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510(k) Summary

Submitted in Accordance with 21 CFR 807.92

510(k) Submitted: Novaflux Technologies
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Date Summary Prepared: April 26, 2010

Trade Name: ClearFlux™ Dialyzer Reprocessing System
Common Name: Dialyzer Reprocessing System
Device Classification: Dialyzer Reprocessing System, Product Code LIF
Panel 78 - unclassified

Device Description: The ClearFlux™ Dialyzer Reprocessing System includes hardware and software designed to preprocess dialyzers before their first use by patients, to assign preprocessed dialyzers to patients, and to reprocess the dialyzer for reuse by the same patient to whom the dialyzer was originally assigned. The ClearFlux™ System employs the Novaflux patented two-phase flow cleaning process which is to be used only with the ClearFlux Formula™ (Cleaning Solution) in reprocessing reusable polysulfone-based high-flux dialyzers, and recovers the total cell volume (TCV) and the clearance of small and middle molecules of the dialyzers to levels that are approximately equivalent to those of new dialyzers.

The ClearFlux™ Dialyzer Reprocessing System consists of the following hardware and software components: the ClearFlux™ Machine(s), which performs the actual processing of the dialyzer; the ClearFlux™ Records Management System (CRMS), a patient-dialyzer tracking software loaded onto a System Computer to manage dialyzer reprocessing and reuse; a System Computer; a wireless hub for communication between the ClearFlux™ Machine(s) and the CRMS on the System Computer; a bar code reader to maintain identification of the dialyzers, the ClearFlux™ Machine(s), and the users of the System (e.g., technicians, administrators); a label printer to print the labels for the dialyzers, as well as to print the bar codes for the dialyzers, the users, and the ClearFlux™ Machine(s); a report printer; and an oil-less air compressor with a HEPA filter to provide the filtered airflow necessary for the operation of the ClearFlux™ Machine(s). The ClearFlux™ Dialyzer Reprocessing System (with one System Computer loaded with the CRMS

software) can operate and track the dialyzer reprocessing operations of up to 12 ClearFlux™ Machines.

The chemicals used by the ClearFlux™ System include: Peracetic Acid Disinfectant used in the preprocessing and reprocessing of the dialyzers and in the daily and weekly disinfection of the fluid pathways of the ClearFlux™ Machine(s); the ClearFlux Formula™, a proprietary cleaning solution used exclusively in the ClearFlux™ Dialyzer Reprocessing System and in the weekly cleaning of the fluid pathways of the ClearFlux™ Machine(s); and optionally, Formula 409 NF for the weekly cleaning of the fluid pathways of the ClearFlux™ Machine(s).

Intended Use: The ClearFlux™ Dialyzer Reprocessing System is indicated for the *in vitro* cleaning and disinfection of reusable polysulfone-based high-flux dialyzers, the recovery of the total cell volume (TCV) of the dialyzers, and the recovery of the small and middle molecules clearance of the dialyzers after processing. The ClearFlux™ Dialyzer Reprocessing System preprocesses polysulfone-based high-flux dialyzers prior to their first use. The ClearFlux™ Dialyzer Reprocessing System is indicated to be used only with the ClearFlux Formula™ cleaning solution. The ClearFlux™ Dialyzer Reprocessing System tracks and maintains dialyzer reprocessing operations, as well as dialyzer assignments to patients, and dialyzer reprocessing and reuse.

Substantially Equivalent Devices:

K860674, K914580, K931336, DRS-4® Dialyzer Reprocessing System, Seratronics, Inc.
Agents: Disinfectant - Peracetic Acid
Cleaning solutions - Bleach
Measures: TCV, Leak Rate (pressure decay), Ultrafiltration

K904210, Renatron II® Dialyzer Reprocessing System, Minntech Corp.
Agents: Peracetic Acid cleaning solution and disinfectant, Formula 409 NF machine cleaner
Measures: TCV, Leak Rate (negative pressure leak)

K024076, Maky® 21.1 Dialyzer Reprocessing System, HDC Maquinolas, LLC
Agents: "any acceptable cleaning agent" including bleach or peracetic acid; "any choice of acceptable germicides" including bleach, peracetic acid, formaldehyde and glutaraldehyde
Measures: TCV, Leak Rate (pressure decay)
Process: "The aggressive agitation process is a result of a hydro-pneumatic design that combines high air pressure with a cleaning agent, forcing particles out of the dialyzer."

K834447, ECHO MM-1000® Automated Dialyzer Reprocessor, Mesa Laboratories, Inc.
Agents: Disinfectants - glutaraldehyde, formaldehyde, peracetic acid
System cleaning - disinfectant, bleach

Measures: TCV, Leak Rate (pressure decay)

Non-clinical Performance Studies: Test results confirm that the patented ClearFlux™ two-phase flow process recovers the TCV and the clearance of small and middle molecules of reusable polysulfone-based high-flux dialyzers to levels that are approximately equivalent to those of new dialyzers, and that the ClearFlux™ process does not cause adverse effects on the dialyzers. The tests include: Cytotoxicity, Scanning Electron Microscopy, X-Ray Photoelectron Spectroscopy, Size Exclusion Chromatography, Total Cell Volume, Complement Activation, Albumin Loss, Clearance of Small Molecules, Clearance of Middle Molecules, Hydraulic Permeability and Pressure Leak. The results from these tests support the effectiveness of the ClearFlux™ System, as indicated.

Summary: Novaflux Technologies has performed *in vitro* and functional tests to show that the ClearFlux™ Dialyzer Reprocessing System does not have adverse effects on polysulfone-based high-flux dialyzers processed with the patented two-phase flow cleaning process, and that the ClearFlux™ System recovers the TCV and the clearance of small and middle molecules to levels that are approximately equivalent to those of new dialyzers.

Conclusion: The information provided in the 510(k) supports the claim that the ClearFlux™ Dialyzer Reprocessing System is substantially equivalent to legally marketed predicate devices for the intended use in reprocessing polysulfone-based high-flux dialyzers for reuse.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mohamed E. Labib, Ph.D.
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PRINCETON NJ 08540

NOV - 3 2010

Re: K091360
Trade/Device Name: ClearFlux™ Dialyzer Reprocessing System
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LIF
Dated: September 17, 2010
Received: September 20, 2010

Dear Dr. Labib:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K091360

Device Name: ClearFlux™ Dialyzer Reprocessing System

Indications for Use:

The ClearFlux™ Dialyzer Reprocessing System is indicated for the reprocessing of polysulfone-based high-flux dialyzers for reuse, for preprocessing the dialyzers prior to their assignment to patients for first use, and for tracking the reprocessed dialyzer for use only by the patient to whom the dialyzer was initially assigned. The steps used in reprocessing hemodialyzers with the ClearFlux™ System include: (1) pre-cleaning, (2) cleaning, (3) rinsing, (4) volume and leak testing, and (5) disinfecting the dialyzers in accordance with the "AAMI Recommended Practice for Reuse of Hemodialyzers." The ClearFlux™ System performs the patented *in-situ* two-phase cleaning cycle during reprocessing, which recovers the total cell volume and the clearance of small and middle molecules of the dialyzers to levels that are approximately equivalent to those of new dialyzers. The ClearFlux™ Dialyzer Reprocessing System is also indicated for performing record keeping of the dialyzer processing operation. The ClearFlux™ Dialyzer Reprocessing System is indicated to be used only with the ClearFlux Formula™ cleaning solution.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K091360