DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 5, 2016

Spectra Medical Devices, Inc.
% Tanya O'Brien
Clinical Affairs Specialist
AJW Technology Consultants, Inc.
445 Apollo Beach Blvd
Apollo Beach, Florida 33572

Re: K151069
Trade/Device Name: SPECTRA Disposable Single Lumen Echogenic Injection Anesthesia Conduction Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: November 23, 2015
Received: December 8, 2015

Dear Ms. O'Brien:

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)*
K151069

Device Name
SPECTRA Disposable Single Lumen Echogenic Injection Anesthesia Conduction Needle

Indications for Use *(Describe)*
The SPECTRA Disposable Single Lumen Echogenic Injection Anesthesia Conduction Needle is intended for use in injecting a single dose of local anesthetic or analgesic into a patient for regional anesthesia or pain therapy with the echnogenic reflective pattern providing visualization of the needle tip using Ultrasound Imaging. The needles are intended to mate with the male connector of a Luer Lock or Luer Slip Syringe or extension set.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

(as required by 807.92)

I. **SUBMITTER**

Spectra Medical Devices, Inc.
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Fax: 757-220-8919

Contact Person: Scott Henderson
Date Prepared: March 26, 2015

REGULATORY CORRESPONDENT

AJW Technology Consultants, Inc.
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Apollo Beach, FL 33572

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II. **DEVICE**

Name of Device: SPECTRA Disposable Single Lumen Echogenic Injection Anesthesia Conduction Needle
Common or Usual Name: Conduction Needle
Classification Name: Needle, Anesthesia Conduction
Device Panel: Anesthesiology
Regulatory Class: 2
Product Code: BSP
Contact Type: Limited Exposure Device

III. **PREDICATE DEVICE**

- Havel's Inc. – K063380 ECHOSTIM FACIT TIP

These predicates have not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The SPECTRA Disposable Single Lumen Echogenic Injection Anesthesia Conduction Needle consists of a stainless steel needle and a clear or colored (translucent) standard female Luer lock square or round Hub locking connector for rapid (flashback) visualization. The stainless steel needles are available with and without an echogenic feature (i.e. mechanical dimpling treatment to the needle point surface), and with or without lubrication. The needles are available in a range of wall thicknesses, gauges and lengths to match the end-user need (16 to 30 gauges).

V. INIDCATIONS FOR USE

The SPECTRA Disposable Single Lumen Echogenic Injection Anesthesia Conduction Needle is intended for use in injecting a single dose of local anesthetic or analgesic into a patient for regional anesthesia or pain therapy with the echogenic reflective pattern providing visualization of the needle tip using Ultrasound Imaging. The needles are intended to mate with the male connector of a Luer Lock or Luer Slip Syringe or an extension set.

VI. COMPMARISOIN OF TECHNOLIGICAL CHARACTERISTICS IWHT THE PREDICATE DEVICE

To inject fluids (drug solutions), or withdraw fluids from parts of the body below the surface of the skin is the technological principle for both the subject and predicate devices. It is based on the use of modules and accessories that are either connected internally or externally to the monitors in order to monitor the specific physiological parameter. At a high level, the subject and predicate devices are based on the following same technological characteristics:

- Design
- Materials of the needle
- Sterility
- No thermal source
- Indications for use

The following technological differences exist between the subject and predicate devices:

- Additional or different sizes of needles are offered
- Some additional/different materials are used for the Spectra hub designs
- Physical dimensions

VII. DEVICE COMPARISON CHART

See Appendix A

VIII. PERFORMANCE DATA

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

Mechanical Testing

- Bond strength of hub and cannula
- ISO 594-1
- ISO 7864:11
- Luer compatibility
- Hub and Needle Strength

IX. BIOCOMPATIBILITY TESTING

The product contact materials utilized in the Disposable Single Lumen Echogenic Injection Anesthesia Conduction Needles have been well characterized chemically and physically. The following table indicates the individual biocompatibility tests performed on the Disposable Single Lumen Echogenic Injection Anesthesia Conduction Needles.

Test	Description
ISO 10993-5	Cytotoxicity Study Using the ISO Elution Method
ISO 10993-4	In Vitro Hemolysis Study (Modified ASTM-Extraction Method)
ISO 10993-11	USP and ISO Systemic Toxicity Study - Extracted
ISO 10993-10	ISO Intracutaneous Study - Extract
ISO 10993-10	ISO Maximization Sensitization Study - Extract

X. CONCLUSIONS

The testing completed demonstrates that the Disposable Single Lumen Echogenic Injection Anesthesia Conduction Needles have exhibited comparable mechanical and functional characteristics to the predicate device in addition to being biocompatible acceptable. Based on these characteristics, the Disposable Single Lumen Echogenic Injection Anesthesia Conduction Needles, ARE substantially equivalent to the predicate device in addition to being intended for the same uses.

APPENDIX A

TOPIC	SPECTRA DEVICE	HAVEL'S	SIMILARITIES	DIFFERENCES
510(K) Number	Pending	K063380	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 SPECTRA Disposable Single Lumen Echogenic Injection Anesthesia Conduction Needle is intended for use in injecting a single dose of local anesthetic or analgesic into a patient for regional anesthesia or pain therapy with the echogenic reflective pattern providing visualization of the needle tip using Ultrasound Imaging. The needles are intended to mate with the male connector of a Luer Lock or Luer Slip Syringe or an extension set.	Havel's Electrically insulated anesthesia conduction needles are used to puncture the tissue in order to gain entry and locally inject anesthetics to induce regional anesthesia. An electrical stimulus may be applied to the needle via a cable and connector to assist the physician to pinpoint the area of application.	The Indications for Use are basically the same, in that they are both conduction needles intended to administer regional anesthesia, and both are used as a non-insulated needle.	None for Non-Insulated Havel's Needle Configuration
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 Injection Anesthesia Conduction Needle with Standard Round Luer Style Hub or Square Hubs and a Stainless Steel Needle. The needle protector is an extracted tube or a molded protector. The square clear hub has a colored printed bevel indicator and the round luer hub is colored with no bevel indicator.	Echogenic Injection Anesthesia Conduction Needle with a molded Square Hub and a Stainless Steel Needle. The needle protector is an extruded tube. The Sq. needle hub has a colored molded insert as a bevel indicator.	The molded Hub for both products is functionally equivalent, as are the stainless steel needle and needle protector.	The Havel's Hub Assembly has a metal Bushing and is Glued; the Spectra Sq. Hub Assembly is over molded and the Round Luer Hub Assembly is glued. The Havel's Hub has a molded bevel indicator; the Spectra hub has a printed bevel indicator. The Havel's needle has depth marks on the needle and the Spectra needles do not.
Design - Needle Bevels	$B = 17^0$ & $C = 30^0$	$B = 17^0$ & $C = 30^0$	Same	None
Design - Needle Size	21G to 25G; 2.0" to 6.0"	21G to 22G; 2.0" to 6.00"	Similar Gauge Range	Spectra has a 25G Needle

Design – Echogenic Treatment of Needle Tip	Echogenic Treatment [dimpling] of Needle Tip for Ultrasound Visualization	Echogenic Treatment [4 x 4 Corner Cube indentations] of Needle Tip for Ultrasound Visualization	Similar; both are functional	Echogenic Treatment methods are different and shape of reflective surface is different.
Materials	Cannula = 304 Stainless Steel Round Hub = Polypropylene Square Hub = K-Resin Protector = LDPE / Polypropylene (Molded) Lubrication = Silicone	Cannula = 304 Stainless Steel Square Hub = N/A (PP) Protector = N/A	Equivalent Materials of Construction	None
Performance	Hub/Cannula Tensile Strength Penetration Force Luer Taper Separation from Luer	Hub/Cannula Tensile Strength Luer Taper Separation from Luer	Same	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	Various, including: Arm, Hand, Neck, Shoulder, Groin, Buttock, Leg, Knee, Foot, etc.	Various, including: Arm, Hand, Neck, Shoulder, Groin, Buttock, Leg, Knee, Foot, etc.	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. Device is designed to connect to a piston syringe (L/S and L/L) or extension set with a male luer connector.	Assumed; Device does not contain any materials considered to be dangerous to the environment. Device is designed to connect to a piston syringe (L/S and L/L) or extension set with a male luer connector.	Same	None
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 Penetration Force	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 requirements.	Assumed; Biocompatibility Testing has been conducted and included with 510(K) Submission to FDA.	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