June 1, 2018

JMS North America Corporation
% Yolanda Smith
Smith Associates
1468 Harwell Ave
Crofton, Maryland 21114

Re: K172499
Trade/Device Name: NEOSHIELD
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: April 30, 2018
Received: May 2, 2018

Dear Yolanda 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172499

Device Name

NEOSHIELD

Indications for Use *(Describe)*

The NEOSHIELD System is an airtight and leak proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills.

The NEOSHIELD system also prevents microbial ingress for 3 days.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K172499
Section 05: 510(k) Summary [807.92(c)]

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: 06/01/2018

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

Classification Name:	Intravascular Administration Set
Common/Usual Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
Proprietary Name:	NEOSHIELD
Classification:	Class II
Product Code:	ONB
Code of Federal Regulations:	21 CFR 880.5440

Predicate Device [807.92(a)(3)]

K Number	Product	Company
K123213 (Primary Predicate)	BD PhaSeal Closed System Drug Transfer Device Protector, injector, Luer connector	Becton Dickinson & Co.

Reference Device

K965027	Vented IV Set	JMS Co., Ltd

Device Description [807.92(a)(4)]

NeoShield is a needle free closed system drug transfer device (CSTD). Neoshield prevents transfer of environmental contaminants into the system and also prevents the escape of drug or vapor from the system.

The ability to prevent microbial ingress for up to 3 days should not be interpreted as modifying, extending, or superseding a manufacturer labeling recommendations for the storage and expiration dating. Refer to drug manufacturer's recommendations and USP compounding guidelines for shelf life and sterility information.

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Device components:

Name of Component	General Description
NEOSHIELD Transfer	NEOSHIELD Transfer is used to transfer a solution from a vial container to another container such as an IV bag. It has a female connector, bag adaptor connector, and vial connector. It also has a stopcock to change the direction of flow Depending on the stopcock's position it can open the flow from female connector to/from NEOSHIELD Bag Adaptor or from female connector to/from vial. During usage, the NEOSHIELD Transfer keeps aerosol and liquid from being exposed to the outer environment to keep a closed system.
NEOSHIELD Bag Adaptor	NEOSHIELD Bag Adaptor is connected to a liquid container such as IV bags for injection or extraction of liquid. The spike is used for the connection to liquid container and the injection port is used for injection or extraction of liquid in/out of container without leakage maintaining closed system.
NEOSHIELD Infusion Set	The NEOSHIELD Infusion Set is used for infusion of drug solution into a patient.
NEOSHIELD plug	The NEOSHIELD Plug is an optional accessory that can be connected with a female connector (such as one from NEOSHIELD Infusion Set) to inject/ extract solution without using needle in a closed system environment. The slit septum of the NEOSHIELD Plug opens upon connection with NEOSHIELD Lever Lock and the flow path opens. The slit septum of NEOSHIELD plug and the flow path closes once male portion of the NEOSHIELD Lever Lock is removed to keep a closed system.
NEOSHIELD Lever Lock	The NEOSHIELD Lever Lock is used for injecting/extracting solution in a closed system by connecting a device such as syringe to the female connector.
NEOSHIELD Vial Cover	NEOSHIELD Vial Cover is attached to drug vials in order to prevent leakage during extraction. The NEOSHIELD Vial Cover keeps the system closed to outer environment

Intended Use [807.92(a)(5)]

The NEOSHIELD System is an airtight and leak proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills.

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The NEOSHIELD system also prevents microbial ingress for 3 days.

Predicate Comparison [807.92(a)(6)]

Device	Modified Device	Currently Legally Marketed Predicate Device (Primary Predicate)
	NeoShield	BD PhaSeal Closed System Transfer Device
Manufacture	JMS Co., Ltd / JMS Singapore Pte Ltd	Becton Dickinson&Co.
510(K) #	----	K123213
Classification	Class II	Class II
Product Code	ONB	ONB
Intended Use	The Neoshield System is an airtight and leak proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The NEOSHIELD system also prevents microbial ingress for 3 days.	The PhaSeal System is an airtight and leak proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress.
Equalizes Vial Pressure when Accessed	Yes	Yes
Prevents Escape of Drug or Vapor Concentration	Yes	Yes
Closed Drug Transfer Mechanism	Elastomeric double membrane(non-ISO)	Elastomeric double membrane(non-ISO)
Activation Mechanism	Push-to connect (Non-ISO)	Push-to connect with bayonet lock (Non-ISO)
Needle Free	Needle free	18G needle with safety sleeve and /or steal spike
Connection to External Equipment	Standard ISO Luer Connections and Vial Spikes	Standard ISO Luer Connections and Vial Spikes

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Single Use	yes	yes
Sterilization Method	EO	EO
Open or Closed System	closed system Following tests were conducted: Leaking Pressure of Pre-Slit Septum Pressure Resistant Test (Liquid Tightness) Pressure Resistant Test (Air tightness) Pressure Resistant Test (Connecting Part of Closed System) Airtight Connection Leakproof Connections Microbial Ingress Testing	closed system
Filter	PTFE （NeoShield Transfer）	PTFE （Protector)
Material	Contains plastics, elastomeric double membrane, PTFE filter	Plastics, elastomeric double membrane, PTFE filter, stainless steel
Performance testing	Leak proof connections Airtight connections Microbial Ingress	Leak proof connections Airtight connections Microbial Ingress

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

The following non-clinical tests were conducted:

Performance test (bench testing)

Name of device	Result
NeoShield Transfer	Pass
NeoShield Bag Adaptor (Also includes tests from ISO 8536-4 : 2010)	Pass
NeoShield Infusion Set (Also includes tests from ISO 8536-4 : 2010)	Pass
NeoShield Plug	Pass
NeoShield Lever Lock	Pass
NeoShield Vial Cover	Pass

Name of Test	Result
Leaking Pressure of Pre-Slit Septum	No leak
Pressure Resistant Test (Liquid Tightness)	No leak
Pressure Resistant Test (Air tightness)	No leak
Pressure Resistant Test (Connecting Part of Closed System)	No leak
Airtight Connection	No leak
Leakproof Connections	No leak
Microbial Ingress Testing	No ingress for 3 days

Other tests

Name of Test	Result
Pyrogen test	Non-pyrogenic
Crack Test for drug compatibility with: • N, N-dimethylacetamide • Polyethylene Glycol • benzyl alcohol • polysorbate 80 • polyoxyethylene castor oil • NaOH • CH3COOH	No cracks except for N, N-dimethylacetamide

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Sterility Testing (EO) ISO 11135	Sterile
Shelf Life Testing	Sterility kept for 3 years
Biocompatibility Testing: • Cytotoxicity • Sensitization • Irritation or Intracutaneous Reactivity • Systematic Toxicity (Acute) • Haemocompatibility • Pyrogen • Particulate Matter	All materials are biocompatible
Package Testing: Seal Strength/dye penetration testing	Pass/Pass

Note: Based on the crack test for drug compatibility results, DO NOT use NEOSHIELD system with anticancer drug or any solution that contains the plasticizer N, N-dimethylacetamide.

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

Conclusion [807.92(b)(3)]

The device is equivalent to the predicate device K123213.
Through non-clinical performance testing the subject devices have demonstrated that they are substantially equivalent to the predicate device.