K093637
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510(k) Summary
807.92(c)

FEB - 9 2010

SPONSOR **807.92(a)(1)**

Company Name:	JMS North America Corporation
Company Address	22320 Foothill Blvd., Suite 350 Hayward, CA 94541 USA
Telephone:	(510) 888-9090
Fax:	(510) 888-9099
Contact Person:	Shinya Nagase

Summary Preparation Date: November 23, 2009

DEVICE NAME **807.92(a)(2)**

Trade Name:	JMS Blunt A.V. Fistula Needle Set with Site Preparation Tool
Common/Usual Name:	Fistula Needle
Classification Name:	Fistula Needle
Regulation Number:	876.5540
Product Code:	FIE
Device Class:	Class II
Panel:	Gastroenterology/Urology

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
JMS North America Corp.	A.V. Fistula Blunt Needle Set	K082882

DEVICE DESCRIPTION **807.92(a)(4)**

JMS A.V. Fistula Blunt Needle Set with Site Preparation Tool is a modification of the previously cleared JMS A.V. Fistula Blunt Needle Set (K082882). The modification is the replacement of the standard needle cover with a site preparation tool "scraper" feature that removes the scabs that have developed over the constant site prior to cannulation.

DEVICE INTENDED USE **807.92(a)(5)**

The JMS Blunt A.V. Fistula Needle Set with Site Preparation Tool is intended for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment and for the removal of scabs that have developed over the constant site prior to cannulation. The device is intended for single use only. The JMS AV Fistula Blunt Needle Set is for use on developed 'constant site' access sites.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

	New Device	Predicate Device
	A.V. Fistula Blunt Needle Set with Site Preparation Tool	A.V. Fistula Blunt Needle Set
Manufacturer	JMS Singapore Pte Ltd	JMS Singapore Pte Ltd
510k Number		K082882
Intended Use	Device is used for needle insertion into a previously mature access site for dialysis procedure using a constant-site technique of needle insertion. The modification of the predicate device consists of a Site Preparation Tool incorporated into the needle cover that allows for site preparation through the use of a "scraper" feature to remove the scabs that have developed over the constant site prior to cannulation.	Device is used for needle insertion into a previously mature access site for dialysis procedure using a constant-site technique of needle insertion.
Similarities		
Material	Same	Same
Physical Specification	Same	Same
Mechanical/ Performance Specification	Met established acceptance criteria	Met established acceptance criteria
Packaging	Same	Same
Sterilization	Same	Same
Biocompatibility	All patient contacting materials meet biocompatibility standards for ISO-10993 for non-implanted blood access contacting device less than 30 days	All patient contacting materials meet biocompatibility standards for ISO-10993 for non-implanted blood access contacting device less than 30 days
Differences		
Needle Cover	Needle Cover with Site Preparation Tool	Needle Cover

SAFETY and EFFECTIVENESS 807.92(b)

Testing information demonstrating safety and effectiveness of JMS A.V. Fistula Blunt Needle Set in the intended environment of use is supported by testing that was conducted in accordance with the following standards:

	Standard	Title
1	ISO 11135:1994	Medical Devices – Validation and Routine control of ethylene oxide sterilization
2	ISO 14971:2000	Medical Device – Application of risk management to medical devices

BIOCOMPATIBILITY

We have assessed all of our patient contacting materials for biocompatibility requirements in accordance with the May 1, 1995 FDA Biocompatibility Guidance, the FDA-modified matrix of the "International Standard ISO-10993", Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", including the flow chart entitled "Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s.

STERILIZATION

The device is sterilized using ETO, utilizing the ISO International Standard 11135 (EN 550). The validations were performed in accordance with EN-550 and ISO 11135.

PERFORMANCE DATA

A clinical usability study was performed to verify ease of use and label comprehension.

CONCLUSION **807.92(b)(3)**

The JMS Blunt A.V. Fistula Needle Set with Site Preparation Tool is a modification of the predicate, JMS Blunt AV Fistula Needle Set (K K082882) and is the same device in its technological and performance characteristics. The addition of a site preparation tool incorporated into the needle cover has changed the Indications for Use to include this feature. Risk Analysis, Design Control and a Clinical Usability Study has verified its safe and effective use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

JMS North America Corporation
c/o E. J. Smith, President
Smith Associates
1468 Harwell Avenue
CROFTON MD 21114

FEB - 9 2010

Re: K093637
Trade/Device Name: JMS Blunt AV Fistula Needle Set with Site Preparation Tool
Regulation Name: Blood access device and accessories
Regulation Number: 21 CFR §876.5540
Regulatory Class: II
Product Code: FIE
Dated: November 23, 2009
Received: November 24, 2009

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,

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): K093637

Device Name: JMS Blunt AV Fistula Needle Set with Site Preparation Tool

Indications for Use:

The JMS Blunt AV Fistula Needle Set with Site Preparation Tool is intended for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment and for the removal of scabs that have developed over the constant site prior to cannulation.. The device is intended for single use only. The JMS AV Fistula Blunt Needle Set is for use on developed 'constant site' access sites.

(Check appropriate designation below)

Prescription Use __√_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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 K093637