DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 26, 2015

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

Re: K143581
Trade/Device Name: Arrow Epidural Catheter Kit
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: May 22, 2015
Received: May 26, 2015

Dear Ms. 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" (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 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.

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Clinical Deputy Director
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Erin I. Keith, M.S.
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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)*
K143581

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.

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)*

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

June 26, 2015

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
Portex Epidural Filter – K083451
Flextip Plus Closed Tip Epidural Catheter - K103658

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.

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: Smiths Medical, Portex Epidural Filter K083451**	**Predicate Device: Flextip Plus Closed Tip Epidural Catheter K103658**	**Proposed Device: Arrow Epidural Catheter Kit with 0.2 Micron In-Line Flat Anesthesia Conduction Filter**
Classification Name	Anesthesia Conduction Filter	Anesthesia Conduction Kit	Same
Product Code / CFR	BSN, 868.5130	CAZ, 868.5140	Same
Intended Use/ Indications for Use	An anesthesia conduction filter is used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.	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.	Similar
Patient Population	Patients that require administration of local anesthetics.	Patients that require administration of local anesthetics.	Same
Design	Round flat filter	Filter Kit Component: Round flat filter	Same
Inlet Connection	Female luer lock	Filter Kit Component: Female luer lock	Same
Outlet Connection	Male Luer with a rotating Locking Hub	Filter Kit Component: Male Luer	Same
Membrane Pore Size	0.2 micron	Filter Kit Component: 0.2 micron	Same
Filtration Area	5.25 cm^2	Filter Kit Component: 4.3 cm^2	3.8 cm^2
Bubble Point Pressure	≥ 46 psi	Filter Kit Component: ≥ 46 psi	Same
Bacterial Retention	100% bacterial retention	Filter Kit Component: 100% bacterial retention	Same

Comparative Characteristic	**Predicate Device: Smiths Medical, Portex Epidural Filter K083451**	**Predicate Device: Flextip Plus Closed Tip Epidural Catheter K103658**	**Proposed Device: Arrow Epidural Catheter Kit with 0.2 Micron In-Line Flat Anesthesia Conduction Filter**
Housing Material	Modified acrylic	Filter Kit Component: Modified acrylic	Cyrolite G20 Hiflo, Modified Acrylic
Filter Material	Not stated	Filter Kit Component: Polyethersulfone	Sterlitech, Polyethersulfone
Membrane Filtration	Hydrophilic	Filter Kit Component: Hydrophilic	Same
Rotating Locking Hub Material	Not stated	N/A – filter design does not include a rotating collar	Titanpro 6331, Polypropylene with Unicolour UYL0845 PP Yellow
Shelf Life	Not stated	Two years	One year
Method of Sterilization	Not stated	Ethylene Oxide	Ethylene Oxide
Single Use	Yes	Yes	Same
Kit Components	Not Applicable	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 replacement of the 0.2 Micron Anesthesia Conduction Filter
IFU	Not stated	Arrow Epidural Catheter IFU	Similar

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.
Packaging	ISO 11607-1 ASTM D4169	Packaging stability Distribution simulation testing

J. Conclusion

The Arrow Epidural Catheter kit has similar 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.