April 25, 2018

Teleflex Medical
Kristen Bisanz
Sr. Regulatory Affairs Specialist
3015 Carrington Mill Blvd.
Morrisville, North Carolina 27560

Re: K173321
Trade/Device Name: StimuQuik Peripheral Nerve Block Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: March 20, 2018
Received: March 22, 2018

Dear Kristen Bisanz:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Geeta K.
Pamidimukkala -S

for 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)*

K173321

Device Name
StimuQuik Peripheral Nerve Block Needle

Indications for Use *(Describe)*
The Arrow StimuQuik Insulated Peripheral Nerve Block Needle permits the stimulation and location of nerves and nerve plexus for single-shot nerve block anesthesia or analgesia techniques.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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
StimuQuik® Peripheral Nerve Block Needle

Name, Address, Phone and Fax Number of Applicant

Teleflex Medical
3015 Carrington Mill Blvd
Morrisville, NC 27560 USA
Phone: 919.433.4932
Fax: 919.433.4996

Contact Person

Kristen Bisanz
Senior Regulatory Affairs Specialist

Date Prepared

10 April 2018

Device Name

Trade Name:	StimuQuik Peripheral Nerve Block Needle
Classification Name:	Needle, Conduction, Anesthetic (W/Wo Introducer)
Product Code:	BSP
Regulation Number:	868.5150
Classification:	II
Classification Panel:	Anesthesiology

Predicate Device

This submission demonstrates substantial equivalence to the predicate devices AVID-NIT Nerve Stimulation Needles (StimuQuik) cleared in submission K014246.

Device Description

The StimuQuik peripheral nerve block needle is used to locate nerves or nerve plexuses and facilitate delivery of regional anesthesia to the desired location. The needles are constructed of a steel needle and insulated by a white, non-conductive siliconized polyester coating. A small area at the distal tip remains exposed to conduct the stimulating current to nerve tissue. The tip features a 30-degree bevel, and black centimeter markings are printed along the shaft of the needle. An electrical wire with a shrouded 2 mm female connector and an extension line with a Luer lock extend from the ergonomic plastic hub of the needle.

The StimuQuik ECHO peripheral nerve block needle is identical to the StimuQuik needle with the addition of 5 echogenic grooves on the needle tip. The five grooves are designed to help clinicians locate the tip of the StimuQuik ECHO needle under ultrasound.

The StimuQuik Peripheral Nerve Block Needle product numbers and descriptions are below.

Product Numbers	Product Description
AB-21090-SS	StimuQuik® 21G x 9cm (3.5”) Peripheral Nerve Block
AB-21090-SSE	StimuQuik® Echo 21G x 9cm (3.5”) Peripheral Nerve Block
AB-21150-SS	StimuQuik® 21G x 15cm (6”) Peripheral Nerve Block
AB-21150-SSE	StimuQuik® Echo 21G x 15cm (6”) Peripheral Nerve Block
AB-22025-SS	StimuQuik® 22G x 2.5cm (1”) Peripheral Nerve Block
AB-22025-SSE	StimuQuik® Echo 22G x 2.5cm (1”) Peripheral Nerve Block
AB-22050-SS	StimuQuik® 22G x 5cm (2”) Peripheral Nerve Block Needle
AB-22050-SSE	StimuQuik® Echo 22G x 5cm (2”) Peripheral Nerve Block

Principle of Action and mechanism of action of the subject device

The StimuQuik Peripheral Nerve Block Needles include a cannula, hub, and fluid extension line with a female luer connector. The needles are used to deliver single-shot anesthesia in peripheral nerve block procedures. An insulated needle with stimulating tip allows for confirmation of needle guidance and placement using stimulation (StimuQuik) and/or ultrasound (StimuQuik Echo). As the needle is advancing in the patient, stimulations are delivered via a nerve stimulator until appropriate muscle twitches occur which demonstrates correct placement. The StimuQuik Echo needles contain 5 rings at the distal end of the needle cannula to help with identification under ultrasound.

Indications for Use

The Arrow StimuQuik Insulated Peripheral Nerve Block Needle permits the stimulation and location of nerves and nerve plexuses for single-shot nerve block anesthesia or analgesia techniques.

Patient Population

The StimuQuik Peripheral Nerve Block Needles are intended for adult patients requiring peripheral nerve block procedures.

Environments of use

The environments of use are hospitals, sub-acute facilities, pain clinics, and physician offices.

Contraindications

Pre-existing nerve injury, neuritis or plexitis are relative contraindications for use of peripheral nerve blocks. These conditions should be considered prior to needle insertion. Skin sepsis in the area where the needle placement is planned and systemic sepsis are relative contraindications. Extreme care should be taken in patients with bleeding tendencies or patients receiving anticoagulants.

Substantial Equivalence

The proposed device is substantially equivalent to the predicate listed below.

Predicate Device	510(k) Number	Date Cleared
AVID-NIT Nerve Stimulation Needles (StimuQuik)	K014246	July 16, 2002

Comparison to Predicate Device

The proposed device has the same operating principles, patient population, sterilization and general design as the predicate device. Biocompatibility testing (Section 020) and Performance testing (Section 023) have been performed on the proposed device to establish substantial equivalence to the predicate device. The proposed changes discussed above do not raise different questions of safety or effectiveness of the StimuQuik Peripheral Nerve Block Needle. The subject device is therefore substantially equivalent to the predicate device identified within this submission.

	Predicate K014246 StimuQuik Peripheral Nerve Block Needle	**Proposed StimuQuik® Peripheral Nerve Block Needle**	**Equivalence**
Classification Name	Anesthesia Conduction Kit	Needle, Conduction, Anesthetic, W/Wo Introducer	**Equivalent**
Product Code	73CAZ	73BSP	**Equivalent**
Classification	Class II	Class II	Identical
Regulation Number	868.5140	868.5150	**Equivalent**
Intended Use	Single Shot nerve block anesthetic administration	Single Shot nerve block anesthetic administration	Identical
Indications for Use	The AVID-NIT Nerve Stimulation Needle consist of an insulated hollow needle intended for locating peripheral nerves by electrical stimulation, and for the single shot administration of a local anesthetic drug. These needles are to be used with battery powered peripheral nerve locators only. These needles are specifically not intended for nerve stimulation for purposes other than nerve location. These needles are specifically not intended for neurolytic ablation.	The Arrow StimuQuik Insulated Peripheral Nerve Block Needle permits the stimulation and location of nerves and nerve plexuses for single-shot nerve block anesthesia or analgesia techniques.	**Equivalent**
Environment of Use	Hospitals, Sub-acute facilities, pain clinics, and physician office	Hospitals, Sub-acute facilities, pain clinics, and physician office	Identical
Patient Population	Patients requiring peripheral nerve block procedures	Patients requiring peripheral nerve block procedures	Identical

Contra-indications	Pre-existing nerve injury, neuritis or plexitis are relative contraindications for use of peripheral nerve blocks. These conditions should be considered prior to needle insertion. Skin sepsis in the area where the needle placement is planned and systemic sepsis are relative contraindications. Extreme care should be taken in patients with bleeding tendencies or patients receiving anticoagulants.	Pre-existing nerve injury, neuritis or plexitis are relative contraindications for use of peripheral nerve blocks. These conditions should be considered prior to needle insertion. Skin sepsis in the area where the needle placement is planned and systemic sepsis are relative contraindications. Extreme care should be taken in patients with bleeding tendencies or patients receiving anticoagulants.	Identical
Biocompat-ibility	Per ISO 10993-1	Per ISO 10993-1	Identical
Basic Components	Insulated cannula with insulated coating and hub, fluid extension tube with luer lock fitting, lead wire for connection to a nerve stimulator	Insulated cannula with insulated coating and hub, fluid extension tube with luer lock fitting, lead wire for connection to a nerve stimulator	**Equivalent**
Gauges/ Dimension	21-24 Ga	21 Ga	Identical
Cannula Length	35-150mm	35-150mm	Identical
Tip Styles	Beveled Pencil Point	Beveled Pencil Point	Identical
Cannula	Smooth	Smooth	Identical
Cannula Insulated	Yes	Yes	Identical
Cannula Markings	Yes	Yes	Identical
Fluid Extension tube	Yes, with female luer lock fitting	Yes, with female luer lock fitting	Identical
Lead Wire	Yes, for connection to nerve stimulator	Yes, for connection to nerve stimulator	Identical
Echogenic Properties	Yes	Yes	Identical
Sterilization	Sterile	Sterile	Identical

Prescription	Yes	Yes	Identical
Shelf Life	5 years	2 years	Equivalent

Discussion

Classification Name/Product Code/Regulation Number: The product code of the predicate device is CAZ (anesthesia conduction kit/868.5150) The design and intended use of the predicate and proposed devices is identical. The product code BSP (anesthesia conduction needle/868.5140) was chosen for the proposed device in this submission because it more accurately reflects the intended use of the StimuQuik Peripheral Nerve Block Needle. While product code CAZ can encompass several components in a kit, product code BSP is specific for a device used in the same manner as the StimuQuik Peripheral Nerve Block Needle.

Indication for Use: The Indications for Use of the proposed device are identical to the Indications for Use cleared in K122690 for the UltraQuik Peripheral Nerve Block Needle. The UltraQuik Peripheral Nerve Block Needle in K122690 was deemed substantially equivalent to K014246, the predicate for this submission. The UltraQuik and StimuQuik needles differ only in the presence and absence of the insulating material on the needle. This does not raise any additional questions of safety and effectiveness. Therefore, the Indications for Use of the predicate and proposed devices are equivalent.

Basic Components: The proposed StimuQuik Peripheral Nerve Block Needle contains a different insulator material on the needle as compared to the predicate. Comprehensive functional testing has been successfully completed on the StimuQuik Peripheral Nerve Block Needle. The functional testing proves the proposed device meets the standard requirements and also performs as well as the predicate devices. The testing included: needle markings, ink adherence, continuity, needle current density, current leakage, resistance to leakage, tensile strength, kink resistance, and echogenicity. As demonstrated by the functional testing, the change in insulator material on the needle has no impact on the function or performance of the StimuQuik Peripheral Nerve Block Needle. Biocompatibility testing has been performed on the final finished proposed device. The following testing has been done: Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material Mediated Pyrogenicity, and Hemolysis. The materials tested all met the ISO 10993 requirements. As demonstrated by the biocompatibility testing, the change in insulator material on the needle has no impact on the performance or intended use of the StimuQuik Peripheral Nerve Block Needle.

Materials

All patient contacting materials, including those with indirect patient contact, are in compliance with ISO 10993-1. Biocompatibility testing has been performed on the proposed device and meets the acceptance criteria.

Test	Acceptance Criteria	Results
Cytotoxicity – L929 MEM Elution Assay	The test article will meet the requirements of the test if it obtains a Grade of 0,1, or 2 (not more than 50% of the cells are round, devoid of intracytoplasmic granules, and no extensive cell lysis)	Acceptable
Sensitization – Kligman Maximization Assay	The test article will be considered a non-irritant if the difference between the test article mean score and the vehicle control mean score is 1.0 or less.	Acceptable
Irritation – Intracutaneous Injection Assay	The test article will meet the requirements of the test if it receives a Grade of 1, 0 or less using the Kligman scoring system.	Acceptable
Acute Systemic Toxicity – Systemic Injection	The test article will meet the requirements of the test if none of the animals injected with the test article show a significantly greater biological reaction than the animals treated with the control article.	Acceptable
Pyrogenicity – Material Mediated Rabbit Pyrogenicity	The test article will meet the requirements of the test if no rabbit shows an individual rise in temperature of 0.5ºC or more above the baseline temperature.	Acceptable
Hemolysis – Rabbit Blood Hemolysis Complete	The test article will meet the requirements of the test and is not considered to have hemolytic activity potential, if the hemolytic index above the negative control article and negative control article extract is <5%.	Acceptable

Performance Data

Non-clinical performance testing has been conducted in order to support that the proposed device performs as intended and the product conforms to user needs.

Test	Test Objective	Acceptance Criteria	Results
Needle Markings	To visually inspect the needle markings	Needles shall be permanently marked with black graduation at 10mm intervals starting from the tip of the needle. The visible needle markings shall be printed on the needle cannula per the drawing.	**Pass**
Ink Adherence	To validate the adherence of ink to the needle	Samples with an initial rating of 4 or 5 shall have an adherence score after the SCOTCH 610 tape test of 3 or greater. Samples with an initial rating of 3 shall have an adherence rating score after the SCOTCH 610 tape test of 3.	**Pass**
Continuity	To validate the continuity of electrical resistance	The electrical resistance of all measured samples shall be less than or equal to 10 Ohms (**Ω**)	**Pass**
Needle Current Density and Current Leakage	To validate the needle current density and current leakage	There shall be no insulation breakdown during the usage of the devices. Insulation breakdown is considered to have occurred when the current which flows because of the application of the test voltage rapidly increased in an uncontrolled manner, i.e. insulation does not restrict the flow of the current. Each needle will be required to withstand a voltage of 47V DC for 1 minute with less than 0.001 mA leakage current.	**Pass**
Resistance to Leakage	To validate the resistance to internal leakage	There shall be no internal leakage with an internal negative pressure of 25mmHg for 120 seconds (per EN1618:1997)	**Pass**
Tensile Strength – Needle Cannula to Needle Hub	To validate the tensile strength from needle cannula to needle hub	The force at break for each UUT of 21Ga size needles between hub and needle tube shall not exceed 44N (per ISO7864:1993)	**Pass**
Adherence of Insulation to the body of the needle	To determine the adherence of the insulator to the body of the	Each needle will be required to withstand a voltage of 47V DC for 1 minute less than 0.001mA leakage current before and after needle is exposed to beef.	**Pass**

	needle		
Kink Resistance for Fluid Extension Line	To establish the kink diameter of the fluid extension line	The kink diameter of the fluid extension line will be determined.	**Completed**

Conclusion

Based on the performance and comparative test results, the proposed StimuQuik Peripheral Nerve Block Needle is substantially equivalent to the predicate devices cleared to market in K014246. The modifications of the new insulator material do not introduce any different questions of safety and effectiveness.