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

October 4, 2016

Teleflex Medical, Inc.
Angela Bouse
Sr. Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, NC 27560

Re: K161075
Trade/Device Name: Arrow Epidural Catheter Kit
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: Class II
Product Code: CAZ
Dated: September 2, 2016
Received: September 6, 2016

Dear Angela Bouse:

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

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
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)*
K161075

Device Name
Arrow Epidural Catheter Kit

Indications for Use *(Describe)*

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

Patient Population: Adult

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

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
3015 Carrington Mill Blvd
Morrisville, NC 27560 USA
Phone: 919-433-4904
Fax: 919-433-4989

B. Contact Person

Angela Bouse
Senior Regulatory Affairs Specialist

C. Date Prepared

October 4, 2016

D. Device Name

Trade Name:	Arrow Epidural Catheter Kit
Classification Name:	Anesthesia Conduction Kit
Product Code:	CAZ
Regulation Number:	868.5140
Classification:	II
Classification Panel:	Anesthesiology

E. Predicate Device

This submission demonstrates substantial equivalence to the predicate device Arrow Epidural Catheter Kit - K143581

F. Device Description

The Arrow Epidural Catheter Kit consists of the epidural catheter packaged with various combinations of accessory components including 0.2 Micron In-Line Flat Anesthesia Conduction Filter necessary for the catheter insertion procedure.

G. Indications for Use

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

Patient Population: Adult

H. Technological Characteristics Comparison to the predicate

The proposed Arrow Epidural Catheter Kit with 0.2 Micron In-Line Flat Anesthesia Conduction Filter is substantially equivalent to the predicate device with respect to indications for use, technology and construction. The differences between the predicate and the proposed devices are minor and any risks have been mitigated through testing. **Table 1** summarizes the differences between the proposed and predicate devices.

Table 1 - Differences Between the Proposed and Predicate Devices

Comparative Characteristic	**Predicate Device: Arrow Epidural Catheter Kit K143581**	**Proposed Device: Arrow Epidural Catheter Kit**
Classification Name	Anesthesia Conduction Kit	Same
Product Code / CFR	CAZ, 868.5140	Same
Intended Use/ Indications for Use	The Arrow Epidural Catheter kit permits access to the epidural space for the administration of epidural anesthetic. The epidural catheter kit is intended for use up to 72 hours.	Same
Patient Population	Patients that require administration of local anesthetics.	Same
Design	Filter Component of the Kit: Round flat filter	Same
Inlet Connection	Filter Component of the Kit: Female luer lock	Same
Outlet Connection	Filter Component of the Kit: Male Luer	Same
Membrane Pore Size	Filter Component of the Kit: 0.2 micron	Same
Filtration Area	Filter Component of the Kit: 3.8 cm^2	Filter Component of the Kit: 5.25 cm^2
Bubble Point Pressure	Filter Component of the Kit: $\geq$ 46 psi	Same
Bacterial Retention	Filter Component of the Kit: 100% bacterial retention	Same
Housing Material	Filter Component of the Kit: Modified acrylic	Filter Component of the Kit: Modified Acrylic
Filter Material	Filter Component of the Kit: Polyethersulfone	Filter Component of the Kit: Supor Polyethersulfone
Membrane Filtration	Filter Component of the Kit: Hydrophilic	Same
Rotating Locking Hub	Filter Component of the Kit:	Filter Component of the Kit:

Comparative Characteristic	**Predicate Device:** Arrow Epidural Catheter Kit K143581	**Proposed Device:** Arrow Epidural Catheter Kit
Material	Polypropylene	Polypropylene
Shelf Life	One year	Same
Method of Sterilization	Ethylene Oxide	Same
Packaging	Thermoformed Tray sealed with Tyvek Lidstock	Same
Single Use	Yes	Same
Kit Components	List of the main kit components: Epidural Catheter Catheter Syringe Adapter 0.2 Micron Anesthesia Conduction Filter SnapLock™ Epidural Needle Injection Needle Standard Syringe LOR Syringe SharpsAway II™ Locking Disposal Cup Clear Fenestrated Drape with adhesive Towel 5 Micron Straw Filter Gauze Pads Prep Sponge Swabs Medicine Cup Tray: Prep	Same, except for the 0.2 Micron Anesthesia Conduction Filter
IFU	Arrow Epidural Catheter IFU	Same

I. Performance Data

A brief summary of tests relied upon to demonstrate substantial equivalence to the predicate can be found in **Table 2** below.

Table 2 – Performance Testing Summary

Test	Reference to Standard (if applicable)	Principle of Test
Luer Strength Test	Internal Requirement	Force is applied to the male and female luer tapers until failure.

Housing Burst Pressure Test	Internal Requirement	Hydrostatic pressure is applied until part bursts.
Flow Rate Test	Internal Requirement	Water is passed through the filter at a pressure of 10 psi and collected in a graduated cylinder for 60 seconds. The volume of water is recorded.
Filter Luer Slip	ISO 594-1	To test unscrewing gauging, liquid leakage, air leakage, separation force.
Filter Luer-Lock	ISO 594-2	To test unscrewing torque, ease of assembly, resistance to overriding, stress cracking.
Bacterial Retention and Bubble Point Test	ASTM F838	To test bacterial retention of membrane filter.
Biocompatibility	ISO 10993	Testing included cytotoxicity, sensitization, irritation, acute systemic toxicity, subchronic systemic toxicity, genotoxicity, implantation, and extractables & leachables.
EO Residuals	ISO 10993-7	The EO residual testing for prolonged contact devices.
LAL Bacterial Endotoxin	AAMI ST72	LAL bacterial endotoxin testing for medical devices that have contact with CSF.
Rabbit Pyrogen	ISO 10993-11	Material Mediated Rabbit Pyrogen
Packaging	ISO 11607-1 ASTM D4169	Packaging stability Distribution simulation testing

J. Conclusion

The Arrow Epidural Catheter kit has the same indications for use and technology of construction as the predicate devices. Performance test results demonstrate that the proposed device meets its intended use. It is for these reasons that the proposed device can be found substantially equivalent.