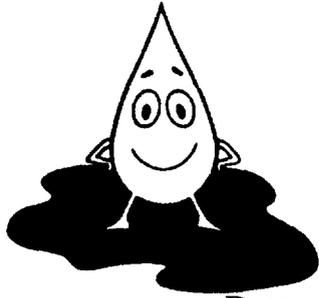


NOV 16 1999



# Better Water, Inc.

## 510(k) SUMMARY

Better Water, Inc.  
698 Swan Dr.  
Smyrna, TN. 37167  
Mike Sterling  
Director of Regulatory Affairs

**Device Names:** Central Concentrate Delivery System for Dialysis, Central Bicarbonate Mixing/Delivery System.

**Substantial Equivalence:** G.E.M Water Systems, International  
Sodium Bicarbonate Mixers/Delivery Systems  
#K970674

**Classification Name:** "Hemodialysis System and Accessories"  
(21 CFR 876.5820)

**Intended Use:** These devices are intended to be used in a hemodialysis facility to allow safe and effective central delivery of concentrates, and central mixing and delivery of sodium bicarbonate solution necessary for a dialysis treatment. When used as a medical device, Federal law restricts this device to sale by or on the order of a physician.

**Device Description:** The central mixing and delivery sodium bicarbonate system (tank) is filled with AAMI standard water, into which a specific amount of sodium bicarbonate powder is poured. It is then mixed in the tank, checked for proper solution, then delivered either manually, or automatically to each patient station on the treatment floor, where it is then mixed/diluted by the dialysis machine for the intended treatment.

The central delivery concentrate system works much the same way, with the exception that the solution is not mixed in the system provided by Better Water, Inc. The solution is either pre-mixed and bulk transferred, or it is mixed in a separate piece of equipment, and then transferred to the bulk storage and delivery system, provided by Better Water, Inc.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Mr. Mike Sterling  
Director of Regulatory Affairs  
Better Water, Inc.  
698 Swan Drive  
Smyrna, TN 37167Re: K992793  
Sodium Bicarbonate Mixing/Delivery System  
and Concentrate Delivery System  
Dated: September 14, 1999  
Received: September 14, 1999  
Regulatory Class: II  
21 CFR § 876.5820/Procode: 78 FIN

Dear Mr. Sterling:

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) 594-4613. 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 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,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATION FOR USE STATEMENT

THE INTENDED USE OF THESE DEVICES IS TO ALLOW THE HEMODIALYSIS FACILITY TO MIX SODIUM BICARBONATE POWDER WITH PURIFIED WATER THAT MEETS AAMI STANDARDS FOR HEMODIALYSIS TREATMENT, AND ALLOW MIXED SOLUTION TO BE AUTOMATICALLY DELIVERED TO THE DIALYSIS MACHINES. IT IS ALSO INTENDED TO AUTOMATICALLY DELIVER A PRE-MIXED CONCENTRATE SOLUTION TO THE DIALYSIS MACHINE.



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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological devices  
510(k) Number K992793

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

Over -the-Counter Use  \_\_\_\_\_