DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 23, 2016

Oxyless Ltd.
% Bob Duffy
President
Bob Duffy Associates
16405 Summer Sage Road
Poway, CA 92064

Re: K150304
Trade/Device Name: Oxyless Blood Tubing Set
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: FJK
Dated: January 28, 2016
Received: January 29, 2016

Dear Bob Duffy,

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,

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

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)*
K150304

Device Name
Oxyless Blood Tubing Set

Indications for Use *(Describe)*
The Oxyless Blood Tubing set with transducer protector and optional priming set comprises disposable blood tubing lines intended to provide extracorporeal access to the patient's blood during hemodialysis. This blood tubing set is indicated for use with a medically prescribed hemodialyzer. The compatibility of available configurations is the responsibility of the physician in charge.

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.

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510(k) Summary
Oxyless Blood Tubing Set

21CFR 807.92 (a)(1) SUBMITTER

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510(K) Summary prepared: 2/22/2016

21CFR 807.92 (a)(2) DEVICE NAME

Trade Name: Oxyless Blood Tubing Set
Common Name: Hemodialysis Blood Tubing Set
Classification Name: Hemodialysis System and Accessories
Product Code: FJK

21CFR 807.92 (a)(3) PREDICATE DEVICE

The predicate for the Oxyless Blood Tubing Set is the:

Nipro Blood Tubing Set cleared under 510(k) K072024:

a. **Device Proprietary Name:** Blood Tubing Set with Transducer Protector and Priming Set
b. **Manufacturer:** Nipro Medical Corporation
c. **Product Code:** FJK
d. **Indications for Use:** Disposable blood lines intended to provide extracorporeal access to the patient's blood during hemodialysis. The compatibility of available configurations is the responsibility of the physician in charge.

The basis for the Oxyless Blood Tubing Set Abbreviated 510(k) submission is for a new device.

21CFR 807.92 (a)(4) DEVICE DESCRIPTION

The Oxyless Blood Tubing Set is a hemodialysis blood tubing set designed to transport blood from a patient for acute or chronic hemodialysis treatment from the point of access to the dialyzer fixed to the hemodialysis machine and returning to the patient to complete the extracorporeal circuit. The tubing line components are pre-configured and packaged as an arterial line, a venous line and in some configurations, a priming line, for use with various dialysis machines from Fresenius, Nikkiso, B. Braun and Gambro.

The components of the Oxyless Blood Tubing Set include pump tubing, air trap

chambers, pressure monitoring lines, injection ports, service lines and tubing clamps.

Major materials used for the various components of the Oxyless Blood Tubing Set are polyvinyl chloride (PVC), polycarbonate (PC), polypropylene (PP), polytetrafluoroethylene (PTFE) and silicone. The device is DEHP-free.

Each Oxyless Blood Tubing Set is packaged as sterile and for single use only. It is for prescription use only on the order of a healthcare professional.

21CFR 807.92 (a)(5) INDICATIONS FOR USE/INTENDED USE

The Oxyless Blood Tubing Set with transducer protector and optional priming set comprises disposable blood tubing lines intended to provide extracorporeal access to the patient's blood during hemodialysis. This blood tubing set is indicated for use with a medically prescribed hemodialyzer. The compatibility of available configurations is the responsibility of the physician in charge.

21CFR 807.92 (a)(6) COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Oxyless Blood Tubing Set with transducer protector and optional priming set has the same technological characteristics (i.e. design, material, chemical composition, energy source) as the predicate device identified above. The following table provides a summary of the technological characteristics of the new device in comparison to those of the predicate device.

Category	**Oxyless Blood Tubing Set** New Device	**Nipro Blood Tubing Set** Predicate Device
1. Trade Name	Oxyless® Set - Blood Tubing Set with Transducer Protector and optional Priming Set	Nipro® Set - Blood Tubing Set with Transducer Protector and Priming Set
2. Model Number	LK36355RO, LK76154RO, LK14529RO, LK46451RO, CK84-14-B, CK84-14-C, CK84-14-D, CK84-14-E	A201-A219, V801-V806, 5M9634, 5M9693
3. 510(k) submitter/holder	Oxyless Ltd.	Nipro Medical Corporation
4. Manufacturer	Oxyless Ltd.	Nipro Medical Corporation
5. 510(k) Number	K150304	K072024
6. Regulation Number	21 CFR 876.5820	21 CFR 876.5820
7. Regulation Name	Hemodialysis system and accessories	Hemodialysis system and accessories
8. Regulatory Class	Class II	Class II

Category	**Oxyless Blood Tubing Set** New Device	**Nipro Blood Tubing Set** Predicate Device
9. Product Code	FJK	FJK
10. Intended Use/Indications for Use	The Oxyless Blood Tubing Set with transducer protector and optional priming set comprises disposable blood tubing lines intended to provide extracorporeal access to the patient's blood during hemodialysis. This blood tubing set is indicated for use with a medically prescribed hemodialyzer. The compatibility of available configurations is the responsibility of the physician in charge.	Disposable blood tubing lines intended to provide extracorporeal access to the patient's blood during hemodialysis. The compatibility of available configurations is the responsibility of the physician in charge.
11. Device design	Blood Tubing lines configured as: 1. Arterial line 2. Venous line 3. Priming line (on some models)	Blood Tubing lines configured as: 1. Arterial line 2. Venous line 3. Priming line (on some models)
12. Blood Tubing Set Components	Tubing, air trap chambers, pressure monitoring lines, service lines, injection ports and tubing clamps	Tubing, air trap chambers, pressure monitoring lines, service lines, injection ports and tubing clamps
13. Sterility	Sterile	Sterile
14. Pyrogenicity	Non-pyrogenic	Non-pyrogenic
15. Single use or reuse	Single use	Single use

In summary, the comparison demonstrates that the Oxyless Blood Tubing Set is substantially equivalent to the Predicate device.

21CFR 807.92 (b)(1) NON-CLINICAL TESTING

Bench performance testing of the Oxyless Blood Tubing Set was conducted and compared to the predicate device to support substantial equivalence, in accordance with the performance testing described in the FDA Guidance for Hemodialysis Blood Tubing Sets. This testing consisted of:

1. pressure leak testing

2. pump segment endurance testing
3. injection port endurance testing
4. priming volume assessment
5. tensile testing of joints and materials of all tubing segments
6. pressure transducers leak testing
7. clamp performance testing
8. tubing kink resistance
9. blood tubing set operational testing with a blood analog fluid for four hours at 37°C

Biocompatibility testing, similar to that performed on the predicate device for its 501(k) submission, was conducted as described in "Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The following suggested tests were conducted and demonstrate that the materials in the Oxyless Blood Tubing Set are biocompatible for its Intended Use:

- Cytoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- System Toxicity (Acute)
- Genotoxicity
- Hemocompatibility and Hemolysis
- Pyrogenicity

21CFR 807.92 (b)(2) CLINICAL TESTING

No clinical tests are submitted, referenced, or relied on in this premarket notification submission for a determination of substantial equivalence.

21CFR 807.92 (b)(3) CONCLUSIONS FROM NON-CLINICAL TESTS

The results of the performance testing of both the Oxyless Blood Tubing Set and the predicate device meet the acceptance criteria for all tests. The results of the testing also demonstrate that the Oxyless Blood Tubing Set is as safe, as effective and performs as well as the legally marketed predicate device, thus demonstrating substantial equivalence. Biocompatibility testing for the Oxyless Blood Tubing Set, similar to that conducted for the predicate device, demonstrates that the materials used are biocompatible for its intended use.