August 21, 2019

Teleflex Medical
Lakshmi Kanuri
Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K190026
Trade/Device Name: Arrow Epidural Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: July 19, 2019
Received: July 22, 2019

Dear Lakshmi Kanuri:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190026

Device Name
Arrow Epidural Needles

Indications for Use *(Describe)*
The Arrow Epidural Needles are intended to inject local anesthetic into a patient to provide regional anesthesia or to facilitate the placement of an epidural catheter.

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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007 - 510(k) Summary

510(k) SUMMARY

K190026

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

Teleflex Medical, Incorporated
3015 Carrington Mill Blvd
Morrisville, NC 27560 USA
Phone: 919-361-4087
Fax: 919-433-4996

2. Contact Person

Lakshmi Kanuri
Regulatory Affairs Specialist

3. Date Prepared

August 21, 2019

4. Device Name

Trade Name:	Arrow Epidural Needles
Classification Name:	Anesthesia conduction needle (w/wo introducer)
FDA Product Code:	BSP
CFR Number:	868.5150
Regulatory Class:	II

5. Predicate Device

K131006 - AN-E Epidural Needle

6. Device Description

The Arrow Epidural Needles are sterile, single use, disposable devices. They are used for the injection of anesthetic agents into a patient for regional anesthesia administration or to facilitate the placement of an epidural catheter for continuous infusion of local anesthetics.

The Arrow Epidural Needles consist of a plastic cannula hub with integrated wings that come with either Luer Connector and NRFit Connector, stainless steel cannula, and plastic stylet. The purpose of the stylet is to prevent tissue coring during needle insertion. The needle assembly is protected with a guard to prevent damage to the needle.

7. Indications for Use

The Arrow Epidural Needles are intended to inject local anesthetic into a patient to provide regional anesthesia or to facilitate the placement of an epidural catheter.

8. Technological Characteristics Comparison to the predicate

CHARACTERISTIC	PREDICATE DEVICE K131006	SUBJECT DEVICE
Applicant Name	LCCS PRODUCTS LIMITED	ARROW INTERNATIONAL INC.
Device Classification Name	Anesthesia conduction needle (w/wo introducer)	Anesthesia conduction needle (w/wo introducer)
FDA Product Code	BSP	BSP
CFR Number	868.5150	868.5150
Regulatory Class	II	II
Trade Name	AN-E Epidural Needle	Arrow Epidural Needle
Intended Use/Indications for Use	Intended for the transient delivery of anesthetics to provide neuraxial anesthetics or to facilitate placement of an epidural catheter.	The Arrow Epidural Needles are intended to inject local anesthetic into a patient to provide regional anesthesia or to facilitate the placement of an epidural catheter.
Needle Guage Size	15 GA - 20 GA	17 GA
Needle Length	50 mm - 150 mm	88.9mm (8.89 cm) (3-1/2")
Tip Design	Tuohy, Quincke, Pencil Point	Tuohy
Needle Cannula Material	304 Stainless Steel	304 Stainless Steel
Needle Hub Material	K-Resin KR03	Clear Acrylic
Stylet Cannula Material	304 STAINLESS STEEL	Clear Polypropylene
Stylet Hub Material	HDPE	Gray Polypropylene
Connector Type	ISO 594 Luer	ISO 594 Luer ISO 80369-6 NRFit
Final Needle Assembly Protection	Not stated	Guard

007 - 510(k) Summary

CHARACTERISTIC	PREDICATE DEVICE K131006	SUBJECT DEVICE
Markings	Not stated	1 cm (10 mm)
Performance	ISO 7864 Hub to Needle Bond Strength ISO 9626 Stiffness ISO 9626 Resistance to breakage ISO 594-1 and ISO 594-2 Luer Connector	BS 6196 Joint Between the Needle Hub and Needle Cannula and Joint Between the Stylet Hub and Stylet Cannula ISO 9626 Stiffness ISO 9626 Resistance to breakage ISO 9626 Resistance to corrosion ISO 594-1 and ISO 594-2 Luer Connector ISO 80369-6 NRFit Connector
Method of Sterilization	Not stated	Ethylene Oxide
Shelf Life	Not stated	One year
Packaging	Not stated	Tyvek Pouch
Use	Single Use	Single Use

9. Performance Data

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

Test	Standard (if applicable)	Principle of Test
Joint Between the Needle Hub and Needle Cannula	BS 6196	A tensile force is applied for a specified time to the union being tested, and the union observed to determine if it parts.
Joint Between the Stylet Hub and Stylet Cannula		
Stiffness	ISO 9626	A specified force is applied to the centre of the specified length of tubing, which is supported at both ends, and the amount of deflection measured.
Resistance to breakage	ISO 9626	One end of the tubing is firmly fixed, and a force applied to the tubing at a specified distance from the point of fixation, so as to bend the tubing through a specified angle, first in one direction and then in the opposite direction, for a specified number of cycles.
Resistance to corrosion	ISO 9626	The tubing is partially immersed in sodium chloride solution for a specified time and afterwards the immersed portion compared visually with the un immersed portion for signs of corrosion.
Luer Connector	ISO 594-1 ISO 594-2	To test unscrewing gauging, liquid leakage, air leakage, separation force.
NRFit Connector	ISO 80369-6	To test unscrewing gauging, liquid leakage, air leakage, separation force.
Biocompatibility	ISO 10993	Testing included Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity and Material Mediated Pyrogenicity
LAL Bacterial Endotoxin	AAMI ST72	LAL Bacterial Endotoxin testing of medical devices that have contact with CSF
Packaging	ISO 11607-1 ASTM D4169	Stability and Distribution simulation testing

10. Conclusion

The Arrow Epidural Needle has similar indications for use and technology of construction as the predicate device. Performance test results demonstrate that the proposed device meets its intended use. It is for these reasons that the proposed device is substantially equivalent to the proposed predicate device and does not raise different questions of safety and effectiveness.