



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

May 13, 2015

JMS North America Corporation  
Sho Hosoki  
Regulatory Affairs  
22320 Foothill Blvd., Suite 350  
Hayward, CA 94541

Re: K151017  
Trade/Device Name: JMS Harmony® A.V. Fistula Needle Set  
Regulation Number: 21 CFR§ 876.5540  
Regulation Name: Blood access device and accessories  
Regulatory Class: II  
Product Code: FIE  
Dated: March 24, 2015  
Received: April 16, 2015

Dear Sho Hosoki,

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,

  
**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Section 04: Indications for Use**

510(K) Number (if known): K151017

Device Name: JMS Harmony® A.V.Fistula Needle Set

Indications for Use: JMS Harmony® A.V.Fistula Needle Set 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 and is used on ‘developed constant site’ access sites. This device is for use on developed ‘constant site’ access sites

Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Section 5: 510(k) Summary**

**Owner [807.92(a)1]:**

Company Name: : JMS North America Corp.  
 Company Address : 22320 Foothill Blvd., Suite 350  
 Hayward, CA 94541  
 Telephone : 510-888-9090  
 Fax : 510-888-9099  
 Contact Person : Sho Hosoki  
 Summary Preparation Date: 03/24/15

**Device of Submission [807.92(a)2]]**

Classification Name : Needle, Fistula  
 Proprietary Name : JMS Harmony® A.V. Fistula Needle Set  
 Classification : Class II  
 Product Code : FIE  
 Code of Federal Regulations: 21CFR876.5540

**Predicate Device [807.92(a)3]]**

K Number	Product	Company
K093637	JMS Blunt A.V.Fistula Needle Set with Site Preparation Tool	JMS North America Corporation
K990470	JMS A.V.Fistula Needle Set	JMS Co., Ltd

**Device Description [807.92(a)4]]**

JMS Harmony® A.V. Fistula Needle Set, the modified device is a non-implantable blood access device, which consists of flexible tube and blunt needle with site preparation tool. The modified device allows for vein puncture access to an Arterial-Venous Fistula (AVF) and the bloodstream of a patient undergoing Hemodialysis with developed constant site access. The tubing of the dialysis machine connects to the luer connectors of the modified device (the arterial side as exit and the venous side as return).

**Intended Use [807.92(a)5]]**

JMS Harmony® A.V.Fistula Needle Set 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 and is used on 'developed constant site' access sites. This device is for use on developed 'constant site' access sites.

**Predicate Comparison [807.92(a)(6)] & [807.92(b)(1)]**

	Modified Device	Predicate	Predicate
Device Name	JMS Harmony® A. V. Fistula Needle Set	JMS Blunt A. V. Fistula Needle Set with Site Preparation Tool	JMS A. V. Fistula Needle Set
510(k) #	---	K093637	K990470
Classification	Class II	Class II	Class II
Intended Use	JMS Harmony® A.V.Fistula Needle Set 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 and is used on ‘developed constant site’ access sites. This device is for use on developed ‘constant site’ access sites	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 and is used on ‘developed constant site’ access sites.	JMS A. V. Fistula Needle Set is intended for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment.
Needle	Blunt	Blunt	Sharp
Material	See Section 15 for Material comparison		
Labeling	See Section 13 for Labeling		
Biocompatibility	See Section 15 for Biocompatibility		
Sterilization	ETO sterilization	ETO sterilization	ETO sterilization
Performance Specification	Met established acceptance criteria	Met established acceptance criteria	Met established acceptance criteria

**Conclusion [807.92(b)(3)]**

JMS Harmony® A. V. Fistula Needle Set has the same intended usage as the predicate devices JMS Blunt A. V. Fistula Needle Set with Site Preparation Tool (K093637) & similar intended use with JMS A. V. Fistula Needle Set (K990470). Bench testing was conducted to verify that the modified device is performing as intended to be a safe and effective medical device. Evaluation data and reports are enclosed within this submission document. The information provided in this submission clearly demonstrates the substantial equivalence of the modified device to the predicate devices JMS Blunt A. V. Fistula Needle Set with Site Preparation Tool (K093637) & JMS A. V. Fistula Needle Set (K990470).