K122027

510(k) SUMMARY

AUG 28 2012

Submitter Information

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Date Prepared:	Aug 22, 2012

Device Name

Device Trade Name:	ARROW FlexBlock Continuous Peripheral Nerve Block Catheter
Common Name:	Peripheral Nerve Block Catheter
Classification Name:	Anesthesia Conduction Kit, CAZ, 21 CFR 868.5140; Anesthesia Conduction Catheter, BSO, 868.5120

Predicate Device

The primary predicate device is Arrow's FlexTip Plus Closed Tip Epidural (K103658). The Continuous Peripheral Nerve Block Catheter (K121403) is the reference predicate.

Device Description

The ARROW FlexBlock Continuous Peripheral Nerve Block Catheter has the following characteristics:

- 19 Ga., 30 to 90 cm with at minimum one flashback window to visualize fluids inside catheter
- Offered in open and closed tip configurations
- Internal radiopaque, echogenic coiled reinforced wire to visualize under Ultrasound
- Catheters are provided in sterile kit/set configurations or as a standalone replacement catheter

Indications for Use and Intended Use

The ARROW® FlexBlock™ Continuous Peripheral Nerve Block Kit/Set permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia

techniques including upper extremity, lower extremity, abdominal and paravertebral locations for periods not exceeding 72 hours.

Technological Characteristics and Substantial Equivalence

The ARROW FlexBlock Continuous Peripheral Nerve Block has the same intended use to deliver anesthesia as the primary predicate (K103658) and referenced predicate (K121403). The FlexBlock is offered in lengths of 30-90 cm with both an open and closed tip configuration. All catheters have internal radiopaque; echogenic coiled reinforced wire to visualize under Ultrasound. The proposed Arrow FlexBlock Continuous Peripheral Nerve Block catheter is a non-stimulating catheter that can be inserted through either a stimulating or non-stimulating needle based on physician preference.

Nonclinical Testing

The results of the performance testing, i.e. tensile strength, column strength and flow rate, demonstrate that the FlexBlock Continuous Peripheral Nerve Block Catheter is as safe, as effective and performs comparably to the primary predicate (K103658) and referenced predicate (K121403).

Pre-clinical evaluations have been conducted on the catheter and extracts thereof. No adverse effects were observed in any in vitro or in vivo study conducted. In accord with ISO 10993-18 recommendations, Extractable and Leachable (E&L) studies were performed using, Bupivacaine, Naropin, Polocaine, Hydromorphone, Morphine, Meperidine, and Fentanyl. The toxicity of the relevant leachable chemicals relating to these drugs was reviewed and addressed. In addition, a comparative chemical analysis study was conducted to assess potential differences in the E&L profile between devices that were EO sterilized after one cycle versus devices that were processed with two EO cycles. There were no appreciable qualitative differences in the extractable profiles for the one time vs. two time EO-sterilized devices. The FlexBlock could potentially be used with Chloroprocaine. This aqueous drug can be used with the FlexBlock catheter with no expected differences in extractability compared to the broad range of solutions and solvents used in the E&L studies conducted above.

The relevant patient contacting components meet the requirements of applicable ISO 10993 Guidelines. The available and relevant toxicological data for a surrogate leachable chemical was reviewed. There was no evidence of significant risk of acute toxicity under the proposed conditions and duration of clinical use.

Conclusions

The FlexBlock Continuous Peripheral Nerve Block Catheter and the predicate Closed Tip Epidural (K103658) and referenced predicate Continuous Peripheral Nerve Block catheter (K121403) have the same indications for use to deliver anesthetic in epidural and nerve block procedures. The results of laboratory testing demonstrate the ARROW FlexBlock Continuous Peripheral Nerve Block Catheter is as safe and effective as the legally marketed devices and therefore is considered substantially equivalent to the cited predicate devices.

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

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Re: K122027
Trade/Device Name: Arrow FlexBlock Continuous Peripheral Nerve Block Catheter
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: July 10, 2012
Received: July 11, 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,

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

510(k) Number (if known): K122027

Device Name: ARROW FlexBlock Continuous Peripheral Nerve Block Catheter

Indications for Use:

The ARROW FlexBlock Continuous Peripheral Nerve Block kit/set permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques including upper extremity, lower extremity, abdominal and paravertebral locations for periods not exceeding 72 Hours.

Intended Use:

The catheter is designed to deliver anesthesia to manage perioperative pain and /or alleviate postoperative analgesia.

Prescription Use ___ X ____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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