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510(k) Executive Summary

FEB 11 2011

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 Corporation
22320 Foothill Blvd., Suite 350
Hayward, CA 94541
USA

1.3 Contact Information
Sho Hosoki
Coordinator of Product Management and RA
JMS North America Corporation
22320 Foothill Blvd., Suite 350
Hayward, CA 94541
Telephone: (510) 888-9090
Fax: (510) 888-9099

2. Trade Name:

JMS SysLoc® MINI A.V. Fistula Needle Set
JMS SysLoc® MINI Apheresis Needle Set

Note: Same trade name is to be used for both modified and predicate device, thus for clearer differentiation, the modified device will be denoted as SysLoc® MINI (V2) while the predicate device as SysLoc® MINI (V3).

3. Device Classification Name

Gastroenterology Devices Panel has classified modified device of JMS SysLoc® MINI (V3) A.V. Fistula Needle Set (21 CFR 876.5540) & JMS SysLoc® MINI (V3) Apheresis Needle Set (21 CFR 880.5200) as Class II.

4. Predicate Device Name

The predicate device used in this submission is JMS SysLoc® MINI A.V. Fistula Needle Set & JMS SysLoc® MINI Apheresis Needle Set (V2) [K070234, dated May 22, 2007].

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5. Device Intended use

SysLoc® MINI(V3) is intended for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment. The device is intended for single use only and has an anti-stick feature integrated as part of the Needle Set which aids in prevention of needle-stick injuries.

6. Device Description

SysLoc® MINI (V3) is intended as non-implanted blood access device, which consists of flexible tube and needle with integrated sharps safety features as described in 21 CFR 876.5540.

SysLoc® MINI (V3) comes with a rotational feature and the needle is retracted with the wing sheath after deliberate release of secured external lock, and final locking is assured by an audible 'click' sound when the hub/tube is pulled rearwards.

The modifications stated for SysLoc® MINI (V3) included in this 510(k) are to have an additional packaging configuration and an alternative Polycarbonate Grade to component (lupilon EB30001R). The modification of the packaging is done accordingly to the device packing, and the modification of polycarbonate grade is evaluated accordingly with the Safety Hub and other components such as wing in order to realize the intended device. The review of modifications is documented within this submission document.

7. Technological Characteristics and Substantial Equivalence

SysLoc® MINI (V3) has the same intended usage used in the blood-contact components, and adopts identical fundamental scientific technology as the SysLoc® MINI (V2). Bench testing was conducted to verify that the SysLoc® MINI (V3) device is performing as intended to be a safe and effective medical device, data and reports are enclosed within this submission document.

Thus, the information provided in this submission clearly demonstrates the substantial equivalence of SysLoc® MINI (V3) to the predicate device JMS SysLoc® MINI A.V. Fistula Needle Set (V2) & JMS SysLoc® MINI Apheresis Needle Set (V2).

8. Modifications

JMS has made 2 modifications to the existing cleared device:

- New packaging configuration
- Additional new Polycarbonate (PC) Grade

Declarations of Conformity

- ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices
- USP 32:2009<71> Sterility Tests
- ISO 594-2:1998 Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2
- ISO 594-1:1986 Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1

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- 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 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices (Sterility)
- ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)
- ISO 10993-4: 2002 medical devices (Sterility)
- ISO 10993-5:2009, Biological evaluation of medical devices -- Part 4: Selection of Tests for Interactions with Blood
- 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

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
c/o E. J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
CROFTON MD 21114

FEB 11 2011

Re: K110157
Trade/Device Name: SysLoc® MINI V# A.V. Fistula / Apheresis Set
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: January 18, 2011
Received: January 19, 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

Indications for Use

510(k) Number (if known): **K110157**

Device Name: SysLoc® MINI V# A.V. Fistula / Apheresis Set

Indications for Use:

Use for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment. The device is intended for single use only and has an anti-stick feature integrated as part of the Needle Set which aids in prevention of needle-stick injuries.

Prescription Use _____X____ (Part 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, Gastro-Renal, and Urological Devices
510(k) Number K110157