AUG 13 1999

K984546

HEMOCLEANSE

Sorbent-based blood treatment systems

510(k) Summary

HemoCleanse Inc.
2700 Kent Avenue
West Lafayette, IN 47906

Contact: Stephen R. Ash, M.D. Phone/765-463-9540, Fax/765-463-4129

Date of Preparation: May 19, 1999

Trade Name: BioLogic-DT-1000 Machine with BioLogic-DT®-1000-TK Treatment Kit

Common Name: BioLogic DT® System

Classification Name:
Sorbent Regenerated Dialysate Delivery System (per 21 CFR 876.5600) and
Sorbent Hemoperfusion Apparatus (per 21 CFR 876.5870)

Device to which Substantial Equivalence is being Claimed:
Claiming equivalence to BioLogic-DT-1000 Machine with BioLogic-DT®-1000-TK Treatment Kit (K923046, K953751)

Device Description:
The BioLogic-DT System is a sorbent regenerated detoxification system consisting of the BioLogic-DT Machine and the single use BioLogic-DT-1000-TK (Treatment Kit). In many ways, it is similar to a standard hemodialysis machine in that blood is removed from the body, passed through a cellulosic dialyzer, and returned to the body. Within the dialyzer, diffusion causes many chemicals and toxins to pass from the blood into the dialysate surrounding the membranes. Depending on the binding characteristics of the sorbents in suspension in the dialysate, some chemicals remain at low concentration in the dialysate, and are therefore efficiently removed from the blood, while others reach concentrations similar to blood, and are therefore not removed from the blood. Like existing single-access dialysis systems, the BioLogic-DT System alternately withdraws and returns blood through a single-lumen catheter. Unlike standard dialysis machines, which use roller pumps to pass blood through the membranes, the DT applies an alternating pressure/ vacuum cycle to the sorbent suspension causing the alternating expansion and compression of the dialyzer's parallel plate cellulosic membranes. This expansion and compression of the membranes is used to pump blood through the system.

An improvement in software of the DT-1000 System mixes the sorbents before prime, obviating the need for the operator to shake the bag.

Photographs and a detailed description of the DT System are provided in the BioLogic-DT System Technical Manual (modified, Appendix A).

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Intended use of the Device
Treatment of patients with (1) acute hepatic encephalopathy, or (2) serious drug overdose.

Comparison of Technological Characteristics:

BioLogic-DT System, DT-1000-TK	**BioLogic-DT System (Rev. 1.05), DT-1000-TK**
Machine operation	
Combines the use of a long life machine fixture and single use disposable kit to provide therapy	Same
All system functions and diagnostic features are controlled through user interface and embedded software	Same
Vacuum/pressure cycle causes air to pass through the sorbent to mix the sorbent components during the first portion of Prime (obviating the need for shaking the bag)	New
Vacuum/pressure cycle causes dialyzer membrane to expand and contract thus providing impetus for blood flow, while monitoring positive transmembrane pressure gradients	Same
Incorporates bubble detectors to prevent air embolism.	Same
Incorporates tubing occluders to immediately stop blood flow in any situation that may compromise patient safety.	Same
Incorporates systems to detect membrane rupture and limit potential patient blood loss.	Same
Automatically reinfuses electrolytes to counteract depletion by sorbents	Same
Automatically infuses saline (prime fluid) to offset ultra-filtration when desired goal has been met.	Same
Sorbent Components/Function	
Utilizes activated charcoal as primary sorbent for removal of hepatic failure toxins.	Same
Contains cation exchangers for removal of potassium, manganese, etc.	Same
Contains flow-inducing agents	Same
Removes aromatic amino acids strongly.	Same
Increases or maintains constant BCAA levels in blood (due to limited binding of BCAA to charcoal).	Same

Studies Supporting Changes:

Sorbent Mixing in Prime

Non-clinical Performance Data - The method for automatically mixing the sorbent suspension is bubbling air through the Sorbent Bag after saline is added to the dry powder. Air is alternately bubbled through the Sorbent Bag for 15 seconds, then removed from the bag for 10 seconds, for 4 cycles. To perform this required only a software change, to direct air from the accumulator through the Sorbent Bag before priming begins.

Studies showed that 4 cycles of bubbling air through the sorbent results in a well mixed suspension that will flow freely through the dialyzer. Bubbling the sorbent for more than the normal 4 cycles does not appreciably change the sorbent concentration profile.

Seven repetitions of the DT System setup with automatic mixing resulted in swift sorbent flow through the dialyzer (0% clogging) during Prime. The previous method of mixing by user shaking resulted in sorbent clogging, thus no sorbent flow through the dialyzer, in 1 out of 4 (25%) setups.

Clinical Performance Data - N/A. Sorbent mixing occurs during setup of the BioLogic-DT System. If the sorbent clogs, the system will not Prime and the user must begin setting up with a new treatment kit.

Conclusions - Using the pneumatic system to automatically mix the sorbent at the beginning of Prime prevents clogging and assures an optimum sorbent flow during Prime. Automatic mixing simplifies setup for the user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

Stephen R. Ash, M.D., FACP
Chairman and Director of Research and Development
HemoCleanse, Inc.
2700 Kent Avenue
West Lafayette, IN 47906

Re: K984546
BioLogic-DT® System (BioLogic-DT-1000 with DT-1000-TK)
Dated: May 18, 1999
Received: May 21, 1999
Regulatory Class: III
21 CFR §876.5870/Procode: 78 FLD

Dear Dr. Ash:

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

Indications for Use

Ver/3 - 4/24/96

Applicant: HemoCleanse, Inc.

510(k) Number: K984546

Device Name: BioLogic-DT® System (BioLogic-DT-1000 with DT-1000-TK)

Indications for Use:

1) Acute Hepatic Encephalopathy: The BioLogic-DT System is indicated for the treatment of acute hepatic encephalopathy due to decompensation of chronic liver disease or fulminant hepatic failure.

2) Drug Overdose and Poisonings: The BioLogic-DT System is indicated for the treatment of drug overdose and poisonings. The only requirement is that the drug or chemical be dialyzable (in unbound form) and bound by charcoal, such as acetaminophen, tricyclics, barbiturates, tranquilizers, anticancer agents, antimicrobials, theophylline, herbicides, and insecticides.

Contraindication: The BioLogic-DT is not indicated for the treatment of chronic liver conditions or as a bridge to liver transplant.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Prescription Use ✓
(Per 21 CFR 801.109)

David G. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K984546/S021