DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 8, 2017

Spectra Medical Devices
% James Wason
Principal
Maelor Group, Inc
7 Village Woods Dr
Amherst, New Hampshire 03031

Re: K163292
Trade/Device Name: Spectra Sonic Block Tuohy, Spectra Sonic Block Quincke, Spectra Sonic Block Chiba, Spectra Sonic Block Crawford
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: August 7, 2017
Received: August 9, 2017

Dear James Wason:

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,

Tara A. Ryan -S

for
Lori Wiggins
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)*
K163292

Device Name
Spectra Sonic Block Tuohy, Spectra Sonic Block Quincke, Spectra Sonic Block Chiba and Spectra Sonic Block Crawford Needles

Indications for Use *(Describe)*
The cannulas/needles for anesthesia and analgesia enhanced for ultrasound visibility - Spectra Sonic Block Tuohy, Spectra Sonic Block Quincke, Spectra Sonic Block Chiba and Spectra Sonic Block Crawford Needles - are intended for the transient delivery of anesthetics to provide regional analgesia or to facilitate placement of a 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.

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K163292

510(k) Summary
for
Spectra Sonic Block Needles

1. SPONSOR

Spectra Medical Devices, Inc.
260-H Fordham Road
Wilmington, MA 01887

Contact Person: Agustin Turriza

Date Prepared: September 8, 2017

2. DEVICE NAME

Proprietary Name:	Spectra Sonic Block Tuohy, Spectra Sonic Block Quincke, Spectra Sonic Block Chiba and Spectra Sonic Block Crawford Needles
Common/Usual Name:	Anesthesia conduction needles/cannulas
Classification Name:	Needle, conduction, anesthetic (w/wo introducer)
Classification Reference:	21 CFR 868.5150
Product Code:	BSP
Regulatory Class:	2

3. PREDICATE DEVICES

Pajunk Medical Systems, K113207

4. DEVICE DESCRIPTION

The Spectra Sonic Block Needles consist of a stainless steel needle and a clear standard female Luer locking hub. The needles are available in a range of needle tip configuration, gauges and lengths to match the end-user need. These needles have an echogenic treatment to help ensure strong reflection during ultrasound procedures. Spectra Sonic Block Needles will be marketed as sterile, non-pyrogenic, and single use devices.

The needles / cannulas for anesthesia and analgesia enhanced for ultrasound visibility are single use sterile and non-pyrogenic devices used to gain entry or puncture the tissue and inject anesthetics to induce single shot anesthesia and analgesia. The needles / cannulas may be used during all anesthesia and analgesia procedures according to the physician's indication.

Needles / cannulas for anesthesia and analgesia enhanced for ultrasound visibility are standard needles /cannulas equipped with dimpled echogenic tip in order to significantly enhance ultrasound visibility. This surface technology allows for a variety of sizes. The inner diameter is not effect by the echogenic treatment. This feature completely encircles the tip of the needles / cannulas so all sides appear bright under ultrasound. In order to enhance ultrasound visibility, the needles / cannulas are equipped with a special dimpled pattern named Sonic Block dimples to the needles / cannulas surface. These reflectors are designed to optimally reflect ultrasound waves.

Brand names of the original file as well as the corresponding brand names of the subject file are:

Predicate: Tuohy SONO	Subject: Spectra Sonic Block Tuohy
Predicate: Quincke SONO	Subject: Spectra Sonic Block Quincke
Predicate: Crawford SONO	Subject: Spectra Sonic Block Crawford
Predicate Chiba SONO	Subject: Spectra Sonic Block Chiba

The detailed discussion of substantial equivalence can be found in Section 12 of this submission.

Technological Characteristics:

Tip Specifications

The tips of the needles / cannulas covered by this 510(k) are identical to the tips of the original predicate devices submission: Tuohy tip, Beveled tip (which is synonymously used with Chiba tip and facetted tip), Crawford tip and Quincke tip.

Length

The length of the needles / cannulas subject to this 510(k) submission are identical to the lengths of the needles cannulas covered by the predicate device submission.

Predicate	Subject
Tuohy Sono: 20mm-180mm	Spectra Sonic Block Tuohy: 20mm-180mm
Quincke Sono: 20mm-l80mm	Spectra Sonic Block Quincke: 20mm-180mm
Chiba Sono: 20mm-l80mm	Spectra Sonic Block Chiba: 20mm-l80mm
Crawford Sono: 20mm-l80mm	Spectra Sonic Block Crawford: 20mm-180mm

Diameters

The diameters of the needles /cannulas subject to this 510(k**)** submission are identical to the diameters of the cannulas covered by the predicate device submission.

Predicate	Subject
Tuohy Sono: 16G-26G	Spectra Sonic Block Tuohy: 16G - 26G
Quincke Sono: 16G-26G	Spectra Sonic Block Quincke: 16G - 26G
Chiba Sono: 16G-26G	Spectra Sonic Block Chiba: 16G - 26G
Crawford Sono: 16G-26G	Spectra Sonic Block Crawford: 16G - 26G

5. INTENDED USE

The cannulas/needles for anesthesia and analgesia enchanced for ultrasound visibility – Spectra Sonic Block Tuohy, Spectra Sonic Block Quincke, Spectra Sonic Block Chiba and Spectra Sonic Block Crawford Needles - are intended for transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of a catheter.

6. SUBSTANTIAL EQUIVALENCE

The Spectra Medical Devices, Inc. Sonic Block needles: Sonic Block Tuohy, Sonic Block Quincke, Sonic Block Chiba and Sonic Block Crawford are substantially equivalent to Pajunk GmbH, Tuohy Sono, Sono TAP, Quincke Sono, Chiba Sono and Crawford Sono.

The above devices were granted marketing clearance by the FDA on February 29, 2012, under 510(k) number K113207.

The differences in the subject and predicate device are minimal of the submission.These diffrences do not raise any different questions of satety and effectiveness.

TOPIC	SPECTRA DEVICE	PAJUNK GmbH	SIMILARITIES	DIFFERENCES
510(K) Number	K163292	K113207	N/A	N/A
Regulation Number	21 CFR 868.5150	21 CFR 868.5150	Same	None
Product Classification	BSP	BSP	Same	None
Class	II	II	Same	None
Indications for use	The cannulas/needles for anesthesia and analgesia enchanced for ultrasound visibility –Spectra Sonic Block Tuohy, Spectra Sonic Block Quincke, Spectra Sonic Block Chiba and Spectra Sonic Block Crawford Needles - are intended for transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of a catheter.	The cannula/needles for anesthesia and analgesia enhanced for ultrasound visibility – Tuohy Sono, Sono TAP, Quincke Sono, Chiba Sono and Crawford Sono – are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of a catheter.	The Indications for Use are basically the same, in that they are both conduction needles intended to administer regional anesthesia and have a echogenic surface feature to enhance visibility under ultrasound imaging. The Spectra device references the intent to mate with a Luer Lock or Slip connector.	None
Target population	Adult and Pediatric	Adult and Pediatric	Same	None
Design	Single Use Disposable Device	Single Use Disposable Device	Same	None
Design – Hub & Needle Protector	Echogenic Anesthesia Conduction Needles with a molded Square Hubs and a Stainless Steel Needle. The needle protector is an extracted tube.	Echogenic Anesthesia Conduction Needles with a molded Square Hub and a Stainless Steel Needle. The needle protector is an extruded tube.	Same	None
Design - Needle Bevels	Sonic Block Tuohy – 8^{o} Sonic Block Crawford - 45^{o} Sonic Block Quincke - 16^{o} Sonic Block Chiba - 30^{o}	Tuohy Sono - 8^{o} Crawford Sono - 45^{o} Quincke Sono - 16^{o} Chiba Sono - 30^{o}	Same	None
Design - Needle Gauge Size	Sonic Block Tuohy: 16G - 26G Sonic Block Crawford: 16G - 26G Sonic Block Quincke: 16G - 26G	Tuohy Sono: 16G – 26G Crawford Sono: 16G – 26G Quincke Sono: 16G – 26G Chiba Sono: 16G – 26G	Same	None

	Sonic Block Chiba: 16G – 26G			
Design – Needle Length	Sonic Block Tuohy: 20 – 180mm Sonic Block Crawford: 20-180mm Sonic Block Quincke: 20-180mm Sonic Block Chiba: 20-180mm	Tuohy Sono: 20-180mm Crawford Sono: 20-180mm Quincke Sono: 20-180mm Chiba Sono: 20-180mm	Same	None
Design – Echogenic Treatment of Needle Tip	Echogenic Surface Treatment [dimpling] of Needle Tip for Ultrasound Visualization	Echogenic Surface Treatment (CornerStone)	Similar; both are functional	Echogenic Treatment methods are different and shape of reflective surface is different.
Life Cycle	5 Years	5 Years	Same	None
Materials	Cannula = 304 Stainless Steel Square Hub = Polycarbonate Protector = LDPE Adhesive = Epoxy Same for all (4) Needles	Cannula = 304 Stainless Steel Square Hub = Polycarbonate Protector = LDPE Adhesive = Epoxy Same for all (4) Needles	Equivalent Materials of Construction	None
Performance	Hub/Cannula Tensile Strength Luer Taper Separation from Luer	Hub/Cannula Tensile Strength Luer Taper Separation from Luer	Equivalent	None
Sterility	Supplied Packaged Sterile	Supplied Packaged Sterile	Same	None
Sterilization Method(s)	EO (Ethylene Oxide)	EO (Ethylene Oxide)	Same	None
Chemical safety	Device does not pose a chemical hazard and is compatible with chemicals commonly used in the areas designated for use.	Assumed; Device does not pose a chemical hazard and is compatible with chemicals commonly used in the areas designated for use.	Same	None
Anatomical Sites	May be used during all anesthetic and analgesic procedures according to the physician's indication.	May be used during all anesthetic and analgesic procedures according to the physician's indication.	Same	None
Energy used and /or delivered	No Energy used or delivered by the Device	No Energy used or delivered by the Device	Same	None
Compatibility with environment and other devices	Device does not contain any materials considered to be dangerous to the environment.	Assumed; Device does not contain any materials considered to be dangerous to the environment.	Same	None

	Device is designed to connect to a piston syringe (L/S and L/L) or extension set with a male luer connector.	Device is designed to connect to a piston syringe (L/S and L/L) or extension set with a male luer connector.		
Where used: hospital, home, ambulance, etc.	Used in Hospital, Clinics, Research Centers, Ambulance, and others	Used in Hospital, Clinics, Research Centers, Ambulance, and others	Same	None
Thermal safety	Device does not contain a thermal source	Device does not contain a thermal source	Same	None
Radiation safety	Device does not admit any form of radiation	Device does not admit any form of radiation	Same	None
Performance testing	Hub/Cannula Tensile Strength	Hub/Cannula Tensile Strength	Same	None
Electrical safety	Device does not contain an electrical source or connect to an electrical source	Device does not contain an electrical source or connect to an electrical source	Same	None
Biocompatibility	Biocompatibility Testing has been conducted for each product configuration with test results confirming compliance with ISO 10993-1 requirements.	Assumed; Biocompatibility Testing has been conducted per ISO 10993-1 and included with 510(K) Submission to FDA based on statement in Patent.	Same	None
Mechanical safety	Device does not include a separate safety feature and does not claim it is a safety device.	Device does not include a separate safety feature and does not claim it is a safety device.	Same	None

7. PERFORMANCE TESTING

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the needles has been conducted in accordance with the FDA "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995. The submission devices meet the requirements. The battery of tests included the following:

- Cytotoxicity
- System Toxicity
- Hemocompatibility
- Sensitization
- Irritation or Intracutaneous Reactivity
- Material Mediated Pyrogen Test

Sterilization and shelf Life

The requirements of ANSI/AAMI/ISO 11135-1:2014 Sterilization of Health Care Products- Ethylene Oxide-Part 1: Requirements for the development, Validation and Routine Control of the Sterilization process for Medical Devices have been met. The information and data is shown in Section 14.

Non-Pyrogenic Testing

The requirements of ANSI/AAMI ST72: 2011 have been met. The information is shown in Section 14.

Other performance tests

Physical tests were performed to ensure that the Spectra Sonic Block Needles had standard ISO Luer hubs with applicable Luer testing in accordance with ISO 594. Needle bond strength tests in accordance with ISO 7864, with hubs were also conducted. All the testing for stiffness and breakage was performed under ISO 9626. The Spectra Medical Devices, Inc. Sonic Block Needles passed all tests.

Conclusion

This 510(k) does not raise any different questions of safety and effectiveness or a new intended use since clearance is only being requested for the same technological characteristics and intended use, which has been previously cleared by the FDA in the predicate devices.

The Spectra Sonic Block Tuohy, Spectra Sonic Block Quincke, Spectra Sonic Block Chiba and Spectra Sonic Block Crawford needles have been compared to the noted predicate needles. This submission demonstrates that the Spectra Medical Devices, Inc. needles are substantially equivalent to the predicate devices.

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