K080703

510(k) Section 5 – 510(k) Summary
BTI Filtration Deionization and Carbon Exchange System

510(k) Summary
(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

JUN - 2 2008

1. **Submitter's name and address:**
   BTI Filtration
   7317 N Classen Blvd
   Oklahoma City, OK 73116

2. **Submitter's telephone number and fax number:**
   405.842.2517
   Fax 405.842.3626

3. **Contact person:**
   Ms. Crystal McKay

4. **Date this 510(k) summary prepared:**
   March 4, 2008

5. **Name of the device:**
   - **Trade/proprietary name** – BTI Filtration Deionization and Carbon Exchange System
   - **Common Name** – Carbon tank and DI tank
   - **Classification name** – Water purification component for hemodialysis (21 CFR 876.5665, Product code FIP)

6. **Legally marketed predicate devices to which substantial equivalence is claimed:**
   - AmeriWater Purification System for Hemodialysis (K991519)
   - US Filter Water Purification System for Hemodialysis (K980182)

7. **Description of the device that is the subject of this premarket notification:**
   BTI Filtration Deionizer and Carbon Tank Exchange Service for Hemodialysis includes carbon filtration for the removal of chlorine and chloramines and deionizer (DI) exchange tanks for the removal of contaminants from the water through an ion exchange process to provide AAMI quality water for hemodialysis applications.

   The renal care facilities will supply their own water treatment system, which may consist of water softeners, sediment filters, ultra-filtration, reverse osmosis system, alarms, monitors, tanks, and pumps. BTI Filtration will only be providing the activated carbon and deionization components to their systems

8. **Intended use and indication for use:**

   The device is intended to be used as components of a hemodialysis water purification system to remove organic and inorganic substances from water used to dilute dialysis concentrate to form dialysate, and to produce purified water for other purposes such as dialyzer reprocessing and equipment rinse and disinfection.

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9. Technological characteristics:
The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate devices. The proposed device is designed and assembled with components commonly found in the predicate devices.

10. Non-clinical performance data
BTI Filtration believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance testing was conducted to characterize performance of the proposed BTI Filtration Deionization and Carbon Exchange System to provide a basis of comparison to the predicate devices. Results of the performance testing have demonstrated that the BTI Filtration Deionization and Carbon Exchange System is substantially equivalent to the predicate devices and is suitable for the labeled indications for use.

This concludes the 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2008

4M Ventures, Inc. DBA
c/o Ms. Denice Carr Gallagher
Shotwell & Carr, Inc.
1415 Halsey Way, Suite 304
CARROLLTON TX 75007-4455

Re: K080703
Trade/Device Name: BTI Filtration Deionizer and Carbon Exchange Service for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: March 4, 2008
Received: March 12, 2008

Dear Ms. Gallagher:

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 such 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

510(k) Number (if known): K080703

Device Name: **BTI Filtration Deionizer and Carbon Exchange Service for Hemodialysis**

Indications for Use:

The device is intended to be used as components of a hemodialysis water purification system to remove organic and inorganic substances from water used to dilute dialysis concentrate to form dialysate, and to produce purified water for other purposes such as dialyzer reprocessing and equipment rinse and disinfection. Upon exhaustion, these tanks will be replaced with other Deionization Tanks containing newly regenerated resin or with new resin altogether, or in the case of Carbon Tanks, with tanks containing fresh virgin carbon.

Note: The renal care facilities will supply their own water treatment system, which may consist of water softeners, sediment filters, ultra-filtration, reverse osmosis system, alarms, monitors, tanks, and pumps. BTI Filtration will only be providing the activated carbon and deionization components to their systems.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 and Radiological Devices
510(k) Number K080703