



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
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Cincinnati, OH 45237-3097
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March 14, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER
CIN-WL-12481-02

William F. Miller, President
Dayton Water Systems
430 Leo Street
Dayton, OH 45404

Dear Mr. Miller:

We are writing to you because during an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on December 3-17, 2001, our Investigator collected information that revealed that your firm introduced into commercial distribution the Belmont Dialysis UltraPure Water Treatment System for Hemodialysis which contained a Pretreatment pH Adjustment System (Citric Acid Feed System). The addition of the Pretreatment pH Adjustment System is a significant change to the device, the Belmont Dialysis UltraPure Water Treatment System for Hemodialysis for which your firm submitted a Premarket Notification submission 510(k) to FDA and received premarket clearance.

Under the Federal Food, Drug and Cosmetic Act (the Act), your firm's Belmont Dialysis UltraPure Water Treatment System for Hemodialysis with a Pretreatment pH Adjustment System (Citric Acid Feed System) is considered to be a medical device. Under Section 510(k) of the Act, you are required to notify the FDA at least ninety (90) days prior to introduction of a device in commercial distribution in the United States if the device has been significantly changed or modified in design, components, method of manufacture, or intended use. This requirement is accomplished by the submission of a Premarket Notification requirement (510(k)). The information necessary to comply with the Premarket Notification (510(k)) requirement is found in 21 CFR Part 807, Subpart E - Premarket Notification Procedures.

Our records do not show that your firm submitted a Premarket Notification submission (510(k)) before you began offering the Belmont Dialysis UltraPure Water Treatment System for Hemodialysis that contains a Pretreatment pH Adjustment System (Citric Acid Feed System) for commercial distribution. Your firm's Premarket Notification (510(k)) submission (K981680) does not identify the Pretreatment pH Adjustment System (Citric Acid Feed System) which was installed in two [REDACTED] Dialysis Centers in Youngstown and Dayton, Ohio.

As suggested in the FDA guidance document "Deciding When to Submit a 510(k) for a Change in an Existing Device", a 510(k) should be submitted when in the case of the Pretreatment pH Adjustment System (Citric Acid Feed System) there are significant changes in the mechanism, materials, and safety of the device. Citric acid by itself, let alone in hemodialysis water, has medical uses. In addition, the pH Adjustment system is directly controlled by the RO unit. Any and all optional components such as a pump, mixer, and static mixer that injects and mixes citric acid from a storage container into the feed-water before entering the reverse osmosis (RO) unit must be evaluated via the 510(k) process.

Your firm's device, the Belmont UltraPure Water Treatment System is misbranded within the meaning of Section 502(o) of the Act in that a notice or other information was not provided to FDA as required by Section 510(k) of the Act (as described by Title 21 Code of Federal Regulations (21 CFR 807.81(a)(3)(i)) for a change or modification in the device that could significantly affect the safety or effectiveness of the device, such as the addition of the pH Adjustment System.

Until your firm submits a 510(k) and receives notice from the FDA, Center for Devices and Radiological Health clearing the device for commercial distribution, the Belmont Dialysis UltraPure Water Treatment System for Hemodialysis containing a Pretreatment pH Adjustment System (Citric Acid Feed System) is adulterated under the Act because you did not obtain premarket approval based on information developed by your firm that shows that the device is safe and effective.

During the FDA inspection our Investigator also collected information that revealed serious regulatory problems involving the Water Treatment Systems for Hemodialysis which are manufactured and distributed by your firm. As stated previously, under the Federal Food, Drug, and Cosmetic Act (the Act) these products are considered to be medical devices. The law requires that manufacturers of medical devices conform with the requirements of the Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your firm's devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System Regulation as follows:

-Failure to validate processes where the results of the processes cannot be fully verified by subsequent inspection and test. For example, the regeneration process for the resin that is placed in the deionize tanks and the process of cleaning the resin regeneration system with chlorine have not been validated.

-Failure to document, review, approve, and validate changes to product design. The Pretreatment pH Adjustment System (Citric Acid Feed System) was a design change that was made to your firm's Belmont Dialysis UltraPure Water Treatment System for Hemodialysis and the verification/validation of the design changes were not documented. In addition, no Design History File was established and no design inputs and design outputs were established for the design change.

-Failure to establish and maintain adequate production and process control procedures to ensure that your devices conform to specifications. The deionize tanks regenerated by your firm are not always filled to the required capacity of ██████%. Of seven device history records examined by the FDA Investigator for tanks that were capacity tested, six of the batches tested were under ██████%.

In addition, your firm did not perform the capacity test on all batches of tanks that were supposed to be tested (20% of the batches i.e., all batches ending in 0 and 5). The FDA Investigator determined that of fifty-two Device History Records reviewed, eight batches of deionize tanks regenerated by your firm did not have the capacity tested.

Also, for the cation and anion regeneration process there are no upper and lower limits established for the acid and caustic flow rates. Although there are set points established, the readings for the flow rates fluctuate throughout the process. No upper or lower limit specifications have been established.

The resin regeneration system is required to be sanitized every fourteen days. Your firm's system had not been sanitized since 8/27/01 (approximately four months).

-Failure to establish and maintain adequate procedures for implementing corrective and preventive actions. There had been a total of fourteen reports of nonconforming products (deionize tanks) at your firm. The cause was that the LAL test results were not within specifications. For ten of the test failures the root cause was not documented and for four of the test failures the root cause was listed as sampling error. There was no documentation that a failure investigation was performed and no corrective action was implemented for the LAL test failures.

In addressing a reoccurring problem of leaking deionize tanks, your firm's Corrective Action Request Conclusion was that there is a certain percent of leaks inherent in your firm's deionize tank regeneration process due to the fact that your firm is a regeneration service, not a manufacturer. However, no statistical methodology for trending/monitoring of this reoccurring problem was implemented by your firm.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We received your firm's letters of response to a Form FDA 483 that was issued to you at the close of the FDA inspection of your firm on December 17, 2001. The letters indicated that your firm would be discontinuing services to all dialysis facilities, effective January 31, 2002 but your firm would continue

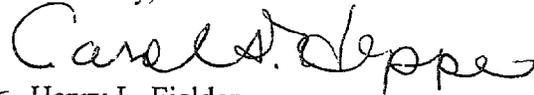
to correct the Quality System Regulations deficiencies that were pointed out to you. The letters also stated that it is your firm's understanding that your firm would not fall under FDA guidelines after January 31, 2002. The letters did not address the issue of premarket clearance (510(k)) from FDA for your firm's device.

Even though you have indicated that your firm does not intend to install any more water treatment systems for hemodialysis (which are medical devices under Section 201(h) of the Act), your firm is still responsible for the systems that were installed at the two Physicians Dialysis Centers in Ohio, and as such your firm is responsible to bring the systems into compliance by submitting a premarket notification 510(k) for the previously mentioned changes to the devices. In addition, your firm is responsible to assure adherence to each requirement of the Act and regulations for all of your firm's medical devices that are in commercial distribution.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237.

Sincerely,



for Henry L. Fielden
District Director
Cincinnati District