyton Road
El Paso, Texas 79927

Re: K991495
Exchange Carbon and Deionization Tanks
for Hemodialysis
Dated: May 22, 2000
Received: May 30, 2000
Regulatory Class: II
21CFR 876.5665/Procode: 78 FIP

Dear Mr. Hambric:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K991495

Device Name: Fluid Process Systems, Inc. Exchange Carbon and Deionization Tanks for Hemodialysis

Indications For Use:

The intended use of this system, comprising of the following components, is to provide water to dilute dialysate for use in HEMODIALYSIS applications.

1. **Carbon Tank (see description inside the application)**
2. **Cation Deionization Tank**
3. **Anion Deionization Tank**
4. **Mixed Bed Deionization Tank**
5. **Mixed Bed Deionization Tank (used as a polisher tank)**

The combination of the above listed components will deliver water which exceeds AAMI Standards for water used to dilute dialysate for HEMODIALYSIS. The system does not come into contact with any patient and is used solely as indicated. The components are used in this series (without exception) and are not designed to be bypassed at any point. The process requires additional components which are added or furnished by the end user. These include an ULTRAVIOLET DISINFECTION UNIT [redacted] and an ULTRAFILTER, with a rating of .05 micron, to reduced the risk of pyrogens being passed through the system. The instruction manual outlines several tests which are required prior to use prior to every patient shift. The final decision to use the water for HEMODIALYSIS rests with the medical director.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991495

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

(Optional Format 1-2-96)