510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

1. Submitter Information

Name:	Arrow International, Inc. (subsidiary of Teleflex, Inc.)
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Contact Person:	Frank Pelc Regulatory Affairs/Quality Engineering Manager
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Email:	frank.pelc@teleflex.com

Date Prepared: April 22, 2014

2. Device Name

Device Trade Name: VectorFlow Antegrade Chronic Hemodialysis Catheter
VectorFlow Retrograde Chronic Hemodialysis Catheter
VectorFlow Retrograde Replacement Hub Set

Common Name: Chronic Hemodialysis Catheter
Catheter Repair Kit (Hub Set only)

Classification Name: Catheter, Hemodialysis, Implanted
Kit, Repair, Catheter, Hemodialysis (Hub Set only)

3. Predicate Devices

Predicate 1: Arrow NextStep Antegrade Chronic Hemodialysis Catheter (K111900)

Predicate 2: Arrow NextStep Retrograde Chronic Hemodialysis Catheter (K130192)

Predicate 3: Arrow NextStep Retrograde Replacement Hub Set (K020430)

4. Device Description

The Arrow VectorFlow Antegrade Chronic Hemodialysis Catheter (herein referred to as the proposed VFA catheter) and the Arrow VectorFlow Retrograde Chronic Hemodialysis Catheter (herein referred to as the proposed VFR catheter) are long-term, single use catheters designed to provide access to the central venous system in a healthcare facility environment. The VFA catheter is a one piece catheter, two lumen, 15 French symmetrical-tipped catheter designed for antegrade placement. The VFR catheter is two-piece, two-lumen, 15 Fr, symmetrical tipped catheter designed for retrograde placement. The VFA and VFR catheters are available in multiple lengths. The Arrow VectorFlow Retrograde Replacement Hub Set (herein referred to as the proposed Hub

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 7, 2014

Arrow International, Inc.
Frank Pelc
Regulatory Affairs/Quality Engineering Manager
2400 Bernville Road
Reading, PA 19605

Re: K141051
Trade/Device Name: Arrow VectorFlow™ Antegrade Chronic Hemodialysis Catheter
Arrow VectorFlow™ Retrograde Chronic Hemodialysis Catheter
Arrow VectorFlow™ Retrograde Replacement Hub Set
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD, NFK
Dated: June 5, 2014
Received: June 9, 2014

Dear Frank Pelc,

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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. 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K141051

Device Name: Arrow VectorFlow™ Retrograde Chronic Hemodialysis Catheter

Arrow VectorFlow™ Retrograde Replacement Hub Set

Indications for Use:

The Arrow VectorFlow Retrograde Chronic Hemodialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. The Arrow VectorFlow Retrograde Chronic Hemodialysis Catheter is inserted percutaneously and is preferentially placed into the internal jugular (IJ) vein. Alternately, this catheter may be inserted into the subclavian vein although the jugular vein is the preferred site. Catheters greater than 40 cm are intended for femoral vein insertion. The Arrow VectorFlow catheter is intended for use in adult patients.

The Arrow VectorFlow Retrograde Replacement Hub Set is indicated for use in the replacement of a Arrow VectorFlow Retrograde hub connection assembly that has been damaged.

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

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Concurrence of CDRH (Signature)

Benjamin R. Fisher -S
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Indications for Use

510(k) Number (if known): K141051

Device Name: Arrow VectorFlow™ Antegrade Chronic Hemodialysis Catheter

Indications for Use:

The Arrow VectorFlow Antegrade Chronic Hemodialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. The Arrow VectorFlow Antegrade Chronic Hemodialysis Catheter is inserted percutaneously and is preferentially placed into the internal jugular (IJ) vein. Alternately, this catheter may be inserted into the subclavian vein although the jugular vein is the preferred site. Catheters greater than 40 cm are intended for femoral vein insertion. The Arrow VectorFlow catheter is intended for use in adult patients.

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

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Concurrence of CDRH (Signature)

Benjamin R. Fisher -S
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Set) is sold separately to perform a repair of the VFR, replacing cracked or broken luer connectors, clamps, and/or damaged extension lines.

The VFA and VFR catheters and Hub Set will be packaged sterile with various components to facilitate insertion.

5. Indications for Use

The Arrow VectorFlow Antegrade Chronic Hemodialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. The Arrow VectorFlow Antegrade Chronic Hemodialysis Catheter is inserted percutaneously and is preferentially placed into the internal jugular (IJ) vein. Alternately, this catheter may be inserted into the subclavian vein although the jugular vein is the preferred site. Catheters greater than 40 cm are intended for femoral vein insertion. The Arrow VectorFlow Antegrade Chronic Hemodialysis Catheter is intended for use in adult patients.

The Arrow VectorFlow Retrograde Chronic Hemodialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. The Arrow VectorFlow Retrograde Chronic Hemodialysis Catheter is inserted percutaneously and is preferentially placed into the internal jugular (IJ) vein. Alternately, this catheter may be inserted into the subclavian vein although the jugular vein is the preferred site. Catheters greater than 40 cm are intended for femoral vein insertion. The Arrow VectorFlow Retrograde Chronic Hemodialysis Catheter is intended for use in adult patients.

The Arrow VectorFlow Retrograde Replacement Hub Set is indicated for use in the replacement of a Arrow VectorFlow Retrograde hub connection assembly that has been damaged.

6. Technological Characteristics and Substantial Equivalence

The Arrow VectorFlow Antegrade Chronic Hemodialysis Catheter is substantially equivalent to the Arrow NextStep Antegrade Chronic Hemodialysis Catheter (K111900) and the Arrow VectorFlow Retrograde Chronic Hemodialysis Catheter is substantially equivalent to the Arrow NextStep Retrograde Chronic Hemodialysis Catheter (K130192) in terms of overall design, manufacturing process, functional performance, and materials of construction. The proposed Arrow VectorFlow Retrograde Replacement Hub Set is substantially equivalent to the Arrow NextStep Retrograde Replacement Hub Set (K020430) in terms of overall design, manufacturing process, functional performance, and materials of construction.

The indications for use for the proposed VFA and VFR catheters are identical to the Arrow NextStep Antegrade Chronic Hemodialysis Catheter and Arrow NextStep Retrograde Chronic Hemodialysis Catheter. The intended use of the product and the principle of operation of the devices are unchanged. The indications for use for the proposed Hub Set are identical to the Arrow NextStep Retrograde Replacement Hub Set.

7. Nonclinical Testing

Bench testing was performed to demonstrate substantial equivalence between the predicate and proposed devices. Dialysis flow rate, mechanical hemolysis, and additional testing that is needed to comply with *Draft Guidance for Industry and Food and Drug Administration Staff- Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis* and *FDA Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters* was performed. Performance and material testing was completed on the proposed devices in accordance with ISO 10555-1, 10555-3, and ISO 10993-1.

8. Clinical Data

Clinical performance data was not used to determine substantial equivalence.

9. Conclusions

The results of the testing performed have demonstrated that the proposed Arrow VectorFlow Antegrade Chronic Hemodialysis Catheter, the Arrow VectorFlow Retrograde Chronic Hemodialysis Catheter and the Arrow VectorFlow Retrograde Replacement Hub Set are safe and perform as intended and therefore are considered substantially equivalent to the cited predicate devices.

Appendix G

Class III Certification and Summary