SEP -3 1999

Fresenius Medical Care
North America
Renal Product Technologies

510(k) Summary
Fresenius Blood Monitor
August 19, 1998

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Prepared by: K. M. Associates
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Contact: Donald A. Lincoln

Telephone: 508-384-2546

Trade Name: FRESENIUS Blood Monitor

Common Name: Blood Monitor

Classification Name: System, Hemodialysis, Access Recirculation Monitoring

Substantial Equivalence is claimed to: CRIT-Line Monitor III (K972470)

Device Description: There are a variety of method for measuring relative blood volume (RBV), and all make use of the fact that certain constituents of blood (cells, haemoglobin, plasma protein, total protein) remain confined to the vascular compartment, whereas the plasma water can pass both the capillary membrane (into the interstitial compartment) and the dialyser membrane (into the dialysis fluid compartment). Therefore the blood volume change can be determined from the concentration change of these blood constituents.

The Fresenius Blood Volume Monitor is only to be installed in an available bay of the Fresenius

Dialysis System 2008H machine. It uses ultrasound pulses from a transmitter through a polycarbonate cuvette installed into the arterial blood line and received on the opposite side. The primary signal measure is the transient time of the sound pulse through the blood sample, from which the sound velocity is calculated. Silicone rubber is used as sound coupling for the cuvette, with the blood passing through from bottom to top to avoid accumulation of air bubbles. Blood temperature is also measure, and a temperature controlled block prevents interference from ambient temperature changes.

The sound speed depends on the blood density, which in turn depends on the mass fraction of protein and the mass fraction of water or blood water content (BWC). Since the mass of blood protein is virtually unchanged during ultra filtration, the mass of blood water changes, and thereby the density changes. Changes in BWC can be detected by changes of sound velocity, and can be converted to relative blood volume changes. Since sound velocity not only depends on density, but also on temperature, a high precision temperature measurement is also required.

Intended use: To non-invasively provide real time information about relative blood volume, only in conjunction with the Fresenius Dialysis System 2008H, so that adjustments in the rate at which fluid is removed from the patient can be made to limit or eliminate the common symptoms of dialysis such as nausea, cramping and vomiting.

Comparison with predicate device: Both devices provide non-invasive information related to blood volume changes so that corrections in dialysis rates can be made to avoid unwanted side affects. The predicate device can be used with any dialysis system, this current device is for use only with the Fresenius Dialysis System 2008H. Both provide information with an accuracy of approximately ±2% and compare well with other methods such as centrifuging, which is a periodic measurement. The principal difference between the two BVM's is that the predicate device makes its measurements using infa-red technologies while the current device uses ultrasound.

Clinical testing: Several studies have been reported upon. One comprising 6 centers and 45 patients examined three times, each time six values of blood volume and/or hematrocite were compared to a standard method. The relative blood volume of the current device and the relative blood volume calculated from the hemoglobin concentration had a high correlation of r = .98.

In another study, 9 patients underwent 104 comparison with the centrifuge method. The agreement to the centrifuge was excellent. The mean difference between ultrasonic and centrifuge measurement was 0.1%±1.8%.

Compliance to standards and regulations: The current device, developed in Europe and currently marketed outside the United States, has been tested and found to be in compliance with relevant standards within the EC for devices of this type.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP -3 1999

Fresenius Medical Care North America
c/o Mr. Donald A. Lincoln
K. M. Associates
10 Oak Point
Wrentham, Massachusetts 02093

Re: K982926
Fresenius Blood Volume Monitor
Dated: February 4, 1999
Received: February 5, 1999
Regulatory Class: III
21 CFR 876.5860/Procode: 78 KDI

Dear Mr. Lincoln:

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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducer intended for use with the Fresenius Blood Volume Monitor, as described in your premarket notification:

Device Model	Transducer Model Number
BVM with Control Module	Ultrasonic Sensor Head (20mW/cm^2)

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G,

(enclosed) of the Center's February 17, 1993 "Revised 510(k) Diagnostic Ultrasound Guidance for 1993." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 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) 594-4591. 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 at (301) 443-6597 or at its Internet address "dsmo@fdadr.cdrh.fda.gov".

If you have any questions regarding the content of this letter, please contact Richard J. Williams at (301) 594-1220.

Sincerely yours,

for 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

510(k) Number: K982926

Device Name(s): Fresenius Blood Volume Monitor

Indications For Use:

For non-invasive monitoring, in real time, of the estimated relative blood volume percent for patients undergoing hemodialysis so that technicians may make system adjustments in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common symptoms of dialysis which include nausea, cramping and vomiting.

The device can also provide estimated values of: (1) relative blood volume trend; (2) hematocrit; (3) hemoglobin and (4) blood water content or mass fraction of blood water in the total blood mass.

The device is ONLY to be used in conjunction with the Fresenius Dialysis System 2008H.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legleiter

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982926 /S001