K103658

MAY 16 2012

510(k) SUMMARY

Submitter Information

Name:	Arrow International, Inc. (subsidiary of Teleflex Inc.)
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Date Prepared: Dec 14, 2010

Device Name

Device Trade Name:	FlexTip Plus Epidural Catheter
Common Name:	Epidural Catheter
Classification Name:	Anesthesia Conduction Catheter, CAZ, 21 CFR 868.5140; Anesthesia Conduction Catheter, BSO, 868.5120

Predicate Device

The predicate device is Arrow's Continuous Epidural Anesthesia kit with polyurethane catheter, K884552

Device Description

The FlexTip Plus Epidural Catheter has the following characteristics:

- 19 Ga. single lumen 900 mm
- Available in open or closed tip
- Internal radiopaque, echogenic coiled reinforced wire
- Catheters are provided in sterile kit configurations

Indications for Use and Intended Use

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

Technological Characteristics and Substantial Equivalence

The Arrow FlexTip Plus Epidural Catheter is substantially equivalent to the Continuous Epidural Anesthesia kit with polyurethane catheter (K884552) in terms of overall design, manufacturing process, functional performance, and materials of construction. The indications for use and intended use for the subject device are the same as those for the Continuous Epidural Anesthesia kit with polyurethane catheter.

Nonclinical Testing

The results of the performance testing, i.e. tensile strength, column strength and flow rate, demonstrate that the FlexTip Plus Closed Tip Epidural Catheter is as safe, as effective and performs comparably to the predicate Epidural catheter.

Pre-clinical evaluations have been conducted on the catheter and extracts thereof. No adverse effects were observed in any in vitro or in vivo study conducted. In accord with ISO 10993-18 recommendations, Extractable and Leachable (E&L) studies were performed using, Bupivacaine, Naropin, Polocaine, Hydromorphone, Morphine, Meperidine, and Fentanyl. The toxicity of the relevant leachable chemicals relating to these drugs was reviewed and addressed. In addition, a comparative chemical analysis study was conducted to assess potential differences in the E&L profile between devices that were EO sterilized after one cycle versus devices that were processed with two EO cycles. There were no appreciable qualitative differences in the extractable profiles for the one time vs. two time EO-sterilized devices.

The relevant patient contacting components meet the requirements of applicable ISO 10993 Guidelines. The available and relevant toxicological data for a surrogate leachable chemical was reviewed. There was no evidence of significant risk of acute toxicity under the proposed conditions and duration of clinical use.

Conclusions

The predicate and the proposed Epidural catheters have the same indications for use and intended use. The results of the testing performed have demonstrated that the FlexTip Plus Epidural Catheter does not raise new issues of safety or performance and therefore is considered substantially equivalent to the cited predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Paul Amudala
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Teleflex Incorporated
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Reading, Pennsylvania 19605

MAY 16 2012

Re: K103658
Trade/Device Name: FlexTip Plus Closed Tip Epidural Catheter
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: May 2, 2012
Received: May 3, 2012

Dear Mr. Amudala:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103658

Device Name: FlexTip Plus Closed Tip Epidural Catheter

Indications for Use:

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.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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