



Food and Drug Administration
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July 24, 2015

Arrow International, Inc. (Subsidiary of Teleflex Inc.)
% Karl J Nittinger
Sr. Regulatory Affairs Specialist, Interventional Access
2400 Bernville Road
P.O. Box 12888
Reading, PA 19605

Re: K143102
Trade/Device Name: Multi-lumen Acute Hemodialysis Catheter for High Volume
Infusions
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: NIE
Dated: June 10, 2015
Received: June 15, 2015

Dear Karl J Nittinger,

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/tray. 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 and Part 809); 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.

In addition, we have determined that your device kit contains antiseptic hand gels, chloraprep-orange, lidocaine, and providone iodine swabsticks, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), 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,

Herbert P. Lerner -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K143102

Device Name

Multi-Lumen Acute Hemodialysis Catheter for High Volume Infusions

Indications for Use (Describe)

The device is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, apheresis, rapid fluid administration, intravenous therapy, blood sampling, pressure injection of contrast media, and central venous pressure monitoring. The catheter may also be used in a variety of renal replacement therapies, such as hemofiltration and hemoperfusion. The catheter may be inserted into the jugular, subclavian, or femoral veins. The maximum pressure injection flow rate is 6 mL / sec.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
Multi-Lumen Acute Hemodialysis Catheter for
High Volume Infusions

1. Submitter Information

Name: Arrow International, Inc (subsidiary of Teleflex Inc.)
Address: 2400 Bernville Road
Reading, PA 19605-9607

Contact Person: Karl J. Nittinger
Sr. Regulatory Affairs Specialist
Telephone Number: (610) 378-0131, ext. 603384
Email: karl.nittinger@teleflex.com

Date Prepared: July 23, 2015

2. Device Name

Device Trade Name: Multi-Lumen Acute Hemodialysis Catheter for High Volume Infusions

Common Name: Acute Hemodialysis Catheter

Classification Name: Catheter, Hemodialysis, Triple-Lumen, Non-Implanted

3. Predicate Devices

Predicate 1: 12 Fr. and 14 Fr. Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip® ARROWg+ard Blue® Antimicrobial Catheter for High Volume Infusions (K993933)

Predicate 2: Bard Power-Trialysis™ Short Term Dialysis Catheter (K083675)

Predicate 3: Medcomp Tri-Flow® Triple Lumen Short Term Hemodialysis Catheter (K973561)

4. Device Description

The Multi-Lumen Acute Hemodialysis Catheter for High Volume (hereafter referred to as the 3-L AHDC) is a short-term, single use catheter designed to provide access to the central venous system in a healthcare facility environment. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a softer, contoured Blue Flex Tip. The catheter is available in a 12 Fr. triple-lumen configuration with usable lengths of 16-25 cm. The catheters can be used for the injection of contrast media. The maximum recommended pressure injection flow rate is 6 mL/sec.

The catheters are packaged sterile with various components to facilitate insertion.

5. Indications for Use

The device is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, apheresis, rapid fluid administration, intravenous therapy, blood sampling, pressure injection of contrast media, and central venous pressure monitoring. The catheter may also be used in a variety of renal replacement therapies, such as hemofiltration and hemoperfusion. The catheter may be inserted into the jugular, subclavian, or femoral veins. The maximum pressure injection flow rate is 6 mL / sec.

6. Technological Characteristics and Substantial Equivalence

The 3-L AHDC is substantially equivalent to the Arrow Acute Hemodialysis AGB Catheters (K993933) and the Bard Power-Trialysis Short Term Dialysis Catheter (K083675) in terms of overall design, manufacturing process, functional performance, materials of construction, and indications for use. The proposed catheter is also substantially equivalent to the Medcomp Tri-Flow Triple Lumen Short Term Hemodialysis Catheter (K973561) in terms of overall functional performance.

7. Nonclinical Testing

Bench testing was performed to demonstrate substantial equivalence between the predicate and proposed devices. Performance and material testing was completed on the proposed devices in accordance with ISO 10555-1, 10555-3, ISO 10993-1, and *FDA Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters*.

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 Multi-Lumen Acute Hemodialysis Catheter for High Volume Infusions is safe and performs as intended and therefore is considered substantially equivalent to the cited predicate devices.