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ZyzaTech Water Purification 510(k)

9/11/96

**SECTION 8****510(k) Summary of Safety and Effectiveness**

This 510(k) Summary of Safety and Effectiveness is provided as part of this Premarket Notification to comply with the provisions of the Safe Medical Device Act of 1990 requiring that either a summary be included in a submission or a statement that a summary is available upon request.

NOV 26 1997

Submitter

Emanuel Amato  
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September 16, 1996

Device Names

## • Trade names

ZyzaTech Portable Series Reverse Osmosis Systems:

- 700 Series
- System 750
- MRE-NF
- F800-F801
- RO-Secura

ZyzaTech V-Series Reverse Osmosis Systems

ZyzaTech Z-Series Reverse Osmosis Systems

ZyzaTech T-Series Reverse Osmosis Systems

ZyzaTech Water Purification Pretreatment System Components

ZyzaTech Water Product Water Distribution System Components

## • Common or usual name

Reverse Osmosis systems with pretreatment and product water distribution components.

## • Classification name

Water purification system for hemodialysis (21 CFR 876.5665)

Intended Use

ZyzaTech Reverse Osmosis Systems and their pretreatment and product water distribution components are intended for use with a hemodialysis system to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysis concentrate to form dialysate, reprocessing of hemodialyzers and equipment rinse and disinfection.

Device Description

The ZyzaTech series RO systems purify feed water through reverse osmosis which is the opposite of osmosis. Osmosis is the natural process wherein concentrated and dilute solutions, separated by a semi-permeable membrane, flow to equalize concentrations. Solvent will flow from the dilute to the concentrated side of the membrane creating equal levels of concentration. Reverse osmosis is the application of high hydrostatic pressure on the concentrated solution; the direction of flow is reversed so that high solute concentrations flow across a semi-permeable membrane and become dilute concentrations. This results in two streams of water; one that is purer than the feed water, and the other

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that is higher in concentrates than the feed water. The pure flow is product water. The high concentrate flow is waste water.

The purpose of a pretreatment section of the system is to remove chlorine/chloramines and to condition the feed water supplying the RO unit. Conditioning the feed water can include: boosting the pressure, tempering, removal of particulates and, often, membrane scaling factors, along with volatile inorganic and organic solutes. The pretreatment section can include: feed water booster pumps, a temperature blend valve, chemical feed unit, cartridge filters, multi-media (sediment) filters, water softeners, dealkalizers and carbon filtration tanks.

The RO unit removes dissolved inorganic solutes, organic solutes with a molecular weight greater than 300, bacteria, viruses, endotoxins and particles. The primary elements of a RO unit are: a prefilter, RO pump and RO membranes housed in pressure vessels.

The purpose of a product water distribution section of a system is to deliver product water that meets AAMI standards to the points of use. Additional post-treatment measures are intended to control or eliminate bacteria prior to the points of use, especially in an indirect feed type of system. The product water distribution section can include: a storage tank, distribution repressurization pumps, distribution loop, UV irradiators, ultra and sub-micron filters.

Depending upon the series and model, ZyzaTech water purification systems produce typically from 250 gpd to 42,000 gpd of product water with a range of 17-75 percent recovery rate. Rejection of total dissolved solids (TDS) and monovalent and polyvalent ions is in the range of 95-99% depending upon feed water characteristics. Bacteria and pyrogens are rejected 99%. Organic size cut-off is a molecular weight greater than 300 Dalton.

ZyzaTech's water purification systems produce product water that meets the requirements of the voluntary standard issued by the American National Standard Institute and the Association for the Advancement of Medical Instrumentation: ANSI/AAMI RDS-1992, Hemodialysis Systems.

Predicate Devices

The ZyzaTech series RO systems and pretreatment and product water distribution components are substantially equivalent to the following legally marketed devices: Water Purification System manufactured by Better Water Inc., HD-100 Hemodialysis Systems & Accessories manufactured by Water Pure Corporation, and Hemo-RO/Milli RO Water Purification Systems manufactured by Millipore Corporation. All these devices use reverse osmosis technology to purify water for hemodialysis applications.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 26 1997

Mr. Emanuel J. Amato  
President  
ZyzaTech Water System, Inc.  
7848 S. 202<sup>nd</sup> Street  
Kent, Washington 98032

Re: K964539  
Water Purification Systems and Components and  
Portable Reverse Osmosis Systems  
Dated: August 25, 1997  
Received: September 9, 1997  
Regulatory class: II  
21 CFR §876.5665/Product code: 78 FIP

Dear Mr. Amato:

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 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 requirement, 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/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE**

**510(k) Number:** K964539

**Device Name:** Reverse Osmosis Systems

**Trade Names:**

ZyzaTech Portable Series, 700 Series, System 750, MRE-NF, F800-F801, RO-Secura

**Central Systems**

ZyzaTech V-Series Reverse Osmosis Systems

ZyzaTech Z-Series Reverse Osmosis Systems

ZyzaTech T-Series Reverse Osmosis Systems

ZyzaTech Water Purification Pretreatment System Components

ZyzaTech Product Water Distribution System Components

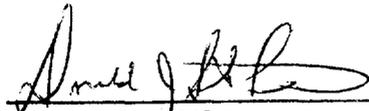
**Classification name**

Water purification system for hemodialysis (21 CFR 876.5665)

**Indications for use:**

A ZyzaTech Portable, V, Z or T Series Reverse Osmosis System and its pretreatment and product water distribution components is intended for use with a hemodialysis system to remove organic and inorganic substances and microbial contaminants from water that is 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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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign/Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K964539

Prescription Use  X   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)