August 12, 2019

Dr. Japan Co., Ltd.
℅ Yolanda Smith
Consultant
Smith Associates
1468 Harwell Ave
Crofton, Maryland 21114

Re: K183316
Trade/Device Name: Dr J Spinal and Epidural Needles
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: July 8, 2019
Received: July 9, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K183316

Device Name
Dr J Spinal and Epidural Needle

Indications for Use *(Describe)*
Dr. J Spinal and Epidural Needles are intended to be used for injection of local anesthetics into a patient to provide regional anesthesia

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

SPONSOR

Company Name:	Dr. Japan Co., Ltd.
Company Address:	1-1 Kagurazaka, Shinjuku-ku Tokyo 162-0825 Japan
Telephone:	813-3513-8766
Fax:	813-3513-8226
Contact Person:	Mitsuko Uchida
Summary Preparation Date:	August 2, 2019

DEVICE NAME

Trade Name:	Dr. J Spinal and Epidural Needles
Common/Usual Name:	Spinal and Epidural Needles
Classification Name:	Needle, Conduction, Anesthetic (W/Wo Introducer)
Regulation Number:	21 CFR 868.5150
Product Code:	BSP
Device Class:	Class II

PREDICATE DEVICE

Legally marketed Equivalent Device

Company	***Product***	***510(k) #***
Myco Medical Supplies, Inc.	Dr. Japan's Phoenix Spinal & Epidural Needles	K990519

DEVICE DESCRIPTION

Dr. J Spinal and Epidural Needles are intended to be used for injection of local anesthetics into a patient to provide regional anesthesia. The Dr. J Spinal and Epidural Needles are supplied sterile, intended to be single use.

Dr. J Spinal Needles are composed of a stainless-steel cannula, a hub, a stainless-steel stylet and plunger.
A guide needle may be attached to this product. The spinal needle is supplied in either the Quincke Point (=K-3 Point) or the Pencil Point.

The Dr. J Epidural Needle is composed of a stainless-steel cannula with depth marker, a hub, a stainless-steel stylet, a plunger and a wing. The Dr J Epidural Needle is supplied in Detachable wing type which has a curved needle tip design to protect the catheter from damage during catheterization.

DEVICE INDICATIONS FOR USE

Dr. J Spinal and Epidural Needles are intended to be used for injection of local anesthetics into a patient to provide regional anesthesia.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Dr. Japan Co., Ltd. is the manufacturer of the predicate device. This premarket notification represents a modification to the outer box only. The technological characteristics of the predicate device are not changed. The subject device is manufactured using the same inert, biocompatible material as the predicate device. In addition, bench testing was performed (see Section 18) to assure the performance and safety of subject device.

COMPARISON OF TECHNICAL CHARACTERISTICS

	Subject New Device Dr. J Spinal and Epidural Needles	Predicate Device Myco Medical Supplies, Inc.	Discussion
K Number		K990519	
Manufacturer	Dr. Japan Co., Ltd. Tianjin Hanaco Medical Co., Ltd.	Dr. Japan Co., Ltd. Tianjin Hanaco Medical Co.,	Same
Brand Name	Dr. J Spinal and Epidural Needles	Dr. Japan's Phoenix Spinal and Epidural Needles	
Regulation Description	Anesthesia conduction needle	Anesthesia conduction needle	Same
Regulation No.	21 CFR 868.5150	21 CFR 868.5150	Same
Product Code	BSP	BSP	Same
Indications for Use	Intended to be used for injection of local anesthetics into a patient to provide regional anesthesia	Intended to be used to inject local anesthetics into a patient to provide regional anesthesia	Same
Principle of Operation – Spinal Needle	Spinal anesthesia is a form of regional anesthesia involving the injection of a local anesthetic into the subarachnoid space through a spinal needle. Regardless of the anesthetic agent used, the desired effect is to block the transmission of afferent nerve signals from peripheral nociceptors. Sensory signals from the site are blocked, thereby eliminating pain.	Spinal anesthesia is a form of regional anesthesia involving the injection of a local anesthetic into the subarachnoid space through a spinal needle. Regardless of the anesthetic agent used, the desired effect is to block the transmission of afferent nerve signals from peripheral nociceptors. Sensory signals from the site are blocked, thereby eliminating pain.	Same

Principle of Operation – Epidural Needle	Epidural anesthesia is a regional anesthesia that blocks pain in a particular region of the body. An epidural needle is used to inject local anesthetic agent into the epidural space of the spinal cord to block the pain. To provide continuous epidural anesthesia, a small hollow catheter is threaded through the epidural needle into the epidural space and left there while the needle is removed.	Epidural anesthesia is a regional anesthesia that blocks pain in a particular region of the body. An epidural needle is used to inject local anesthetic agent into the epidural space of the spinal cord to block the pain. To provide continuous epidural anesthesia, a small hollow catheter is threaded through the epidural needle into the epidural space and left there while the needle is removed.	Same
Intended Patient Population	Adult and child	Adult and child	Same
Material Specifications			
Needle/cannula material	Cold-rolled stainless steel (JIS G4305-SUS304)	Cold-rolled stainless steel (JIS G4305-SUS304)	Same
Cannula depth markings	The system to cause a chemical change of the metal ion on the surface to a black color by electrolysis without changing the material of cannula.	The system to cause a chemical change of the metal ion on the surface to a black color by electrolysis without changing the material of cannula.	Same
Stylet material	Spinal Needle: Stainless steel wire for spring Epidural Needle: Stainless steel wire for spring	Stainless steel wire for spring Epidural Needle: Stainless steel wire for spring	Same
Stylet hub material	Polycarbonate	Polycarbonate	Same
Retaining plate (Plunger)	Polycarbonate	Polycarbonate	Same
Final Needle assembly protection	Protector (polyethylene)	Protector (polyethylene or polypropylene)	Similar Minor difference (*1)
Sterilization Method	Sterile EO (=ETO)	Sterile ETO	Same
Sterile package	Peel open type package using laminate film of polyester and polyethylene / Tyvek high density polyethylene or medical grade craft paper.	Peel open type package using laminate film of polypropylene or polyethylene / polyethylene of high density or medical grade craft paper.	Similar Minor difference (*2)

Comparison Table of devices - Subject device

Dr.J Brand	Item no	Length	Gauge	Point
Spinal Needle	18Gx90mm (3.5")	3.5"	18G	K-3
Spinal Needle	19Gx90mm (3.5")	3.5"	19G	K-3

Spinal Needle	20Gx90mm (3.5")	3.5"	20G	K-3
Spinal Needle	22Gx90mm (3.5")	3.5"	22G	K-3
Spinal Needle	25Gx90mm (3.5")	3.5"	25G	K-3/ Pencil
Spinal Needle	26Gx90mm (3.5")	3.5"	26G	K-3/ Pencil
Spinal Needle	27Gx90mm (3.5")	3.5"	27G	K-3/ Pencil
Epidural Needle	16Gx90mm (3.5")	3.5"	16G	Tuohy
Epidural Needle	17Gx90mm (3.5")	3.5"	17G	Tuohy
Epidural Needle	18Gx90mm (3.5")	3.5"	18G	Tuohy
Epidural Needle	20Gx90mm (3.5")	3.5"	20G	Tuohy

Comparison Table of devices – Predicate device

Phoenix Brand	Item no	Length	Gauge	Point
Spinal Needle	18Gx90mm (3.5")	3.5"	18G	K-3
Spinal Needle	19Gx90mm (3.5")	3.5"	19G	K-3
Spinal Needle	20Gx90mm (3.5")	3.5"	20G	K-3
Spinal Needle	22Gx90mm (3.5")	3.5"	22G	K-3 / Pencil
Spinal Needle	25Gx90mm (3.5")	3.5"	25G	K-3/ Pencil
Spinal Needle	26Gx90mm (3.5")	3.5"	26G	K-3/ Pencil
Spinal Needle	27Gx90mm (3.5")	3.5"	27G	K-3/ Pencil
Epidural Needle	16Gx90mm (3.5")	3.5"	16G	Tuohy
Epidural Needle	17Gx90mm (3.5")	3.5"	17G	Tuohy
Epidural Needle	18Gx90mm (3.5")	3.5"	18G	Tuohy
Epidural Needle	20Gx90mm (3.5")	3.5"	20G	Tuohy

Discussion of Similarities

The subject device and the predicate device have the same intended use, design, technological characteristics and similar materials.

Discussion of Differences

*1: Predicate device used 2 types of protector, made in either polyethylene or polypropylene while subject device used only 1 type in polyethylene (in same material and specification as predicate device).

*2: Tyvek high density polyethylene used in subject device showed similar safety and stability as polyethylene of high density used in predicate device. See Section 14 for test results.

*3: Models of subject device (needle specification, gauge size and length etc.) are all included in the family of predicate device.

SAFETY AND EFFECTIVENESS CONCLUSIONS:

This submission represents only a modification to the outer box for the currently marketed predicate. Therefore, the similarities between the subject device and predicate device are numerous (as shown in the comparison table). These equivalencies combine to justify a substantially equivalent determination.

Shelf life – Packaging testing, Shelf life- Functionality testing and Sterilization Validation (See Section 14 and Section 18) were conducted to show that the safety, integrity or functional characteristics of the subject device is assured.

SUMMARY OF NON-CLINICAL TESTING

Nonclinical testing as shown in the summary below was conducted to ensure the safety and effectiveness of subject device. Subject device passed all the testing and successfully demonstrate that subject device is as safe, as effective, and performs as well as legally marketed device predicate.

Summary of Non-Clinical Testing

Category	Evaluation	Test Criteria
Functional Performance	Stability test bonding to hub	ISO 7864 Sterile hypodermic needles for single use -- Requirements and test methods
	Stability test bending rigidity	ISO 9626 Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods
	Penetration force and drag force for needles	ISO 7864 Sterile hypodermic needles for single use -- Requirements and test methods
	Breakage test	ISO 9626 Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods
	Fluid leakage test	ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
	Separation axial load test	ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
	Separation unscrewing test	ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
	Overriding test	ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
	Stability test bonding to hub	ISO 7864 Sterile hypodermic needles for single use -- Requirements and test methods
	Stability test bending rigidity	ISO 9626 Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods
Packaging	Dye Penetration Test	ASTM F 1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration Method A
	Seal Strength:	EN 868-5:18 Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods Annex D
	Transit Test	ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems DC13 ASTM F1886/ F1886M-09 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection.
Sterilization	Sterility	<Japan> Japanese Pharmacopoeia 16th revised edition <China> GB/T14233 2-2005 Test methods for medical infusions, blood transfusions and injection device - Part 2: Biological test methods
	Residuals	<Japan> ISO10993-7 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals <China> EO: GB/T14233.1 Test methods for medical infusions, blood transfusions and injection device - Part 1: Chemical analysis method ECH: ISO10993-7 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals

	Bioburden	ISO11737-1 Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
Biocompatibility	Cytotoxicity	ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
	Intracutaneous Reactivity	ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
	Irritation	ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
	Sensitization	ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
	Acute Systemic Toxicity	ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
	Hemolytic	ISO 10993-4 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
	Pyrogen	ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity

SUBSTANTIAL EQUIVALENCE CONCLUSION

The evaluation of subject device classification, indications for use, and technological characteristics demonstrate substantial equivalence to the predicate device. The only difference between marketed predicate device and subject device is a modification to the outer box.

No new issues of safety and effectiveness questions are raised by the subject device when compared to the predicate device.