510(k) Summary K121403
Page 1 of 6
07-May-2012

JUN 20 2012

Arrow International Inc.
2400 Bernville Road
Reading, PA 19605

Official Contact: Paul Amudala
Regulatory Affairs Specialist

Tel: 610-378-0131
Fax: 610-478-3179

Proprietary or Trade Name: Continuous Peripheral Nerve Block Catheter Kit and Set

Common/Usual Name: Peripheral Nerve Block

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

Predicate Devices: Arrow – StimuCath™ - K030937

Device Description:
The Arrow Continuous Peripheral Nerve Block Catheter set and kit is comprised of components and accessories which have already been cleared for the same indications for use under earlier 510(k)s.

This submission is intended to clarify that the catheter and the associated components and accessories, which we refer to as kits and sets, may be used for non-stimulating procedures. Many of the components and accessories of these kits and sets are already cleared for use in PNB stimulating procedures as well. It is the option of the clinician as to whether they would or would not use stimulation

A typical basic Peripheral Nerve Block ("PNB") set / kit includes the following components. The primary components of any PNB set or kit are:

- Catheter with stylet
- Anesthesia Conduction ("AC") Needle
- SnapLock™

Indications for Use:
Continuous nerve block kit and set permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques for periods not exceeding 72 hours.

510(k) Summary
Page 2 of 6
07-May-2012

Patient Population:
Patients requiring peripheral nerve block procedures including upper extremity, lower extremity, abdominal and paravertebral locations.

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 contraindications for use of continuous nerve or plexus blocks. These conditions should be considered prior to needle or catheter insertion. Skin sepsis in the area where the catheter placement is planned and systemic sepsis are relative contraindications. Extreme care should be taken in patients with bleeding tendencies or patients receiving anticoagulants.

Discussion of Substantial Equivalence

The use of the Continuous Peripheral Nerve Block catheter kit and set for non-stimulating procedures is viewed as substantially equivalent to the predicate device because:

Indications –
The proposed indications for use permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques for periods not exceeding 72 hours are identical to predicate – K030937 – StimuCath™.

The use of the proposed PNB catheter for non-stimulating procedures is not new and the use of ultrasound to assist the clinician in catheter tip location and guidance is a common practice. The clinician may use the predicate device StimuCath™ as a non-stimulating catheter simply by not connecting it to a stimulator.

The clarification for non-stimulating use by the clinician does not change the cleared indications for use and does not introduce any new safety or efficacy concerns as compared to the predicates.

Technology –
The components of the proposed device are identical to the predicates.

Materials –
The materials are identical to the predicates.

K030937 – Arrow – StimuCath™
K021567 – Arrow – StimuCath™
K001587 – Arrow – Plastic Reinforced Epidural Catheter

510(k) Summary
Page 3 of 6
07-May-2012

Environment of Use –
The proposed environments of use are identical to the predicate K030937. They are – hospital, sub-acute facilities, pain clinics, and physician offices.

Patient Population –
It is for patients requiring peripheral nerve block procedures including upper extremity, lower extremity, abdominal and paravertebral locations

The patient population is identical to the predicate, K030937 – Arrow StimuCath™.

Comparative Performance

The components are identical to the predicates and the proposed clarification of use for non-stimulating procedures does not change the safety or effectiveness of the device, thus no additional bench testing is required.

510(k) Summary
Page 4 of 6
07-May-2012

Substantial Equivalence Comparative Table

Features	Proposed PNB Catheter Kit / Set	Predicates K030937 – StimuCath™ Continuous Nerve Block Set
Classification name	Anesthetic Conduction Kit	Anesthetic Conduction Kit
Product Code	CAZ 868.5140	CAZ 868.5140
Indications for use	Permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques for periods not exceeding 72 hours	Permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques for periods not exceeding 72 hours (K030937)
Environment of Use	Hospital, sub-acute facilities, pain clinics, physician offices	Hospital, sub-acute facilities, pain clinics, physician offices (K030937)
Patient Population	Patients requiring peripheral nerve block procedures including upper extremity, lower extremity, abdominal and paravertebral locations.	Patients requiring peripheral nerve block procedures including upper extremity, lower extremity, abdominal and paravertebral locations. (K030937) The submission was silent on patient population but the intended patient population are identical
Contraindications	Pre-existing nerve injury, neuritis or plexitis are contraindications for use of continuous nerve or plexus blocks. These conditions should be considered prior to needle or catheter insertion. Skin sepsis in the area where the catheter 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 contraindications for use of continuous nerve or plexus blocks. These conditions should be considered prior to needle or catheter insertion. Skin sepsis in the area where the catheter placement is planned and systemic sepsis are relative contraindications. Extreme care should be taken in patients with bleeding tendencies or patients receiving anticoagulants.

510(k) Summary
Page 5 of 6
07-May-2012

Features	Proposed PNB Catheter Kit / Set	Predicates K030937 – StimuCath™ Continuous Nerve Block Set
Basic components	Catheter with stylet Anesthesia Conduction ("AC") Needle Snap Lock	Catheter with stylet Anesthesia Conduction ("AC") Needle Snap Lock Tunneler (K030937)
Kit / Set Components	Numerous accessories or components may be included in a kit or set. In all cases these have been cleared under previous 510(k) s A partial list of typical kit or set components are: Touhy Needle StatLock Drape SteriStrips Skin Prep Pad Skin Prep Swab Tegaderm Injection needles 18 G, 22 Ga, 25 Ga Syringe: 3mL, 10 mL, 20 mL SharpsAway II ChloraPrep Extension Tubing Marker Lidocaine with or without epinephrine Stopcock Gauze Towel Filters Filter Straw	Numerous accessories or components may be included in a kit or set. In all cases these have been cleared under previous 510(k) s A partial list of typical kit or set components are: Touhy Needle StatLock Drape SteriStrips Skin Prep Pad Skin Prep Swab Tegaderm Injection needles 18 G, 22 Ga, 25 Ga Syringe: 3mL, 10 mL, 20 mL SharpsAway II ChloraPrep Extension Tubing Marker Lidocaine with or without epinephrine Stopcock Gauze Towel Filters Filter Straw
Component Design and Specifications		
Catheter		
Effective length	30 cm to 90 cm	30 cm to 90 cm (K030937)
Catheter Gauge	19 Ga and 20 Ga	19 Ga and 20 Ga (K030937)
Catheter Body material	Stainless steel spring core encased in a polyurethane outer jacketing Catheter is echogenic with ultrasound-guided techniques	Stainless steel spring core encased in a polyurethane outer jacketing Catheter is echogenic (K030937)
Catheter Outer Jacket Color	White (19 Ga) and Blue (20 Ga)	White (19 Ga) and Blue (20 Ga) (K030937)
Printed along the length	Distal end printed with length markings to aid in depth determination	Distal end printed with length markings to aid in depth determination (K030937)
Exposed Length at Distal Tip	5 mm (19 Ga) and 6 mm (20Ga)	5 mm (19 Ga) and 6 mm (20Ga) (K030937)

510(k) Summary
Page 6 of 6
07-May-2012

Features	Proposed PNB Catheter Kit / Set	Predicates K030937 – StimuCath™ Continuous Nerve Block Set
Component Design and Specifications		
Stylet	Clip available if stimulating, but not required to be used, at election of clinician	Clip available if stimulating, but not required to be used, at election of clinician (K021567)
Anesthetic Conduction Needle		
Needle Length	38 mm to 152 mm	38 mm to 152 mm (K030937)
Needle Gauge	17 Ga and 18 Ga	17 Ga and 18 Ga (K030937)
Needle Geometry	5 mm (17 Ga) and 6 mm (18 Ga)	5 mm (17 Ga) and 6 mm (18 Ga) (K030937)
Exposed Length – Distal needle	5 mm (17 Ga) and 6 mm (18 Ga)	5 mm (17 Ga) and 6 mm (18 Ga) (K030937)
SnapLock™		
Non-stimulation connector	Connector for non-stimulating procedures	Connector for non-stimulating procedures (K001587)
Stimulation connector	Integral wire Connection Tab Use of these SnapLock connectors do not require connection to a stimulator, this is only if the clinician wants to	Integral wire (K030937) Connection Tab (K021567)
Materials		
	All materials in all components are identical to the predicates	K001587 K021567 K030937

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Paul Amudala
Regulatory Affairs Specialist
Teleflex Inc
2400 Bernville Road
Reading, Pennsylvania 19605

JUN 20 2012

Re: K121403
Trade/Device Name: Continuous Peripheral Nerve Block Catheter Kit and Set
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: May 7, 2012
Received: May 21, 2012

Dear Mr. Amudula:

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,

for

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

Enclosure

Indications for Use Statement

510(k) Number: K121403 (To be assigned)

Device Name: **Continuous Peripheral Nerve Block Catheter Kit and Set**

Indications for Use:

Continuous nerve block kit and set permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques for periods not exceeding 72 hours.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K121403