DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 8, 2017

Nipro Medical Corporation
Jessica Oswald-Mcleod
Director, Quality and Regulatory
3150 NW 107th Avenue
Doral, FL 33172

Re: K160444
Trade/Device Name: Nipro FB-U Hemodialyzer
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: January 5, 2017
Received: January 9, 2017

Dear Jessica Oswald-Mcleod:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Charles Viviano -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160444

Device Name
Nipro FB-U Hemodialyzer

Indications for Use *(Describe)*

Hemodialysis with the FB-U 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary: Nipro FB-U Hemodialyzer

Applicant: Nipro Medical Corporation
3150 NW 107th Ave.
Miami FL 33172
Tel: 305-599-7174
Establishment Reg.: 1056186

Contact Person: Jessica Oswald-McLeod
Director, Quality Assurance & Regulatory Affairs

Date of summary preparation: September 29, 2016

Description of Device

Trade Name: NIPRO FB-U Hemodialyzer
Common Name: Dialyzer
Classification Name: dialyzer, high permeability with or without sealed dialysate system
Regulation Number: 21 CFR part 876.5860
Regulatory Class: II
Panel: Gastroenterology/Urology
Product Code: KDI

Legally marketed substantial equivalent device:

Nipro Elisio-M (K131935)
Baxter Exeltra (K030974)

Description of device:

The Nipro FB-U hemodialyzer is a medical device intended for use as an artificial kidney system for the treatment of patients with renal failure. During treatment, blood is circulated from the patient, through the extracorporeal system, into 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.

Indications for Use:

Hemodialysis with the Nipro FB-U 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.

Comparison of technological characteristics:

The dialyzer is substantially equivalent to the predicate device in the following technological characteristics:

Element of Comparison	Proposed	Predicate/s
Materials	Housing: Polypropylene Membrane: Cellulose Triacetate	Housing: Polypropylene/polycarbonate Membrane: Polyether sulfone/ Cellulose Triacetate
Design	Mechanical device consisting of a cylindrical rigid housing enclosing hollow fibers	same
Intended Use	Intended to be used as part of an artificial kidney system for the removal of toxins and excess water from the blood	same
Energy Source	To be used with dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system	same

Non-clinical tests submitted:

Dimensional and performance to include: positive and negative pressure tests, blood compartment integrity, clearances, Ultrafiltration coefficient, volume of blood compartment, and pressure drop.

Other test items include: Transportation tests, biocompatibility, and shelf-life testing. These tests along with their associated results and conclusions are included in this submission.

Clinical tests:

This submission does not warrant any clinical testing, therefore no clinical testing performed for or provided in this submission.

Conclusions drawn from non-clinical and clinical tests:

The results of the performance testing and the comparison of technological characteristics with the predicate device demonstrate that the Nipro FB-U Dialyzer performs equivalent to the predicate device and is safe and effective when used as intended.