AUG 16 2004

K032975

510(k) Summary of Safety and Effectiveness

1. Manufacturer and contact Information

1.1 Manufacturer

JMS Singapore Pte Ltd
440 Ang Mo Kio Industrial Park 1
Singapore 569620

1.2 Sponsor

JMS North America Corperation
22320 Foothill Blvd., Suite 350
Hayward, CA 94541
USA

1.3 Contact Information

Swee Cheau, Chong
Manager of RA & QA
JMS North America Corperation
22320 Foothill Blvd., Suite 350
Hayward, CA 94541
Telephone: (510) 888-9090
Fax: (510) 888-9099

2. Device Classification Name

Gastroenterology Devices Panel has classified Hemodialysis System and accessories as Class II. Reference 21 CFR 876.5820

3. Predicate Device Name

JMS Blood Tubing Sets which are substantially equivalent to the following predicate devices which are legally marketed in market in intended use, design, safety and effectiveness:

- Nipro® Blood Tubing Set (K001465)
- OFI Biomedica SpA Blood Tubing Set (K001971)
- Nextron medical Technologies Blood Tubing Set (K852605)
- Fresenius Blood Tubing Set (K001107)
- Medisystems Blood Tubing Set (K953823)

4. Device Intended use

The JMS Blood Tubing Sets are disposable bloodlines, intended to transfer blood from patients' vascular access system to the hemodialyzer through an arterial tubing, and from the hemodialyzer to the patient vascular system via a venous tubing. JMS Blood Tubing set is for Single use only.

5. Device Description

The tubing sets that JMS intended to market include arterial and venous dialysis blood tubing as described in 21 CFR 876.5820. Various models of blood tubing sets are being manufactured for application with different dialysis machines, such as Baxter, Fresenius, Althin, etc.

All components of blood tubing set, including drip chambers, infusion tubing, monitoring lines, ports, and segments which are use to pump blood, retain and capture air and blood debris, infuse medications or fluid, sampling blood, pressure monitoring and making connections to other devices, are all included.

The materials used are mainly, polyvinylchloride (PVC), polyethylene (PE), polypropylene (PP), acrylonitrite butadiene styrene (ABS), and polycarbonate (PC).

6. Technological Characteristics and Substantial Equivalence

The configuration, labeling, packaging, materials and mode of sterilizations of the subject device are similar to legally marketed predicate devices. The subject device and all other predicate devices are used for hemodialysis, which are labeled sterile, non-pyrogenic and for single use only. JMS Blood Tubing Set and predicate devices are all composed of various tube sizes, connectors and clamps for connection to all arterial or venous access system.

The JMS Blood Tubing Set complies with AAMI/ANSI RD 17 : 1994 standard for <Hemodialyzer Tubing set>. The JMS Blood Tubing Set has also been tested for its biocompatibility as accordance to ISO 10993.

JMS believes that the information provided in this submission clearly describes the JMS Blood Tubing Sets and demonstrates that they are substantially equivalent to the said predicate devices with regards to intended use, material, biocompatibility, and overall performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 6 2004

Swee Cheau, Chong
Manager of Regulatory Affairs & Quality Assurance
JMS North America Corporation
22320 Foothill Blvd., Suite 350
HAYWARD CA 94541

Re: K032975
Trade/Device Name: JMS Blood Tubing Sets
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Codes: 78 FJK and KOC
Dated: August 5, 2004
Received: August 9, 2004

Dear Ms. Chong:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K032975

Device Name : JMS Blood Tubing Sets

Indication for use: The JMS Blood Tubing Sets with transducer protector and priming sets are disposable bloodlines intended to provide extracorporeal access to the patient's blood during hemodialysis.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrently of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over The-counter use _____

(per 21 CFR 801-109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032975