OCT 2 4 2011

510(k) Summary

Date Prepared:	October 20, 2011
Manufacturer:	JMS Singapore Pte Ltd 440, Ang Mo Kio Industrial Park 1 Singapore, 569620
Sponsor:	JMS North America Corporation 22320 Foothill Blvd., Suite 350 Hayward, CA 94541
Contact Information:	Mr. Sho Kosoki Coordinator of Product Management and Regulatory Affairs JMS North America Corporation 22320 Foothill Blvd., Suite 350 Hayward, CA 94541 Email: SHosoki@jmsna.net Telephone: (510) 888-9090 Fax: (510) 888-9099

Trade Name:
JMS A.V. Fisula Needle Set "WingEater®"

JMS North America Corp will continue to name the new modified device as "JMS A.V. Fistula Needle Set "WingEater®". For the purpose of this submission, we will refer our predicate and new modified device as:

Predicate Device	JMS Fistula Needle Set "WingEater®V1
New Modified Device	JMS Fistula Needle Set "WingEater®V2

Device Classification Name:
Gastroenterology Devices Panel has classified modified device of JMS A.V. Fistula Needle Set "WingEater®V2 (21 CFR 876-5540) as Class II.

Predicate Device Name
Predicate device used in this submission is JMS A.V. Fistula Needle Set "WingEater®V1 (510(k) number – K010406, cleared on June 20, 2001).

Device Intended Use
Use for temporary cannulation for vascular access for extracorporeal blood treatment. This device is intended to single use only and is for temporary catheterization less than 30 days. The safety feature (foldable wing and Wing Eater) aids in prevention of needlestick injury when removing and discarding needle after dialysis session.

Device Description
JMS A.V. Fistula Needle Set "WingEater®V2 is a device whereby an anti-needlestick feature (WingEater guard) is assembled with predicate device under 510(k), K000845.

Needlestick injury can be prevented when removing needle so as to encapsulate the whole needle within the WingEater guard.

Modifications to JMS A.V. Fistula Needle Set "WingEater®V2 in this special 510(k) are:

a) Additional new polypropylene (PP) materials used for WingEater guard, needle cover, luer lock cover and clamp (non fluid pathway)

There are other non-significant changes which were made to 510(k) – K010406 in the past. These changes are listed under Attachment 004_List of Past Changes of this special 510(k).

Evaluation of the new packaging configuration was performed accordingly to simulated conditions experienced during transportation. New design and material used for the WingEater guard was evaluated accordingly with folded wing in order to realize the actual device usage. Reviews of the modifications were documented within the special 510(k) submission.

Technological Characteristics and Substantial Equivalence
JMS A.V. Fistula Needle Set "WingEater®V2 has the same intended use and identical fundamental scientific technology as JMS A.V. Fistula Needle Set "WingEater®V1. Bench testing was conducted to verify performance of JMS A.V. Fistula Needle Set "WingEater®V2 and it was found to be safe and effective. The following data and reports were enclosed within this submission document.

- ISO 10993-4:2002 Biological Evaluation of Medical Devices – Part 4 – Selection of Tests for Interactions with Blood
- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5 – Tests for In Vitro Cytotoxicity

- ISO 10993-10 Biological Evaluation of Medical Devices – Part 10 – Tests for Irritation and Delayed-Type Hypersensitivity
- ISO 10993-11 Biological Evaluation of Medical Devices – Part 11 – Tests for Systemic Toxicity
- ISO 594-1: 1986 Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1 – General Requirements
- ISO 594-2: 1998 Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2 – General Requirements
- ISO 1135-4 4th Edition 2010-04-15, Transfusion Equipment for Medical Use _ Part 4 – Transfusion Sets for Single Use
- ISO 11135-1:2007 Sterilization of Health Care Products – Ethylene Oxide – Part 1 – Requirements for Development, Validation and routine control of a sterilization process for medical devices. (Sterility)
- ISO 11137-1 Sterilization of Health Care Products – Radiation – Part 1 – Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices. (Sterility)
- ISO 11137-2:2006 Sterilization of Health Care Products – Radiation – Part 2 – Establishing the Sterilization Dose
- ISO 11137-3:2006 2010 Sterilization of Health Care Products – Radiation – Part 3 – Guidance on Dosimetric Aspects
- ISO 11607-2: 2006 Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
- USP 32:2009 <71> Sterility Tests
- USP 33:2010 <85> Bacterial Endotoxins
- ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices

Thus, the information provided in this submission clearly demonstrated Substantial Equivalence of the JMS A.V. Fistula Needle Set "WingEater®V2 to the predicate device JMS A.V. Fistula Needle Set "WingEater®V1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JMS North America Corporation
% Mr. E.J. Smith
Consultant
Smith Associates
1468 Harwell Ave.
CROFTON MD 21114

OCT 2 4 2011

Re: K111948
Trade/Device Name: Needle, Fistula
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: September 29, 2011
Received: September 30, 2011

Dear Mr. Smith:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 006 - Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(K) Number: K111948

Device Name: Needle, Fistula

Indications For Use: Use for temporary cannulation for vascular access for extracorporeal blood treatment. The device is intended to single use only and is for temporary catheterization less than 30 days. The safety feature (foldable wing and WingEater guard) aids in prevention of needlestick injuries when removing and discarding needle after dialysis session.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR Section 801.109)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111948