K132321

JMS
North America Corporation

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Section 05: 510(k) Summary [807.92(c)]

FEB 20 2014

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
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Contact Person: Sho Hosoki
Summary Preparation Date: 09/01/2013

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

Classification Name: Piston Syringe
Common/Usual Name: Piston Syringe
Proprietary Name: JMS Syringe
Classification: Class II
Product Code: FMF
Code of Federal Regulations: 21 CFR 880.5860

Predicate Device [807.92(a)(3)]

K Number	Product	Company
K991904	JMS Needle & JMS Syringe	JMS Co., Ltd

Device Description [807.92(a)(4)]

JMS syringe is a single use standard piston syringe without hypodermic needle, which consists of a calibrated hollow barrel and a movable plunger with a male Luer lock or Luer slip connector on the tip of barrel.

Intended Use [807.92(a)(5)]

JMS Syringe is intended to be used to inject fluids into or withdraw fluids out of the body.

Predicate of this device includes intended use of JMS needle and JMS syringe. This submission only covers JMS syringe so the intended use portion which describes JMS needle has been excluded.

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Predicate Comparison [807.92(a)(6)]

	Modified Device	Predicate
Device Name	JMS Syringe	Modification of JMS Needle and Syringe
510(k) #	---	K991904
Classification	Class II	Class II
Intended Use	JMS Syringe is intended to be used to inject fluids into or withdraw fluids out of the body.	JMS Needle is intended to be used for infusion of drug, collecting solution or blood. Insert the Needle to patient's body and use it as a fluid pathway which connects inside and outside of the body. JMS Syringe is intended to be used for infusion of solution or collecting blood connecting JMS Needle. It is also used for continuous drug infusion put in Syringe Pump. JMS Needle and JMS Syringe must be discarded after one time use.
Material	See Section 15 for material comparison Used materials are the same, but some have different grades	
Syringe tip type	Luer Slip/Luer Lock	Luer Slip/Luer Lock
Syringe Volume	30, 50, 100mL	1, 2, 2.5, 5, 10, 20, 30, 50, 100mL
Nozzle Type	Center/ Side	Center/ Side
Graduation Legibility	Legible	Legible
Movability (KPa)	30, 50 100mL : Less than 98	30, 50 100mL : Less than 98
Leakage (KPa)	30, 50 100mL : More than 196	30, 50 100mL : More than 200
Dead Space	30mL: Less than 0.17mL 50mL: Less than 0.20mL 100mL : Less than 0.20mL	30mL: Less than 0.17mL 50mL: Less than 0.20mL 100mL : Less than 0.20mL
Labeling	See Section 13 for Labeling	See Section 13 for Labeling
Sterilization	E-beam sterilization	γ-sterilization

The submitted device is equivalent to the predicate device. It has same technological characteristics as a syringe. The only difference is the method of sterilization and material grade in which respective section of this submission show equivalency to predicate.

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Non-Clinical Performance Data [807.92(b)(1)]

Summary of Non-clinical performance data

Test		Pass or Fail
Physical requirements	cleanliness	Pass
Chemical requirements	Limits for acidity or alkalinity	Pass
	Limits for extractable metals	Pass
Lubrication	Amount of lubrication	Pass
Tolerance of the nominal capacity	Tolerance on graduated capacity	Pass
Piston/plunger assembly	Design	Pass
Nozzle	Nozzle Lumen	Pass
Performance	Dead space	Pass
	Freedom from air and liquid leakage past piston (positive pressure)	Pass
	Freedom from air and liquid leakage past piston (negative pressure)	Pass

More detailed description of non-clinical performance data is described in section 18 of this submission and all show acceptable results.

[807.92(b)(2)]
Not applicable as no clinical tests were referenced in this submission

Conclusion [807.92(b)(3)]
The device of submission is the modification of predicate device (K991904). This submission does not include needles so the needle portion has been omitted from the submission. In addition, only the larger sizes (30, 50, and 100mL) will be covered in this modification. The only difference between the submitted device and predicate are some material components and method of sterilization. The intended use of the predicate syringe is identical to the intended use of the submitted device for the syringe portion (JMS needle excluded).

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

February 20, 2014

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

Re: K132321
Trade/Device Name: JMS Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 15, 2013
Received: August 1, 2013

Dear Mr. 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 contact 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. 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,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number (if known): K132321

Device Name: JMS Syringe

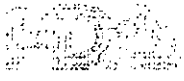
Indications for Use:

JMS Syringe is intended to be used to inject fluids into or withdraw fluids out of the body.

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)



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