

Section 6- 510(k) Summary

MAR 30 2009

a. Company name, address

NIKKISO CO., LTD.
43-2, Ebisu 3-Chome, Shibuya-ku
Tokyo, 150-8677, Japan

b. Contact

Masashi Yoshida
Manager Regulatory Affairs

c. Date prepared

August 18, 2008

d. Name of device

Trade Name: NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS
Common Name: Hemodialysis system and accessories
Classification Name: Hemodialysis system and accessories

e. Predicate devices

The NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS is substantially equivalent to:

510(k): K010264
Trade name: Nipro® Blood Tubing Set with Transducer Protectors and Priming Set
Product code: FIB, FJK

f. Description of the device

The NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS includes arterial and venous dialysis blood tubing (non-implanted blood access device) as described in 21 CFR 876.5820.

The devices are packaged together for convenient use during for hemodialysis procedures. Three models of the NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS (AV06A-P, AV06B-P, AV06C-P) are being manufactured for use with the Nikkiso DBB-05 Hemodialysis Delivery System (K061519).

The components of the NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS include pump tubing, air trap chambers, transducer filters, pressure monitoring lines,

NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS
PREMARKET NOTIFICATION 510(k)

infusion lines for saline, access ports and tubing clamps which are all used to pump blood, retain and capture blood debris, infuse medications or fluids, sample blood, monitor pressure, and make connections to other devices.

Major materials used for the various components are Polyvinyl chloride (PVC), polycarbonate (PC), polypropylene (PP). Materials in direct or indirect contact with blood are Polycarbonate (PC), Polyvinyl chloride (PVC), Silicone, Polypropylene (PP) and Polytetrafluoroethylene (PTFE).

The NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS are restricted for sale by or on the orders of a physician.

The NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS are packaged sterile and labeled for single use only and non-pyrogenic. Sterility and non-pyrogenicity were confirmed by sterilization validation and pyrogenicity testing.

Biocompatibility tests were performed in compliance with ISO10993 requirements and include acute toxicity, intracutaneous reactivity, hemolysis testing, and implantation testing. The results of biocompatibility testing did not raise any question regarding biocompatibility, and support the equivalence to the predicate device.

The NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS are designed for use with the Nikkiso DBB-05 Hemodialysis Delivery System (K061519).

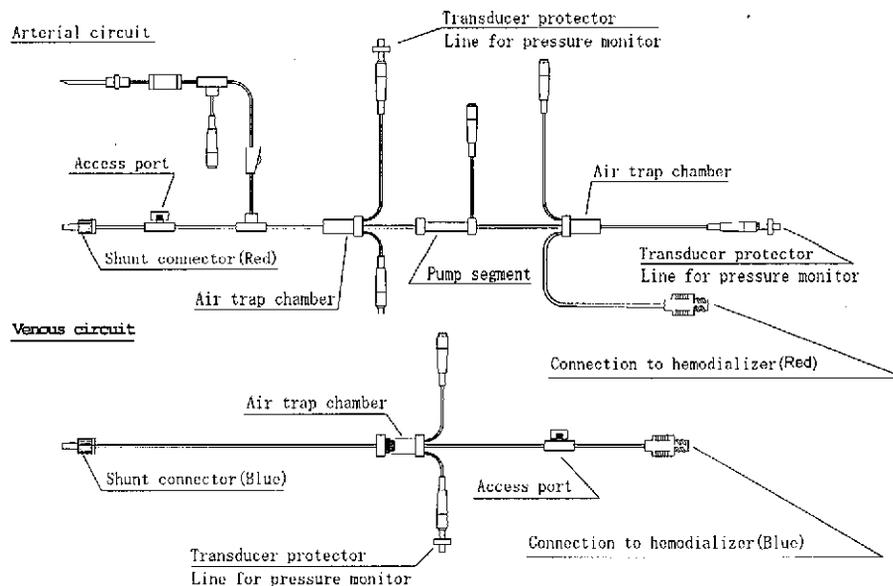


Figure 1. NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS (AV06A-P)

g. Indications for Use**Indication for Use**

The NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS are disposable bloodlines intended to provide extracorporeal access to a patient's blood during hemodialysis. The compatibility of available configurations is the responsibility of the physician or other licensed practitioner.

h. Statement of substantial equivalence

The NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS is substantially equivalent to the Nipro® Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming Set (K010264) (Hereinafter "the Nipro tubing set").

Table 1 compares NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS to the Nipro tubing set. Both tubing lines have the same intended use, same configurations and same major materials. Both of the tubing lines are sterile and labeled as single use only and non-pyrogenic. Tests results from biocompatibility tests for the NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS in compliance to ANSI/AAMI RD17: 2007 "Cardiovascular implants and artificial organs - Extracorporeal blood circuit for hemodialyzers, hemodiafilters, and hemofilters" (Hereinafter "RD17") and ISO10993 did not raise any concerns regarding biocompatibility. Nikkiso performed all tests required in RD17 for both NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS and the Nipro tubing set.

As shown in Table 1, both tubing lines met the requirements in RD17 including sterility, pyrogenicity and mechanical characteristic tests.

Based on the above considerations, Nikkiso concludes that the NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS is substantially equivalent to the Nipro tubing set.

NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS
PREMARKET NOTIFICATION 510(k)

Table 1. Comparison table

| No. | Item | Proposed Device | Predicate Device |
|-----|---|--|---|
| | | NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS | The Nipro Tubing Set (K010264) |
| 1 | Indication for use | The NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS are disposable bloodlines intended to provide extracorporeal access to a patient's blood during hemodialysis. The compatibility of available configurations is the responsibility of the physician or other licensed practitioner. | The Nipro Blood Tubing Set with Transducer Protector and Priming Sets are 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 |
| 2 | Configuration | The NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS are composed of various components such as tubing, luer locks, connectors, tubing clamps and air trap chambers that are configured for connecting a patient's vascular access system to a dialyzer. The tubing lines components are pre-configured and packaged as an arterial line, a venous line, an infusion line, a saline line and pressure monitoring lines for use with the Nikkiso DBB-05 Hemodialysis Delivery System (K061519). | The Nipro blood tubing lines are composed of various components such as tubing, luer locks, connectors, clamps and drip chambers that are configured for connecting a patient's vascular access system to a dialyzer. The tubing lines components are pre-configured and packaged as an arterial line, a venous line, an infusion line, a saline line and pressure monitoring lines for use with various dialysis systems such as Fresenius, Baxter, Cobe, Althin, etc. |
| 3 | Biological Safety | Meets ANSI/AAMI RD17: 2007 and ISO10993. Tests results from biocompatibility tests for The NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS did not raise any concerns regarding biocompatibility including: <ul style="list-style-type: none"> • Cytotoxicity • Sensitization • Irritation or intracutaneous reactivity • Acute Systemic toxicity • Hemocompatibility • Genotoxicity | Meets ANSI/AAMI RD17 and ISO10993. |
| 4 | Sterility | | |
| | -method -SAL 10 ⁻⁶ | Steam sterilization Assured SAL 10 ⁻⁶ by validation met ISO11134 and EN554. | Ethylene Oxide sterilization Assured SAL 10 ⁻⁶ by validation met ISO11135-1 |
| 5 | Pyrogenicity | Non- pyrogenic | Non-pyrogenic |
| 6 | Single use or reuse | Single use only. | Single use only. |
| 7 | Structural integrity | Meets 4.4.1 Structural integrity AAMI RD17: 2007. | Meets 4.4.1 Structural integrity AAMI RD17: 2007. |
| 8 | Connection to hemodialyzer, hemodiafilter or hemofilter | Meets 4.4.2 Connection to hemodialyzer, hemodiafilter or hemofilter AAMI RD17: 2007. | Meets 4.4.2 Connection to hemodialyzer, hemodiafilter or hemofilter AAMI RD17: 2007. |

NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS
PREMARKET NOTIFICATION 510(k)

Table 1. Comparison table (continued)

| No. | Item | Proposed Device | Predicate Device |
|-----|--------------------------------------|---|--|
| | | NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS | The Nipro Tubing Set (K010264) |
| 9 | Connection to vascular access device | Meets 4.4.3 Connection to vascular access device AAMI RD17: 2007. | Meets 4.4.3 Connection to vascular access device AAMI RD17: 2007. |
| 10 | Connection to ancillary components | Meets 4.4.4 Connection to ancillary components AAMI RD17: 2007. | Meets 4.4.4 Connection to ancillary components AAMI RD17: 2007. |
| 11 | Color coding | Meets 4.4.5 Color coding AAMI RD17: 2007. The arterial patient-connection is red, the venous patient-connection is blue. | Meets 4.4.5 Color coding AAMI RD17: 2007. The arterial patient-connection is red, the venous patient-connection is blue. |
| 12 | Needle access ports | Meets 4.4.6.1 Needle access ports AAMI RD17: 2007. | Meets 4.4.6.1 Needle access ports AAMI RD17: 2007. |
| 16 | Transducer protector | Meets 4.4.9.1 Integral transducer protectors AAMI RD17: 2007. | Using Borla's transducer protector (K000702). |
| 20 | Raw materials | PVC, PC, PP, Silicone are used for the components in the product. PBT and PTFE are used specifically for the transducer protectors. | PVC, PE, PC, PP, POM are used for the components in the product. PBT and PTFE are used specifically for Borla's transducer protectors. |

PBT : Polybutylene terephthalate

PC : Polycarbonate

PE : Polyethylene

POM : Polyoxymethylene

PP : Polypropylene

PTFE : Polytetrafluoroethylene

PVC : Polyvinyl chloride

Silicone : Silicone Rubber

Note:

Tests including blood pathway volume, blood pathway flow dynamics, pump segment performance and occlusive clamping of tubing for the NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS were performed successfully in accordance with AAMI RD17: 2007. Since the Nipro Tubing Set (K010264) was cleared by FDA and subjected to the same tests by Nipro, Nikkiso concludes that the test results for the Nipro Tubing Set and the NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS are substantially equivalent.

K082719

NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS
PREMARKET NOTIFICATION 510(k)

i. Conclusion

Based on the above discussion and enclosed sections regarding substantial equivalence to predicate devices, NIKKISO CO., LTD. concludes that the NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS is substantially equivalent to the Nipro® Blood Tubing Set with Transducer Protectors and Priming Set (K010264) and does not raise any new questions regarding safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 30 2009

Nikkiso Co. Ltd.
c/o Dr. Fumiaki Kanai
MIC International
4-1-17 Hongo
Bunkyo-ku, Tokyo 113-0035
JAPAN

Re: K082719
Trade/Device Name: NIKKLINE Blood Tubing Lines with Transducer Protectors
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KOC
Dated: March 11, 2009
Received: March 17, 2009

Dear Dr. Kanai:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

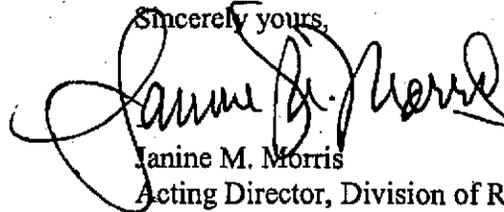
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|----------------|----------------------------------|----------------|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | (240) 276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | (240) 276-0115 |
| 21 CFR 892.xxx | (Radiology) | (240) 276-0120 |
| Other | | (240) 276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry.support/index.html>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K082719

Device Name: NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS

Indication for Use

The NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS are disposable bloodlines intended to provide extracorporeal access to a patient's blood during hemodialysis. The compatibility of available configurations is the responsibility of the physician or other licensed practitioner.

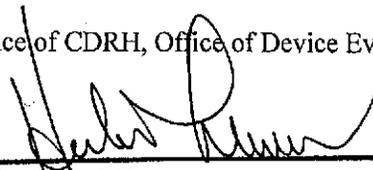
Prescription Use
(Per 21 CFR 801 Subpart D)

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, Abdominal,
and Radiological Devices

510(k) Number K082719