K122690

510(k) Summary
Page 1 of 6
29-Nov-12

DEC 2 1 2012

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Proprietary or Trade Name: ARROW UltraQuik Peripheral Nerve Block Needle

Common/Usual Name: Peripheral Nerve Block

Classification Name: Product code – CAZ
CFR 868-5140 – anesthetic conduction kit
Class 2

Predicate Device: AVID-NIT (Arrow) – StimuQuik™ PNB Needle - K014246

Device Description:
The Arrow UltraQuik Peripheral Nerve Block (PNB) Needle is a single shot needle which is comprised of a cannula, hub, and fluid extension tube with female luer fitting. The single shot needles are available in various gauges, lengths, and point styles. These include:

- Gauge
  - 20 Ga (Touhy only)
  - 21 to 24 Ga
- Lengths
  - 35 mm to 150 mm
- Point style
  - Bevel tip
  - Pencil point
  - Touhy tip
- Cannula echogenicity
  - The cannula is naturally echogenic but the addition of grooves on the cannula enhance the echogenicity

The UltraQuik may be used with medical imaging, i.e., ultrasound to assist in needle tip location.

Basic Components for Peripheral Nerve Block needle

A typical basic Peripheral Nerve Block ("PNB") needle includes the following components.

- Cannula with sharp tip
- Hub
- Fluid extension line with female luer connector

Indications for Use:
The Arrow UltraQuik® Peripheral Nerve Block Needle is indicated for the delivery of single-shot peripheral nerve block anesthesia or analgesia using medical imaging devices.
Patient Population:
Patients requiring peripheral nerve block procedures.

Environment of Use:
The environment of use is – hospital, sub-acute facilities, pain clinics, 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.

Comparison to Predicates

The UltraQuik PNB Needle for single shot non-stimulating nerve block procedures is viewed as substantially equivalent to the predicate device because:

Indications –
The intended uses are identical and the indications for use are identical except for the non-stimulating feature. Use of a non-stimulating PNB needle is common and not a new procedure. Equivalent to predicate – K014246 – AVID-NIT StimuQuik PNB Needle.

Technology –
The components of the proposed UltraQuik PNB Needle are identical to the predicate K014246, AVID-NIT StimuQuik PNB Needle and there is no new technology or materials.

Materials –
The materials are identical to the predicate, K014246 – AVIV-NIT StimuQuik PNB Needle.

Environment of Use –
The proposed environments of use are identical to the predicate K014246 – AVID-NIT StimuQuik PNB Needle. They are – hospital, sub-acute facilities, pain clinics, and physician offices.

Patient Population –
Patients requiring peripheral nerve block procedures. Identical to the predicate, K014246 – AVID-NIT StimuQuik PNB Needle.

Non-clinical Testing Summary -

The components of the proposed device are identical to the predicate K014246, except the addition of echogenic grooves. We have performed bench testing after 5 year accelerated shelf-life. This testing included:

- Tensile strength for regions of the needle not intended for insertion into the body
- Injection tubing to needle hub
- Injection tubing to Luer Lock connector
- Tensile strength for the needle cannula to needle hub
- Needle sharpness
- Injection tubing leakage
- Resistance to leakage during aspiration or vacuum
- Corrosion resistance of metallic components
- Needle Stiffness
- Luer Lock connector

Summary of Test Results

Description	**Results**
Tensile Strength For regions not Inserted in body	Pass / fail criteria force to break is > 15 N Injection Tubing to needle hub – mean 27 N Injection Tubing to Luer Lock – mean 27 N
Tensile Strength Needle cannula to Hub joint	Pass / fail criteria force to break > 40 N All have a mean > 99 N
Needle Sharpness	Pass / fail criteria – none Penetration force – all have a mean >3.17 N
Injection leakage	Pass / fail criteria – no leak at 50 psi for 30 sec No leakage observed
Resistance to leakage	Pass / fail criteria – no internal leakage at – 25 mmHg for 120 sec No leakage observed
Corrosion Resistance	Pass / fail - no visible sign of corrosion No observed corrosion

Needle Stiffness	Pass / fail criteria – deflection < 0.5 mm Deflection – all have a mean < 0.5 mm
Needle Markings	Pass / fail – permanent markings at 10 mm Cannula are so marked
Component Capability	Pass / fail – usability testing Results were favorable

Imaging and Echogenic property evaluation:

Comparative ultrasound imagines were performed on the proposed design vs. the predicate. In addition a clinical preference survey was done with clinicians and all found the echogenic design to be easier to recognize.

Predicate Comparative Table

Features	Proposed UltraQuik PNB Needle	Predicates K014246 – AVID-NIT – StimuQuik PNB Needle
Classification name	Anesthetic Conduction Kit	Anesthetic Conduction Kit
Product Code	CAZ 868.5140	CAZ 868.5140
Intended Use	Single Shot nerve block anesthetic administration	Single Shot nerve block anesthetic administration
Indications for use	The Arrow UltraQuik® Peripheral Nerve Block Needle is indicated for the delivery of single-shot peripheral nerve block anesthesia or analgesia using medical imaging devices.	The AVID-NIT Nerve Stimulation Needles consist of an insulated hollow needles 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.
Environment of Use	Hospital, sub-acute facilities, pain clinics, physician offices	Hospital, sub-acute facilities, pain clinics, physician offices
Patient Population	Patients requiring peripheral nerve block procedures	Patients requiring peripheral nerve block procedures
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.	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.
Basic components	Non-insulated cannula with hub Fluid extension tube with luer lock fitting	Insulated cannula with insulated coating and hub Fluid extension tube with luer lock fitting Lead wire for connection to a nerve stimulator

Features	Proposed UltraQuik PNB Needle	Predicates K014246 – AVID-NIT – StimuQuik PNB Needle
Component Design and Specifications		
Cannula		
Gauges / dimensions	20 Ga for Touhy 21 – 24 Ga	21 – 24 Ga
Cannula length	35 – 150 mm	35 – 150 mm
Tip styles	Beveled Pencil point Touhy	Beveled Pencil point
Cannula	Smooth Grooved	Smooth
Cannula insulated	No, not required	Yes
Cannula markings	Yes	Yes
Fluid Extension Tube	with female luer lock fitting	with female luer lock fitting
Lead wire	No, this is not a feature of the proposed device	Yes for connection to nerve stimulator
Echogenic Properties	Yes	Yes
Provided Sterile	Yes	Yes
Shelf-life	5 years	5 years

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 21, 2012

Mr. Paul Amudala
Regulatory Affairs Specialist
Arrow International, Incorporated
2400 Bernville Road
READING PA 19605

Re: K122690
Trade/Device Name: UltraQuik Peripheral Nerve Block Needle
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: November 29, 2012
Received: December 3, 2012

Dear Mr. Amudala:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K122690

Device Name: **UltraQuik Peripheral Nerve Block Needle**

Indications for Use:

The Arrow UltraQuik® Peripheral Nerve Block Needle is indicated for the delivery of single-shot peripheral nerve block anesthesia or analgesia using medical imaging devices.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122690