K121488

510(k) Summary

MAR 0 5 2013

807.92(c)

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

Company Name: JMS North America Corp.

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Hayward, CA 94541

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Contact Person: Sho Hosoki

Summary Preparation Date: April 9, 2012

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

Trade Name: JMS Safe Wing Cath (SWC)
Common/Usual Name: Intravascular Catheter
Classification Name: Intravascular Catheter
Regulation Number: 21 CFR 880.5200
Product Code: FOZ
Device Class: Class II

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

Legally Marketed Equivalent Devices

K Number	Product	Company
K102520	BD Nexiva™ Closed IV Catheter System	Dickinson Infusion Therapy Systems, Inc.
K895481	SHAMROCK Winged Needle Infusion Set	Smiths Medical
K110157	SysLoc Mini V3	JMS Singapore Pte Ltd

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

JMS Safe Wing Cath (SWC) is a single lumen intravenous catheter device for vascular access incorporating an anti-needle stick safety feature. The anti-needle stick feature is integrated in the Safe Wing Cath (SWC) body and functions during retraction of the needle, after vascular access is accomplished (there is a stopper to prevent unwanted retraction of needle during insertion). During retraction, the needle will slide into the body and will lock at the final locking position. An audible clicking sound is heard or locking force is felt when the needle is fully retracted into the final locking position. The entire needle is encapsulated within the body and prevents needle-stick injuries, while the catheter still has vascular access for intravenous fluid administration.

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

JMS Safe Wing Cath (SWC) is intended for short-term (less than 30 days) access to patient's vascular system for intravascular fluid administration and to sample blood, and to monitor blood pressure. The device is intended for single use only and has an anti-stick feature integrated which aids in prevention of needle-stick injuries.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Device	Modified Device	Currently Legally Marketed Predicate Device (Predicate 1)
	JMS Safe Wing Cath (SWC)	BD Nexiva Closed IV Catheter System
Manufacture	JMS Japan	Becton, Dickinson and Company
510(K) #	----	K102520
Classification	Class II	Class II
Intended Use	JMS Safe Wing Cath (SWC) is intended for short-term (less than 30 days) access to patient's vascular system for intravascular fluid administration, to sample blood, and to monitor blood pressure. The device is intended for single use only and has an anti-stick feature integrated which aids in prevention of needle-stick injuries.	The NexivaTM4 intravascular catheter is inserted into a patient's vascular system for a short-term use (less than **30** days) to sample blood, monitor blood pressure, or administer fluids intravascularly. The needle-shielding feature and luer access port, aid in the prevention of needle-stick injuries. Blood is contained within the device during the catheter insertion process aiding in the prevention of **blood** exposure. This catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure. The **18-22** gauge NexivaTM catheters are suitable for use with power injectors rated for a maximum of **300** psi when the luer access port(s) is removed and a direct connection is made.
Catheter ID (mm)	20G: 0.8 (0.7 ~ 0.9) 22G: 0.6 (0.5 ~ 0.7) 24G: 0.5 (0.4 ~ 0.6)	20G: 0.83 22G: 0.67 24G: 0.53
Catheter OD (mm)	20G: 1.1 (0.950 ~ 1.149) 22G: 0.9 (0.750 ~ 0.949) 24G: 0.7 0.650 ~ 0.749)	20G: 1.10 22G: 0.90 24G: 0.71
Length of Exposed Catheter	All gauges: 19.0 (±8%) mm 0.76 Inches	20G: 1.00, 1.25, or 1.75 Inches 22G: 1.00 Inches 24G: 0.56 or 0.75 Inches
Number of Lumens	1	1
Distal End Configuration	Needle and catheter	Needle and catheter
Intended Anatomical Location of Distal End	Peripherals	Peripherals
Proximal End Configuration	Luer Lock	2 ports: Luer Access Split Septum & Vent Plug
Water Flow Rate	20G: 38	20G, 1.00 catheter length: 54

(mL/min)	22G: 28 24G: 16	22G: 1.00 catheter length: 27 24G: 0.75 catheter length:13
Catheter Body Tensile Strength	20G: 29.3N 22G: 21.5 N 24G : 14.3N	20G: 28.6 N 22G: 21.6 N 24G: 12.8 N
Catheter to Catheter Hub Strength	20G: 19.9N 22G: 14.7N 24G: 12.6N	20G: 19.3N 22G: 15.4N 24G: 9.7N
Catheter Stiffness (Elastic Modulus)	20G: 487.9 MPa 22G: 440.7 MPa 24G: 401.0 MPa	20G: 487.9 MPa 22G: 405.8 MPa 24G: 423.0 MPa
Catheter Tensile Elongation	20G: 951.6% 22G: 717.7% 24G: 779.4%	20G: 815.0% 22G: 772.8% 24G: 453.6%
Flexural Modulus	22G: 734.3 MPa	22G: 582 MPa
Tubing to Hub Tensile Strength	20G: 35.4N 22G: 32.9N 24G: 34.5N	20G: 56.6N 22G: 46.7N 24G: 42.1N
Tubing to Female Connector Tensile Strength	Same for All Gauges: 32.2N	20G: 65.6N 22G: 51.8N 24G: 42.0N
Needle to Need Hub Strength	20G: 128.4N 22G: 92.3N 24G: 72.4N	20G: 118.8N 22G: 66.5N 24G: 38.2N
Leakage at Hub	None (at 150kPA for 15min)	None
Catheter Burst Pressure	22G: 2.22MPa	22G: 2.66MPa 24G: 2.84MPa
Catheter Collapse Pressure	Tested up to -99.3MPa with no leakage	Tested up to -99.3MPa with no leakage
Open or Closed System	Closed System	Closed System
Labels	Similar to Predicate(Refer to Section 13)	Refer to Section 13

Side by Side Comparison of Substantial Equivalent Appearance and Safety Feature, with Legally Marketed Device with Comparable Patient Exposure

Please note that the predicate 2 does not have a catheter, but has substantial equivalence with the JMS SWC due to its appearance, safety mechanism feature, and intended use. Please consider JMS SWC device as a modification of predicate 2 with a catheter, in which has substantial equivalence to predicate 1. Also, please note that SysLoc Mini v3 is a legally marketed device with comparable patient exposure and this device is used to show material biocompatibility in section 15.

Device	Modified Device	Legally Marketed Predicate Device (Predicate 2)	Legally Marked Device with Comparable Patient Exposure
	JMS Safe Wing Cath (SWC)	SHAMROCK Winged Needle Infusion Set	SysLoc Mini V3
Manufacture	JMS Japan	Smiths Medical (JMS Singapore Pte Ltd provide unfinished medical device)	JMS Singapore Pte Ltd
510(K) #	----	K895481	K110157
Classification	Class II	Class II	Class II
Intended Use	JMS Safe Wing Cath	This device is used by the healthcare	SysLoc@ MINI(V3) is

	(SWC) is intended for short-term (less than 30 days) access to patient's vascular system for intravascular fluid administration, to sample blood, and to monitor blood pressure. The device is intended for single use only and has an anti-stick feature integrated which aids in prevention of needle-stick injuries.	professional to administer I.V. fluids to a patient. The materials used in the manufacture of this device (See Exhibit VIII) are comparable to similar on the market. The parallel of similar materials from this device to existing devices will allow the healthcare worker to administer the same I.V. fluids which are currently being administered. The uniqueness of the device of this submission lies in the ability of the user to retract the needle, after use, into the wings. Thus reducing the probability of accidental needle sticks. Hospital policy will determine the length of time that this device, or currently marketed devices, may be used prior to changing. The similarity of the materials used in this device to currently marketed devices will allow the healthcare worker to maintain the same procedure which they are currently following. Neither this device, nor the currently marketed devices for the same intended use make any claims or recommendations for length of administration prior to set change.	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.
Material	Refer to section 15. Most of the material used in this device is from K895481 and K110157.	Refer to K895481	Refer to K110157

SAFETY AND EFFICACY **807.92(b)**

Biocompatibility

Biocompatibility Testing		
Test	Test Method	Results
Cytotoxicity	ISO 10993-5	Pass
Sensitization	ISO 10993-10	Pass
Irritation Or Intracutaneous Reactivity	ISO 10993-10	Pass
Systemic Toxicity (Acute)	ISO 10993-11	Pass
Subchronic Toxicity (Subacute Toxicity)	ISO 10993-6 ISO 10993-11	Pass
Genotoxicity	ISO 10993-3	Pass
Implantation	ISO 10993-6	Pass
Hemocompatibility	ISO 10993-4	Pass

Sterilization

Sterilization conditions have been validated according to ANSI/AAMI/ISO 11135, *Sterilization of Health Care Products – Part 1; Requirements for development validation and routine control of sterilization process for medical devices* to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals will meet requirements for limited exposure devices (contact up to 24 hours) prior to use, based on ANSI/AAMI/ISO 10993-7, *Biological Evaluation of medical device – Part 7; Ethylene Oxide Sterilization residuals.* Residual EO will not exceed 4 mg per device and residual ECH will not exceed 9 mg per device.

PERFORMANCE

Conformance to ISO 10555-1

The JMS SWC successfully passed the following performance tests, demonstrating conformance with ISO-10555-1:

ISO 10555-1 Compliance Testing of the JMS Safe Wing Cath (SWC)		
Test	Test methods	Results
Surface inspection	ISO 10555-1	Passed
Corrosion resistance	ISO 10555-1	Passed
Force at break (catheter and hub, tubing and female connector, tubing to needle hub	ISO 10555-1	Passed
Freedom for leakage (Positive pressure)	ISO 10555-1 & JIS T3223:2011	Passed
Test Method of Air Leakage into Hub Assembly during Aspiration (Negative Pressure)	ISO 10555-1	Passed
Flow rate	ISO 10555-1	Passed
Catheter under X-Ray		
Determination of Strength of Union Hub and Needle tube	ISO 10555-1	Passed
Leakage Needle hub/Tubing/Female Connector	ISO 10555-1 & JIS T3223:2011	Passed
Additional Tests		
Catheter under X-Ray		Passed

2. Simulated Use and Device Performance

A Simulated Clinical Use Test for the JMS Safe Wing Cath was conducted comprising 43 healthcare workers from the Washington /Baltimore area to evaluate product performance and

usability. Performance Testing on over 500 samples was 100% success with no device failures and all devices performing as intended.

3. Comparison to predicate

The following in-house bench testing was conducted to demonstrate equivalent performance with the predicate device.

In-House Comparative Performance Testing	
Test	**Result**
Catheter (Elastic Modulus in Tension, Tensile Strength, and Tensile Elongation)	No significant difference
Catheter Flexural Modulus (Three Point Bend)	No significant difference
Force Break of Tubing and Female Connector	No significant difference
Force Break of tubing to needle hub	No significant difference
Force Break needle and needle hub	No significant difference
Determine maximum positive pressure for Nexvia & SWC	Pressure determined
Catheter collapse Pressure test	No significant difference
Priming volume determination	Volumes determined

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

The JMS SWC is a modification of predicate 2 into a catheter equivalent that of predicate 1. The JMS SWC has similar appearance and safety anti needle stick feature as predicate 2. As a catheter, the JMS SWC has fewer applications than that of predicate 1, but for the intended applications, it has equivalence in intended use and mechanical / performance specifications. The appearance of JMS SWC is different from predicate 1 device, but they are both closed I.V. catheter systems. All specifications addressed have been analyzed, verified and validated with supporting data enclosed in this 510(k) document and there are no issue on the safety and effectiveness of the device performance if used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 5, 2013

JMS North America Corporation
C/O Ms. Yolanda Smith
Regulatory Consultant
Smith Associates
1468 Harwell Avenue
CROFTON MD 21114

Re: K121488
Trade/Device Name: JMS Safe Wing Cath (SWC)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: February 19, 2013
Received: February 25, 2013

Dear Ms. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121488

Device Name: JMS Safe Wing Cath (SWC)

Indications for Use:

JMS Safe Wing Cath (SWC) is intended for short-term (less than 30 days) access to patient's vascular system for intravascular fluid administration and to sample blood, and to monitor blood pressure. The device is intended for single use only and has an anti-stick feature integrated which aids in prevention of needle-stick injuries.

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)

Alan M. Stevens Date: 2013.03.04 14:01:29 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121488