

Fresenius USA, Inc.

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510 (k) Summary of Safety and Effectiveness Information
for the
Fresenius On Line Clearance Monitor

JUL - 3 1997

1. Applicant:

Fresenius USA, Inc
2637 Shadelands Drive
Walnut Creek, CA 94598

Contact Person: Thomas I. Folden
Director, Product Development

Telephone: 1-510-295-0200
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Date Summary Prepared: April 15, 1996

2. Device Name: Fresenius On Line Clearance Monitor

3. Predicate Devices

Fresenius USA, Inc. claims that the On Line Clearance Monitor is substantially equivalent to equipment adaptors for determination of dialyzer performance using conductivity that were made commercially available and found substantially equivalent under premarket notifications K830190 and K841153. Fresenius also claims substantial equivalence to manual invasive blood urea determinations of dialyzer performance.

4. Intended Use

The Fresenius On Line Clearance Monitor is a module that is incorporated into the Fresenius 2008H hemodialysis equipment to be used during a dialysis treatment to determine dialyzer clearance efficiency using changes in conductivity of the dialysate solution.

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5. Device Description

The Fresenius On Line Clearance Monitor (OLC) is a module that is incorporated into the Fresenius 2008H hemodialysis equipment. The OLC consists of hardware modifications to the 2008H dialysate fluid circuit which includes a second conductivity probe in the effluent dialysate line and software. The dialyzer clearance determination is made using changes in dialysate conductivity (Sodium concentration). The software either increases or decreases the dialysate conductivity. This change in conductivity causes a sodium concentration gradient to be formed between the blood and dialysate sides of the dialyzer. Sodium is then either diffused into the blood or out of the blood depending whether the dialysate conductivity is high or low. Accurate conductivity readings of the inlet and outlet dialysate solution can be used to calculate the flux of sodium (or change in conductivity because of changes in sodium concentration) in the dialysate. This value can then be used to calculate the dialyzer clearance of sodium. The clearance of sodium has been used as a surrogate dialyzer performance solute since the beginning of dialysis since urea and Sodium (from NaCl) pass through the dialysis membrane at essentially the same rate.

The use of the On Line Clearance Monitor is non invasive and is performed automatically by the hemodialysis equipment with no effect to the patient or action of the operator and minimizes the need for blood based urea analysis and dialyzer performance determination.

6. Comparison of Technological Characteristics and Statement of Substantial Equivalence

The Fresenius On Line Clearance Monitor utilizes conductivity as a marker to determine dialyzer performance in the same manner as the Colorado Medical equipment adaptor previously found substantially equivalent under premarket notifications K 830190 and K841153 by monitoring the inlet and outlet dialysate conductivities with standard conductivity probes and calculating a clearance value for the dialyzer. The OLC also is equivalent to blood urea clearance determinations currently used clinically to rate dialyzer efficiency.

Testing:

Non Clinical Testing: The use of Sodium (conductivity) as a clearance marker was compared to urea using a number of different dialyzer membranes and found that there was statistically significant correlation that the clearance values obtained were the same.

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Clinical Testing: A modified 2008H hemodialysis machine was used clinically to evaluate dialyzer performance during dialysis comparing clearance performance from the OLC to identical blood side urea measurements. The results of the testing indicated that there was no difference in the clearance determinations between the two methods.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tom Földen
Director, Product Development
Fresenius USA
2637 Shadelands Drive
Walnut Creek, California 94598

JUL - 3 1997

Re: K961465
2008H On Line Clearance Monitor
Dated: April 2, 1997
Received: April 4, 1997
Regulatory class: III
21 CFR §876.5860/Product code: 78 KDI

Dear Mr. Folden:

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/dsmmain.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: K961465

Device Name: Fresenius 2008H On Line Clearance Monitor

Indications for Use:

The Fresenius On Line Clearance Monitor is intended to be used as a module with the Fresenius 2008H hemodialysis machine for determination of dialysis treatment urea clearance efficiency using Sodium conductivity as the surrogate solute marker.

Robert R. Rathbone
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K961465

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use _____