August 31, 2022

Arrow International, LLC (a subsidiary of Teleflex, Inc.)
Fallon Young
Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K220280
Trade/Device Name: Arrow Stiffening Stylet
Regulation Number: 21 CFR 870.1380
Regulation Name: Catheter Stylet
Regulatory Class: Class II
Product Code: DRB
Dated: July 25, 2022
Received: July 28, 2022

Dear Fallon Young:

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,

for Hetal Odobasic
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular 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)*

K220280

Device Name

Arrow Stiffening Stylet

Indications for Use *(Describe)*

The Arrow Stiffening Stylet is intended to be placed inside a catheter to stiffen the catheter for placement.

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.

510(k) SUMMARY

(as required by the Safe Medical Devices Act of 1990 and in accordance with 21 CFR 807.92)

Arrow Stiffening Stylet

1. Applicant Information:

Name:	Arrow International LLC (subsidiary of Teleflex Incorporated)
Address:	3015 Carrington Mill Blvd Morrisville, NC 27560 USA
Contact Person:	Fallon Young
Email:	fallon.young@teleflex.com
Telephone Number:	(610) 984-7188
Fax Number:	(610) 478-3128
Date Prepared:	August 30, 2022

2. Device Name:

- Trade/Proprietary Name: Arrow Stiffening Stylet
- Classification Name: Catheter, Stylet
- CFR Number: 21 CFR 870.1380
- Device Class: II
- Product Code: DRB

3. Predicate Device(s):

- K182660: Galt Medical Corp's GaltTWS Stylet

4. Description of Device:

The Arrow Stiffening Stylet is a sterile, single use, percutaneous peripheral vasculature catheter stylet intended for transient use (up to 24 hours) to be placed within a catheter to render it stiff to aid in catheter placement. The proposed device will be delivered as a sterile accessory within a convenience kit for the Arrow Peripherally Inserted Central Catheter (PICC)s. The Stylet is a PTFE coated solid nitinol core wire with straight tip. The stylet is available in 0.015-0.017-inch diameters and in 29.5-inch length with distance markings along the stylet body.

The Arrow Stiffening Stylet is provided with an existing, commercially available flushable hub with side arm and slide clamp cleared under K790408. The flushable hub maintains the stylet position within the catheter during catheter placement, is intended to minimize blood loss during catheter introduction, and allows the clinician to flush through the catheter to aid in catheter placement, if needed. There is no change to the flushable hub cleared under K790408 introduced by this submission.

5. Indications for Use:

The Arrow Stiffening Stylet is intended to be placed inside a catheter to stiffen the catheter for placement.

6. Substantial Equivalence

Intended Use / Indications for Use:
The intended use of the subject Arrow Stiffening Stylet is equivalent to the intended use of the predicate stylet. The subject and predicate devices are both intended to be placed within a catheter to stiffen the catheter for placement.

The indications for use of the Arrow Stiffening Stylet and the predicate stylet include the placement within a percutaneous catheter to stiffen the device for placement. The indications for use of the subject Arrow Stiffening Stylet are equivalent to the indications for use of the predicate stylet.

Technological Characteristics:
The subject Arrow Stiffening Stylet incorporates the same fundamental technology as the predicate stylet. The subject Arrow Stiffening Stylet and the predicate stylet are both metal body stylets of similar configurations with a flushable hub.

Table 2 summarizes the substantial equivalence comparison of the subject Arrow Stiffening Stylet with the predicate stylet.

Table 2 – Substantial Equivalence Comparison Summary

	Proposed Device Arrow Stiffening Stylet	**Predicate Device – K182660** GaltTWS Stylet
Indications for Use	The Arrow Stiffening Stylet is intended to be placed inside a catheter to stiffen the catheter for placement.	The GaltTWS Stylet is a percutaneous catheter stylet placed inside a catheter, lead, or cannula to stiffen the device for placement.
Device Design Feature		
Design	A solid nitinol wire	A stainless steel twisted/braided wire
Accessories	Existing, commercially available flushable hub with side arm (K790408)	Existing, commercially available flushable hub with side arm
Tip Type	Straight on both ends	Straight on both ends
Coating	PTFE	N/A
Core Material	Nitinol	Stainless Steel
Coil Material	N/A - no coil	N/A - no coil
Distal Atraumatic Tip	Yes	Yes
Diameter	Diameter: 0.015-0.017 inch (0.39 mm-0.44 mm)	Diameter: 0.012-0.015 inch (0.30 mm-0.39 mm)
Length	Length: 29.5 inch (75 cm)	Length: 30-72 inches (76 cm-182 cm)
Depth Control	Distance markings every 5 cm starting at 20 cm from distal end of stylet	No distance markings
Sterilization		
Sterility	Ethylene Oxide	Ethylene Oxide
Biocompatibility		
Biocompatibility	Biocompatible materials used (per ISO 10993-1)	Biocompatible materials used (per ISO 10993-1)

7. Non-Clinical Performance Data.

The technological differences between the subject Arrow Stiffening Stylet and the predicate stylet have been evaluated through verification testing. The testing conducted that supports substantial equivalence of the subject Arrow Stiffening Stylet is listed below.

Testing Included:

- Mechanical/Physical testing in accordance with ISO 11070, Guidance

Documents, and Arrow International Internal Requirements:

- Surface: Extraneous Matter and Defects
- Corrosion Resistance
- Radio-detectability
- Guide wire Fracture
- Guide wire Flexure
- Guide wire Tensile
- Retainer Leak (Flushable Hub Interface)
- Retainer Grip (Flushable Hub Interface)
- Coating Integrity
- Particulate
- Torque Test
- Stiffness
- Removal Force from Catheter

- Human Factors/Usability Testing

- Biocompatibility testing in accordance with ISO 10993-1:
  - Cytotoxicity (MEM Elution)
  - Sensitization Kligman Maximization Test (polar and non-polar extracts)
  - Intracutaneous Injection (polar and non-polar extracts)
  - Acute Systemic Toxicity (polar and non-polar extracts)
  - Materials Mediated Pyrogenicity
  - Hemolysis (direct and indirect contact)

- The Arrow Stiffening Stylet will be packaged as a convenience kit component with Arrow Peripherally Inserted Central Catheter (PICC) products. There are no changes to the packaging introduced by this submission.

8. Clinical Performance Data.

No human clinical data was required to support substantial equivalence.

9. Conclusion Regarding Substantial Equivalence

The information included in this premarket notification supports the substantial equivalence of the subject Arrow Stiffening Stylet to the

predicate stylet. The subject device has a substantially equivalent intended use, indications for use, and incorporates the same fundamental technology as the legally marketed predicate device to which it is compared.

Performance, human factors/usability, and biocompatibility testing has been conducted and has passed all acceptance criteria to verify that the proposed Arrow Stiffening Stylet meets its design, physical integrity, functional, and safety requirements and that any dimensional or material differences between it and the predicate stylet do not raise new issues of safety and effectiveness. The results of the testing included in this premarket notification support a determination of substantial equivalence.