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SUMMARY OF SAFETY AND EFFECTIVENESS FOR NIPRO BRANDED DISPOSABLE BLOOD TUBING SET FOR HEMODIALYSIS

§807.92 (a)(1)

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§807.92 (a)(2)

Trade Name: Nipro Arterial and Venous Blood Tubing Set for Hemodialysis
Common Name: Blood tubing set
Classification Name: Blood access device and accessories (21 CFR 876.5540)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Devices:

Kawasumi Blood Tubing Line
gambro® Blood line set for hemodialysis

§807.92 (a)(4)

Description of Device: The tubing sets that we intend to market include arterial and venous dialysis blood tubing (nonimplanted blood access device) as described in 21 CFR 876.5540. Various models of blood tubing sets are being manufactured for application with different dialysis machines. Twenty-seven arterial line models (A001 - A021, A026, A029-A032, and A035) and 14 venous line models are described (V600 - V607, V609 - V613, and V616). All components



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of blood tubing, including drip chambers, infusion tubing, monitor lines, ports and segments which are used to pump blood, retain and capture air and blood debris, infuse medications or fluids, sample blood, monitor pressure, and make connections to other devices are included. The materials used for the components include polyethylene (PE), polyvinylchloride (PVC), acrylonitrile butadiene styrene (ABS), polyoxymethylene (POM), polypropylene (PP), polycarbonate (PC) and polyethylene high density (PEHD).

§807.92 (a)(5)

Intended Use:

The blood tubing sets are used to transport blood or fluids to a patient's vascular access device from a hemodialyzer. The reverse is also true in that the tubing set is used as to transport blood or fluids from a patient's vascular access device to a hemodialyzer.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The configuration of the subject device is similar to legally marketed devices from Kawasumi and Gambro®. Colored parts (red - arterial and blue- venous) as well as tubing colors are similar. Accessory lines are designed similarly also. Caps are placed at both ends of the blood circuit to maintain sterility.

Labeling for the competitor's devices is similar to the subject device. According to the device names on the labeling, the intended use for the competitors' products is similar to that of the subject device. They are arterial and venous blood tubing sets for hemodialysis. All of the devices are labeled as sterile and for single use only. The devices are restricted to sale by or on the order of a physician

The materials used to fabricate the tubing sets are similar as well. IR spectra of component materials of the predicate devices were used to identify them as similar to those of the subject device. The conclusion is that the materials of which the subject device is composed are substantially equivalent to those of the legally marketed predicate devices. Results from chemical and biological

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tests demonstrate that Nissho's blood tubing sets are similar to those of gambro® and Kawasumi.

§807.92 (b)(1)

The following performance and biocompatibility tests were performed on the subject device as well as the legally marketed devices for comparison.

1. Priming Volume Test

Auxiliary tubing is closed with clamp connectors and pathways are filled with distilled water. The tubing set is weighed and then the water is drained. Empty tubing sets are weighed again. Volume is expressed in milliliters (ml).

Observations found to be within acceptable range and tests results were similar to values obtained for Kawasumi and gambro® blood tubing sets.

2. Pull Force at Connecting Joints (A tensile strength tester is used.)

- a. Between the main tubing (or saline line) and connected parts or other tubing.
- b. Between heparin lines and connected parts.

A 50 mm sample of tubing with the connected part or other tubing is cut and set on the apparatus. After disengagement of the test tubing from the part or other tubing, the result is recorded from the printer.

The specification is defined as $\pm 10\%$ variance from nominal values mean of outer diameter of the pump segment. The subject and the legally marketed devices conformed to this specification.

3. Torque Force

The torque gauge is connected to the tubing which is connected with a female luer lock. The male luer lock cap is turned by hand and torque force read and recorded from dial gauge.

4. Endurance Test of the Pump Segment

The diameter of the rolling tube is measured before and after pumping at 200 ml/min for 4 hours at 37° C. The percentage of diameter increase is calculated and recorded.

The specification is defined as $\pm 10\%$ variance from nominal values mean of outer diameter of the pump segment. The subject and the legally marketed devices conformed to this specification.

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5. Air Leakage above Atmospheric Pressure

Air compressor is set at 2.5 kgf/cm² G and connections of tubing attached appropriately. Sample is then immersed into the water bath and pressure applied at 0.1kgf/cm² G within seconds. If there is no leakage at the connection, then pressure is gradually increased at 0.1 kgf/cm² G intervals. The pressure at which leakage occurs is recorded.

Results were similar to those obtained with legally marketed devices. Leaks occurred at pressures more than 2.0 kgf/cm²G. No clogging was noted.

6. Air Leakage below Atmospheric Pressure

The access port is punched 6 times in the same location using an 18G needle. The blood line is then attached to the appropriate fitting and the pathway filled with distilled water. The pressure is set 200 mmHg below atmospheric pressure at sea level. The presence or absence of air bubbles in the pathway is noted.

No air bubbles occurred in samples tested and results were similar in legally marketed devices for comparison.

The following tests were conducted on the finished sterilized device: pyrogenicity, cytotoxicity, acute toxicity (systemic injection) test, intracutaneous reactivity (skin reaction), sensitization, hemolysis, mutagenicity, and implantation. Specifications for these tests are outlined below.

Biocompatibility Test Specifications

Test	Specification
Pyrogenicity	Nonpyrogenic
Cytotoxicity (Elution Test)	No biological reactivity
Acute Toxicity (systemic injection)	No biological reactivity/death
Intracutaneous reactivity	No erythema, edema, or necrosis
Sensitization	Not a sensitizer
Hemolysis	Not to exceed 10%
Ames Mutagenicity	Not mutagenic
Implantation	No hemorrhage, film or encapsulation

Results indicate that the blood tubing sets conform to the specifications set forth. Predicate devices for comparison show similar results when tested using these methods.

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§807.92 (b)(3) Results from nonclinical tests performed on both the subject and legally marketed devices demonstrate that Nipro Disposable Blood Tubing Set for Hemodialysis is substantially equivalent. Similar results were obtained from tests on subject and predicate devices.

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