DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 4, 2015

Remington Medical, Inc.
Caitlin Senter, M.S., RAC
Regulatory Affairs Manager
6830 Meadowridge Court
Alpharetta, GA 30005

Re: K150266
Trade/Device Name: Remington Medical Inc. Tuohy Epidural Needles
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: May 1, 2015
Received: May 4, 2015

Dear Ms. Senter:

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150266

Device Name
Remington Medical, Inc. Tuohy Epidural Needle

Indications for Use *(Describe)*
Remington Medical, Inc. Tuohy Epidural Needles are to be used to inject local anesthetics into a patient to provide regional anesthesia or to facilitate the placement of an epidural catheter.

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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Section 5 – 510(k) Summary

Preparation Date	June 2, 2015
Applicant	Remington Medical, Inc. 6830 Meadowridge Court, Alpharetta, GA, USA 30005 Registration Number: 1056553 Owner/Operator Number: 9006473
Contact Person	Caitlin Senter, MS, RAC Regulatory Affairs Manager 770-888-8520, extension 207 caitlins@remmed.com
Trade Proprietary Name(s)	Remington Medical, Inc. Tuohy Epidural Needle
Common Name (s)	Needle, Conduction, Anesthetic (W/Wo Introducer)
Classification Name	21 CFR 868.5150 (Anesthesia conduction needle); Product Code: BSP
Device Class:	Class II

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

Myco Medical Supplies, Inc. Dr. Japan's Phoenix Epidural & Spinal Needles, (K990519)
B. Braun Medical, Inc. Perican™ Ultra Needle, (K133632)

Description of the Device:

The Tuohy Epidural Needle is a device used for the injection of anesthetic agents into a patient for regional anesthesia administration or to facilitate the placement of an epidural catheter for continuous infusion of local anesthetics.

Tuohy Epidural Needles consist of a plastic cannula hub, containing a stainless steel bushing, affixed to a stainless steel cannula with medical grade adhesive and a stainless steel stylet affixed to a plastic stylet hub with medical grade adhesive. The cannula hub has the option of a permanent, fixed wing or a removable wing depending on user preference. The needle assembly is protected with a polypropylene sheath.

Tuohy Epidural Needles are provided as a sterile, single use, disposable devices. The Tuohy Epidural Needles will be available in a variety of lengths and gauges. They may be packaged individually or included in regional anesthesia trays (kits).

Intended Use/Indications for Use

Remington Medical, Inc. Tuohy Epidural Needles are to be used to inject local anesthetics into a patient to provide regional anesthesia or to facilitate the placement of an epidural catheter.

Technological Characteristics:

The technological characteristics (design, specifications, and performance) of the subject device and the predicate devices are substantially equivalent. Remington Medical Inc. Tuohy Epidural Needles meet performance standards where applicable for:

Hub to Needle Bond Strength: ISO 7864

Color: ISO 6009

	Subject Device: Remington Medical Inc. Tuohy Epidural Needles			**Predicate Device: Myco Medical Supplies, Inc. Dr. Japan's Phoenix Epidural & Spinal Needles (K990519)**			**Predicate Device: B. Braun Medical, Inc. Perican™ Ultra Needle, (K133632)**
Device Class FDA Product Code Regulation	Class II BSP 21 CFR 868.5150			Class II BSP 21 CFR 868.5150			Class II BSP 21 CFR 868.5150
Indications for Use Statement	Remington Medical, Inc. Tuohy Epidural Needles are to be used to inject local anesthetics into a patient to provide regional anesthesia or to facilitate the placement of an epidural catheter.			Spinal and Epidural needles are to be used to inject local anesthetics into a patient to provide regional anesthesia.			The B. Braun Perican Ultra needle is intended for use in injecting local anesthetics and/or analgesics into a patient to provide regional anesthesia and/or to facilitate the placement of a catheter.
Cannula Material	Metal, Stainless Steel			Metal, Stainless Steel			Metal, Stainless Steel
Cannula Depth Marking	10 mm, Wide Band			Wide Band			Wide Band
Cannula Hub Material	Plastic (Polycarbonate), Stainless Steel Bushing and UV Cured Medical Grade Adhesive			Plastic, Metal Bushing, and Adhesive			Plastic, Spacer (Bushing) and Adhesive
Stylet Material	Metal, Stainless Steel			Metal, Stainless Steel			
Stylet Hub Material	Color-coded Plastic (Polycarbonate) and UV Cured Medical Grade Adhesive			Color-coded Plastic and Adhesive			
Gauge/Length (inches)/Color Depiction				16 GA	3.5"	White	
	17 GA	3.5", 5.0"	Violet	17 GA	3.5", 6.0"	Violet	
	18 GA	3.5", 5.0"	Pink	18 GA	2.5", 3.5", 6.0"	Pink	
	19 GA	2.0"	Cream				
	20 GA	3.5", 5.0", 6.0"	Yellow	20 GA	3.5", 4.5", 6.0"	Yellow	
	22 GA	3.5"	Black	22 GA	2.5", 3.5"	Black	
Final Needle Assembly Protection	Sheath			Sheath			Sheath
Sterilization Method	ETO			ETO			ETO

Performance Data:

Tests were performed on the Remington Medical Inc. Tuohy Epidural Needles including verification/validation testing to internal functional specifications (e.g. catheter placement, and bond strength between cannula, hub, and stylet) including comparison data (e.g., needle flow) to the K990519 predicate device. These tests demonstrated that the Remington Medical Inc. Tuohy Epidural Needles are substantially equivalent to the predicate device. Visual inspection of the test catheter under magnification confirmed no negative impact to the catheter post-placement. Testing confirmed that the Remington Medical Inc. Tuohy Epidural Needles comply with relevant standards, specifically ISO standards 7864 and 6009. In addition, evaluations and validations have been performed to demonstrate compliance to the applicable standards for biocompatibility (ISO 10993-1) and sterilization. Biocompatibility testing performed includes cytotoxicity, sensitization, irritation or intracutaneous reactivity, and acute systemic toxicity. Pyrogenicity was also tested.

Clinical testing:

Clinical testing was not required.

Conclusion:

The results of the non-clinical testing demonstrated that the subject device, Remington Medical Inc. Tuohy Epidural Needles, is substantially equivalent to the predicate devices, Myco Medical Supplies, Inc. Dr. Japan's Phoenix Epidural & Spinal Needles and B. Braun Medical, Inc. Perican™ Ultra Needle, (K133632) with respect to intended use, materials, design, and technological characteristics.