

AUG 4 - 2005

K051814  
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## 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 Corporation  
22320 Foothill Blvd., Suite 350  
Hayward, CA 94541  
USA

1.3 Contact Information  
Swee Cheau, Chong  
Manager of RA & QA  
JMS North America Corporation  
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 JMS SysLoc MINI™ A.V. Fistula Needle Set & JMS SysLoc MINI™ Apheresis Needle Set as Class II. Reference 21 CFR 876.5540.

### 3. Predicate Device Name

The predicate device used in this submission is JMS SysLoc® A.V. Fistula Needle Set & JMS SysLoc® Apheresis Needle Set (K030479, 8/18/2003).

### 4. Device Intended use

JMS SysLoc MINI™ A.V. Fistula Needle Set & JMS SysLoc MINI™ Apheresis Needle Set 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.

### 5. Device Description

JMS SysLoc MINI™ A.V. Fistula & JMS SysLoc MINI™ Apheresis Needle Set 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.

Just like the predicate device, JMS SysLoc MINI™ A.V. Fistula Needle Set & JMS SysLoc MINI™ Apheresis Needle Set 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.

JMS SysLoc MINI™ A.V. Fistula Needle Set & JMS SysLoc MINI™ Apheresis Needle Set included in this 510(k) is a modification from the legally marketed device, JMS SysLoc® A.V. Fistula Needle Set & JMS SysLoc® Apheresis Needle Set. The SysLoc MINI™, is a 'mini' version of the predicate device (JMS SysLoc®) with modification made to reduce the overall length, so that the device is more user/patient friendly. Modifications are done accordingly to the other components such as wing and hub in order to realize the intended device. The review of modifications is documented within this submission document.

## 6. Technological Characteristics and Substantial Equivalence

JMS SysLoc MINI™ A.V. Fistula Needle Set & JMS SysLoc MINI™ Apheresis Needle Set has the same intended usage, same materials used in the blood-contact components, and adopts identical fundamental scientific technology as the predicate device. Bench testing was conducted to verify that the SysLoc MINI™ 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 JMS JMS SysLoc MINI™ A.V. Fistula Needle Set and JMS JMS SysLoc MINI™ Apheresis Needle Set to the predicate device JMS SysLoc® A.V. Fistula Needle Set & JMS SysLoc® Apheresis Needle Set.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K051814  
Trade/Device Name: JMS SysLoc MINI AVF Needle Set and JMS SysLoc  
MINI Apheresis Needle Set  
Regulation Number: 21 CFR §876.5540  
Regulation Name: Blood access device and accessories  
Product Code: FIE  
Regulation Number: 21 CFR §880.5200  
Regulation Name: Intravascular catheter  
Product Code: FOZ  
Regulatory Class: II  
Dated: June 27, 2005  
Received: July 5, 2005

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 (Premarket Approval), 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K051814

Device Name: JMS SysLoc MINI AVF Needle Set  
JMS SysLoc MINI Apheresis Needle 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.

(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)

Nancy Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal, and  
Radiological Devices  
510(k) Number K051814