510(k) Summary per 21 CFR 807.92

Submitter	Nipro Medical Corporation 3150 NW 107th Avenue Miami, FL 33172 FDA Establishment #: 1056186
Contact Person	Jessica Oswald-McLeod Phone: 305-599-7174 Fax: 305-592-4621
Date of Preparation	November 18, 2013
Device Trade Names	Nipro PUREFLUX™-L Hemodialyzer
Device Classification Name	Conventional Dialyzer per 21CFR 876.5820
Common Name	Hemodialyzer
Substantial Equivalence	K062079 Baxter Xenium Hemodialyzer K926005 Fresenius Hemoflow K043244 Fresenius Optiflux
Device Description	The PUREFLUX™-L hemodialyzer is a medical device used as an artificial kidney system for the treatment of patients with renal failure. During treatment, blood is circulated from the patient through the hemodialyzer's blood compartment, while the dialysate solution flows countercurrent through the dialysate compartment. In this process, toxins and/or fluid are transferred across the membrane from the blood to the dialysate compartment. The PUREFLUX™-L hemodialyzer is composed of polyethersulfone fiber and is available in various sizes, which are differentiated by membrane surface area.

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Intended Use	Hemodialysis with a PUREFLUX™-L dialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs. The device is for prescription use only. This product is intended for single use only. The performance properties of reused dialyzers have not been established.
Technological Aspects	Both the PUREFLUX-L dialyzer and the Baxter Xenium predicate dialyzer are composed of polyethersulfone fiber. The hemodialyzer design and membrane composition are equivalent between the PUREFLUX-L dialyzer and the predicate device. Non-clinical studies included those for analyte clearance (urea, creatinine, phosphate, Vitamin B_{12}), ultrafiltration coefficient and pressure drop. Results of these studies establish substantial equivalence to Fresenius hemodialyzer performance and PUREFLUX-L results are included in product labeling.
Conclusion	Testing performed on the PUREFLUX™-L dialyzer indicates that it is safe, effective and performs as well as the predicate devices, when used in accordance with the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 4, 2013

Nipro Medical Corporation
% Carolyn K. George
Consultant
Quality System Engineering
3150 NW 107th Avenue
Miami, FL 33172

Re: K122952
Trade/Device Name: PUREFLUX™-L Hemodialyzers
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FJI
Dated: November 18, 2013
Received: November 19, 2013

Dear Carolyn K. George,

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 -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K122952

Indications for Use

510(k) Number:

Device Name: PUREFLUX™-L Hemodialyzers

Indications for Use:

Hemodialysis with a PUREFLUX™-L hemodialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

The device is for prescription use only.

This product is intended for single use only. The performance properties of reused dialyzers have not been established.

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)

Herbert P. Lerner -S
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