DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 21, 2016

Arrow International, Inc. (subsidiary of Teleflex Inc.)
Jim Cochie
Senior Regulatory Affairs Manager
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K153652
Trade/Device Name: ARROW® FlexBlock® Continuous Peripheral Nerve Block Kit/Set
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: Class II
Product Code: CAZ
Dated: May 13, 2016
Received: May 16, 2016

Dear Jim Cochie:

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.
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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)*
K153652

Device Name
ARROW® FlexBlock® Continuous Peripheral Nerve Block Catheter Kit/Set

Indications for Use *(Describe)*

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.

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)*

510(k) SUMMARY

Submitter Information

Name	ARROW International, Inc. (subsidiary of Teleflex Inc.)
Address	3015 Carrington Mill Blvd Morrisville, NC, 27560
Phone number	919-433-2703
Fax number	919-433-4996
Contact Person	Jim Cochie, Sr. Manager, Regulatory Affairs, Anesthesia, Teleflex, Inc. Date prepared December 17, 2015, revised June 14, 2016

Trade Name

ARROW® FlexBlock® Continuous Peripheral Nerve Block Catheter Kit/Set

Common/Usual Name

Anesthesia Conduction Kit

Classification

Regulation: 21 CFR 868.5140

Class: II

Product Code: CAZ – Anesthesia Conduction Kit

Predicate Device

ARROW FlexBlock Continuous Peripheral Nerve Block Catheter – K122027

Modification and Changes to Predicate

The purpose of this 510(k) is to update the MR Conditional statements in the Instructions for Use (IFU). The update is based on magnetic resonance testing performed by Shellock R&D Services and Exponent, Inc. The purpose of the update is to align the MR Conditional statements to the current best practices, and to respond to questions from the FDA on the possibility of induced heating and unintended stimulation (induced voltage) that were posed during the review of K140110.

The update to the MR Conditional statements in the IFU is the only modification. The device that is the subject of this submission is identical to it's predicate in all other respects, including the technological characteristics, materials, indications for use, and FDA classification.

Device Description

The Arrow® FlexBlock® Continuous Peripheral Nerve Block Catheter Kit/Set features a wire reinforced, polyurethane body with centimeter markings to facilitate placement for continuous plexus and peripheral nerve blocks. The catheter includes a SnapLock™ adapter to enable infusion of medications, and a stylet for enhanced maneuverability. Procedural trays also include a stimulating or non-stimulating plexus block needle, and other procedural components.

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.

Substantial Equivalence Comparison to Predicate

ARROW FlexBlock Continuous Peripheral Nerve Block Catheter Kit/Set was cleared under K122027. No changes have been made to the catheters or components since receiving clearance. Substantial equivalence between the devices subject of this submission and their respective predicate devices is based on the fact that they are identical in regards to technological characteristics, design, materials, indications for use, and FDA classification.

The only change for these devices is an update to the MR Conditional labeling. Table 1 provides a substantial equivalence comparison to the predicate.

Table 1 Substantial Equivalence Comparison to Predicate

Characteristic	Predicate	Proposed
Product Classification	II	No change
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.	No change
Technological Characteristics	The catheter features a wire reinforced, polyurethane body with centimeter markings.	No change
Materials	Inner coil = XM19 Stainless Steel Outer body = Polyurethane	No change

Substantial Equivalence Conclusion

The proposed update to the MR Conditional labeling establishes parameters for the use of these catheters in a magnetic resonance environment. It does not impact the substantial equivalence of ARROW FlexBlock Continuous Peripheral Nerve Block Catheter Kit/Set, and does not raise different questions of safety or effectiveness.

Non-Clinical Testing

Non-Clinical testing was conducted as the basis of the MR Conditional claims that are proposed in this 510(k). The testing is listed in Table 2 below. Summaries of the testing are provided as well. The test article in both cases was the 19 ga FlexBlock catheter.

Table 2 Non-Clinical Testing

Testing	Summary
MRI Testing, Shellock, 2011	Evaluation of magnetic field interactions at 3-Tesla; MRI-related heating at 1.5-Tesla and 3-Tesla; and MRI imaging artifacts at 3-Tesla. The evaluation concluded that the FlexBlock Catheter should be labeled as MR Conditional and included labeling guidelines in the report.
MRI Testing, Exponent, 2015	This study evaluated the MRI compatibility of the catheter in regards to radiofrequency (RF)-induced heating in 1.5 T and 3 T clinical scanners. The evaluation was conducted using methodologies prescribed in ASTM F2182 as a guide and modified for using a transmit/receive (TR) head coil. The evaluation concluded that the FlexBlock Catheter should be labeled as MR Conditional and included labeling guidelines in the report.

The conclusions drawn from the non-clinical tests inform the MRI labeling that is proposed in this 510(k), K153652. As there is no change to the catheter itself, we can conclude that the device is substantially equivalent to the predicate 510(k) K122027.