August 30, 2023

Kristen Bisanz
Regulatory Affairs Team Lead
3015 Carrington Mill Blvd.
Morrisville, North Carolina 27560

Re: K230603
Trade/Device Name: Arrow Non-Stimulating SnapLock Adapter (K-05520-005C); Arrow Non-Stimulating Next Gen SnapLock Adapter (Luer Connection) (CA-000010-19); Arrow Non-Stimulating Next Gen SnapLock Adapter (Neuraxial Connection) (CA-000014-19); Arrow Stimulating SnapLock Adapter (with cable) (TZ-02060-001); Arrow Stimulating SnapLock Adapter (with tab) (TZ-05000-002)
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: Class II
Product Code: CAZ, BSO
Dated: July 27, 2023
Received: August 1, 2023

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230603

Device Name
Arrow Non-Stimulating SnapLock Adapter (K-05520-005C); Arrow Non-Stimulating Next Gen SnapLock Adapter (Luer Connection) (CA-000010-19); Arrow Non-Stimulating Next Gen SnapLock Adapter (Neuraxial Connection) (CA-000014-19); Arrow Stimulating SnapLock Adapter (with cable) (TZ-02060-001); Arrow Stimulating SnapLock Adapter (with tab) (TZ-05000-002)

Indications for Use *(Describe)*

SnapLock Catheter/Syringe Adapter is intended to be used in conjunction with 19 and 20 Ga. Arrow Pain Management Catheters to facilitate access to the catheter so that an infusion device may be used. Please refer to applicable Arrow Pain Manager Catheter IFU for complete catheter instructions for use.

The Arrow Epidural Catheter permits access to the epidural space for the administration of epidural anesthetic. The epidural catheter is intended for use up to 72 hours.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
Arrow SnapLock Catheter Adapter
K230603

Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
3015 Carrington Mill Blvd
Morrisville, NC 27560 USA
Phone: 404.290.9807
Fax: 919.433.4996

Contact Person

Kristen Bisanz
Kristen.bisanz@teleflex.com
Regulatory Affairs Team Lead

Date Prepared

August 14, 2023

Device Name

Trade Name:	Arrow SnapLock Catheter Adapter
Classification Name:	Anesthesia Conduction Kit
Product Code:	CAZ, BSO
Regulation Number:	868.5140
Classification:	II
Classification Panel:	Anesthesiology

Device Models

K-05520-005C Arrow Non-Stimulating SnapLock Adapter
CA-000010-19 Arrow Non-Stimulating Next Gen SnapLock Adapter (Luer Connection)
CA-000014-19 Arrow Non-Stimulating Next Gen SnapLock Adapter (Neuraxial Connection)
TZ-02060-001 Arrow Stimulating SnapLock Adapter (with cable)
TZ-05000-002 Arrow Stimulating SnapLock Adapter (with tab)

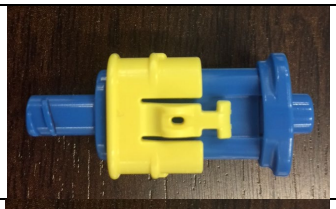
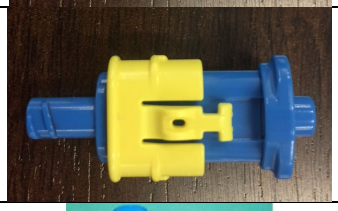
Predicate Device

The primary predicate device for this submission was cleared in K103658 on May 16, 2012. The reference predicate device for this submission was cleared in K1220247 on Aug 28, 2012.

Device Description

The Arrow SnapLock Catheter Adapter serves as the connecting link between the anesthesia catheter and an infusion device. The adapters facilitate delivery of the desired substance through the adapter-catheter system, into the patient.

Arrow markets two versions of the SnapLock Adapter. The non-stimulating version is used with epidural and peripheral nerve block catheters and the stimulating version includes an integral electrical connector or tab for use with stimulating Peripheral Nerve Block catheters. Both versions of the adapters are included as accessories in their respective kits. The non-stimulating version is also available separately as a replacement component.

Product Code	Product Code Description	Representative Photo	Description
K-05520-005C	Arrow Non-Stimulating SnapLock Adapter		The non-Stimulating SnapLock contains no elecrical connectors and is used with epidural and peripheral nerve block catheters.
CA-000010-19	Arrow Next Generation Non-Stimulating SnapLock Adapter (Luer Adapter)		The Next Generation SnapLock features a snap-of-center style closing mechanism.
CA-000014-19	Arrow Next Generation Non-Stimulating SnapLock Adapter (Neuraxial Adapter)		
TZ-02060-001	Arrow Stimulating SnapLock Adapter (with cable)		The Simulating SnapLock is designed for use with the StimuCath Peripheral Nerve Block Catheter. An electrical current can be conducted through the connector.
TZ-05000-002	Arrow Stimulating SnapLock Adapter (with electrical connector tab)		

Indications for Use

SnapLock Catheter/Syringe Adapter is intended to be used in conjunction with 19 and 20 Ga. Arrow Pain Management Catheters to facilitate access to the catheter so that an infusion device may be used. Please refer to applicable Arrow Pain Management Catheter IFU for complete catheter instructions for use.

The Arrow Epidural Catheter permits access to the epidural space for the administration of epidural anesthetic. The epidural catheter is intended for use up to 72 hours.

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.

Patient Population

This device is for adult patients requiring administration of local anesthetics for up to 72 hours.

Environment of use

The device is to be used in a hospital and sub-acute facility environment as directed by a physician.

Contraindications

There are no known contraindications for this device.

Substantial Equivalence

The proposed device is substantially equivalent to the predicate device:

Predicate Device	Manufacturer	510(k) Number	Date Cleared
SnapLock Adapter (component of FlexTip Plus Epidural Catheter Kit)	Arrow	K103658	May 3, 2012
Reference Device : SnapLock Adapter (component of StimuCath PNB Catheter Kit)	Arrow	K122027	Aug 28, 2012

Comparison to Predicate Device

The proposed device has similar or equivalent indications for use, operating principles, classification, sterilization and general design as the predicate device. Biocompatibility testing and performance testing has been performed on the proposed device in order to establish substantial equivalence to the predicate device. The proposed changes discussed above do not impact the safety or effectiveness of the SnapLock Catheter Adapter. The subject device is therefore substantially equivalent to the predicate device identified within this submission.

	Primary Predicate K103658 SnapLock Adapter (component of FlexTip Plus Epidural Catheter Kit)	**Reference Predicate K122027 SnapLock Adapter (component of FlexBlock Peripheral Nerve Block Kit)**	**Proposed SnapLock Catheter Adapter**	**Equivalence**
Classification Name	Anesthesia Conduction Kit and Catheter, Conduction, Anesthetic	Anesthesia Conduction Kit and Catheter, Conduction, Anesthetic	Anesthesia Conduction Kit	Identical
Device Name	SnapLock Adapter (component of FlexTip Plus Epidural Catheter Kit)	SnapLock Adapter (component of FlexBlock Peripheral Nerve Block Kit)	Arrow SnapLock Catheter Adapter	Identical
Common Name	Catheter Adapter	Catheter Adapter	Catheter Adapter	Identical
Product Code	73CAZ (primary) and 73BSO (secondary)	73CAZ (primary) and 73BSO (secondary)	73CAZ (primary)	Identical
Classification	Class II	Class II	Class II	Identical
Regulation Number	868.5140	868.5140	868.5140	Identical
Indications for Use	The Arrow Epidural Catheter permits access to the epidural space for the administration of epidural anesthetic. The epidural catheter is intended for use up to 72 hours.	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	SnapLock Catheter/Syringe Adapter is intended to be used in conjunction with 19 and 20 Ga. Arrow Pain Management Catheters to facilitate access to the catheter so that an infusion device may be used. Please refer to applicable Arrow Pain Manager Catheter	Identical

		extremity, lower extremity, abdominal and paravertebral locations of the adult and pediatric patient for periods not exceeding 72 hours.	IFU for complete catheter instructions for use. The Arrow Epidural Catheter permits access to the epidural space for the administration of epidural anesthetic. The epidural catheter is intended for use up to 72 hours.	
Prescription	Yes	Yes	Yes	Identical
Environment of Use	Hospitals, Sub-acute facilities, and emergency medical services	Hospitals, Sub-acute facilities, and emergency medical services	The device is to be used in a hospital and sub-acute facility environment as directed by a physician.	Identical
Patient Population	Patients requiring administration of local anesthetics for up to 72 hours	Patients requiring administration of local anesthetics for up to 72 hours	Patients requiring administration of local anesthetics for up to 72 hours	Identical
Contraindications	None for stand-alone SnapLock	None for stand-alone SnapLock	None for stand-alone SnapLock	Identical
Shelf Life	Two (2) years from date of manufacture	Two (2) years from date of manufacture	Two (2) years from date of manufacture	Identical
Tensile Strength	The joint tensile force between the SnapLock Adapter and catheter shall be 5N or greater, when tested in accordance with BS 6196	The joint tensile force between the SnapLock Adapter and catheter shall be 5N or greater, when tested in accordance with BS 6196	The joint tensile force between the SnapLock Adapter and catheter shall be 5N or greater when tested in accordance with BS 6196	Identical
Flow Rate	The SnapLock shall have a minimum flow rate of 10cc water per minute at 30psi.	The SnapLock shall have a minimum flow rate of 10cc water per minute at 30psi.	The catheter flow capacity shall be higher than 60mL/hour when tested by distilled water under pressure of 10psi	**Equivalent, see substantial equivalence section**
Leakage	There shall be no evidence of water leakage on the SnapLock surface	There shall be no evidence of water leakage on the	Shall not have a leak sufficient to form a falling drop	**Equivalent, see substantial equivalence**

	when subjected to 15psi water for 30 seconds.	SnapLock surface when subjected to 15psi water for 30 seconds.	when pressurized to 25psi (172 kPa) for 30 seconds	**section**
Sterilization	The sterility assurance level of the device is 10^{-6}.	The sterility assurance level of the device is 10^{-6}.	The sterility assurance level of the device is 10^{-6}.	Identical
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Per ISO 10993-1	Identical
Pyrogenicity	Non-Pyrogenic	Non-Pyrogenic	Non-Pyrogenic	Identical
Materials	Polycarbonate, Resin, Delrin, Polyethylene	Polycarbonate, Resin, Delrin, Polyethylene	Polycarbonate, Resin, Delrin, Polyethylene	**Equivalent, see substantial equivalence section**

Substantial Equivalence Discussion:

Flow Rate: The flow rate for the proposed SnapLock reflects an updated acceptance criteria which more accurately reflects what is seen in the clinical setting. Additional details and testing are included in the Performance Testing section. Due to the updated testing and clinical rationale, the acceptance criteria for the flow rate is equivalent to the predicate acceptance criteria.

Leakage: The acceptance criteria for the proposed SnapLock Adapter leakage test is more stringent than the predicate. The leakage tests the maximum duration usage of the SnapLock to ensure leakage will not occur. Due to this, the acceptance criteria for the leakage test is equivalent to the predicate acceptance criteria.

Materials: The proposed SnapLock Adapter contains a new resin for the extrusion tubing. Additionally, the Next Gen SnapLock Adapter contains an updated design of the slider as compared to the predicate. The slider helps to secure the catheter tightly and prevent disconnection during use. Comprehensive functional testing has been successfully completed on the SnapLock Adapter. The functional testing proves the proposed device meets the standard requirements and performs as well as the predicate device. Biocompatibility testing has been performed on the final finished proposed device. The materials tested all met the ISO 10993 requirements. There is no difference between the subject and predicate with respect to indications for use or technology

Materials and Biocompatibility Testing

All patient contacting materials, including those with indirect patient contact, are in compliance with ISO 10993-1. The SnapLock device is classified as an external communicating device with tissue/bone/dentin contact for a prolong duration.

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 Test	The test article will meet the requirements of the test if it does not induce a significantly greater biological reaction than the control.	Acceptable
Acute Systemic Toxicity – Material Mediated Test	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
Hemocompatibility – Rabbit Blood Hemolysis (Complete) ASTM Test	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
Genotoxicity – Mouse Lymphoma Mutagenesis Assay	The test article will meet the requirements of the test and will be considered non-mutagenic if its IMF is less than the Global Evaluation Factor (GEF) 128 X 10^{-6}.	Acceptable
Genotoxicity – *Salmonella Typhimurium* and *Escherichia Coli* Reverse Mutation Assay with Confirmation – ISO	The test article will be considered to have a positive response in the assay if at least one strain exhibits a reproducible and statistically significant increase ($p<0.05$) an a two -fold (for TA98, TA100, and WP2 strains) or three-fold (for TA1535 and TA1537 strains) increase in the numbers of mutants over its concurrent negative control.	Acceptable
Subacute Systemic Toxicity -	Overall, if animals treated with the test article show a similar biological reactivity, as determined by clinical observations, body weights, morbidity and moribundity, and gross and histopathical evaluation, to the animals tested with the control article, the test article meets the requirements of the test.	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.
All samples passed the established acceptance criteria. The results concluded that the SnapLock Adapter has successfully passed all functional requirements to establish product safety and effectiveness for its intended use.

Test	Acceptance Criteria	Result
Closing Force – SnapLock Adapter to Catheter body	The SnapLock Adapter, when used with a 19Ga or 20Ga catheter, shall require no greater than 17lb force (75N) to close. Next Gen SnapLock Only: The SnapLock Adapter, when used with a 19Ga or 20Ga catheter, shall require no greater than 12lb force (53.8N) to close.	Pass
Opening Force – SnapLock Adapter to Catheter Body	It shall not be possible to open the SnapLock adapter without causing the retaining tab to fail while in the closed position. A minimum 10lb force (44.48N) is required to cause the retaining tab to fail.	Pass
Component Compatibility/ Interaction	The SnapLock Adapter shall allow easy insertion of mating catheter.	Pass
Tensile Force – SnapLock Adapter to Catheter Body	The joint tensile force between the SnapLock Adapter and catheter shall be $\geq$ 5N (1.12lbf) at failure.	Pass
Leakage – SnapLock adapter to catheter body	The SnapLock Adapter to catheter body joint shall not leak when pressurized to 25 psi (172 kPa) for 30 seconds in a closed system.	Pass
Occlusion – SnapLock Adapter to Catheter Body	The SnapLock Adapter locked into a mating position shall not occlude the catheter.	Pass
Spontaneous Partial Opening Test	The SnapLock Adapter, when closed must remain closed, with the retaining tab in place for 72 hours after full closure of the adapter over a mating catheter.	Pass
Flow Rate – Continuous Flow SnapLock	When the SnapLock Adapter is locked over a mating catheter, the catheter flow capacity shall be at minimum 60mL/hour (1mL/min) when tested by deionized or distilled water under 69 kPa (10psi)	Pass

Flow Rate – Single Shot or Bolus	When the SnapLock Adapter is locked over a mating catheter (19 or 20Ga), the catheter single shot or bolus shall be at minimum 3.47 mL/min when tested with a 20mL syringe using deionized or distilled water.	Pass
Aspiration	When deionized or distilled water is drawn through the SnapLock Adapter as it is locked over a mating catheter and connected to a 20mL syringe, fluid presence shall be visually verified.	Pass
Leakage, Maximum Duration at Continuous Pressure	In an occluded set-up, the SnapLock Adapter shall not leak over 72 hours when the continuous pressure is 1 psi.	Pass
Weld Force	A minimum 20lb force (88.96N) shall be required to cause weld joint between the catheter insertion component and the female housing to fail.	Pass
Conical Fittings	For luer version: The threaded and tapered portions of the SnapLock Adapter housing shall comply with the applicable sections of BS 6196 For neuraxial version: The threaded and tapered portions of the SnapLock Adapter shall meet the requirements of AAMI/CN6:2016 (ISO 80369-6)	Pass

Conclusion

Based on the performance and comparative test results, the proposed Arrow SnapLock Catheter Adapter is substantially equivalent to the predicate device cleared to market in K103658. The modifications made to the SnapLock Adapter do not introduce any new issues of safety and effectiveness.