November 9, 2018

Arrow International, Inc. (Subsidiary of Teleflex, Inc.)
Frank Pelc
Sr. Regulatory Affairs Specialist
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K180395
Trade/Device Name: EZ-IO Intraosseous Vascular Access System
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: October 9, 2018
Received: October 10, 2018

Dear Frank Pelc:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180395

Device Name
EZ-IO Intraosseous Vascular Access System

Indications for Use *(Describe)*

For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent, or medically necessary cases for up to 24 hours. Insertion sites:
ADULTS (≥22 years old): proximal humerus, proximal tibia, distal tibia
PEDIATRICS (≤21 years old): proximal humerus, proximal tibia, distal tibia, distal femur

Use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established. Insertion sites:
ADULTS (≥22 years): proximal humerus, proximal tibia, distal tibia
PEDIATRICS (≥12 years through 21 years old): proximal humerus, proximal tibia, distal tibia, distal femur

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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K180395 510(k) SUMMARY

EZ-IO Intraosseous Vascular Access System

1. Submitter Information

Name:	Arrow International, Inc. (subsidiary of Teleflex Inc.)
Address:	2400 Bernville Road Reading, PA 19605-9607
Telephone Number:	(610) 378-0131
Contact Person:	Frank Pelc
Telephone Number:	(610) 478-3107
Fax Number:	(610) 478-3179
Email:	frank.pelc@teleflex.com

Date Prepared: November 9, 2018

2. Device Name

Device Trade Name:	EZ-IO Intraosseous Vascular Access System
Common Name:	Intraosseous Infusion System
Classification Name:	Needle, Hypodermic, Single Lumen (Class II, FMI, 21 CFR 880. 5570)

3. Predicate Device

EZ-IO Intraosseous Infusion System (K141117)

4. Device Description

The EZ-IO System previously cleared with K141117 is designed to allow the user to insert a needle set consisting of a stylet and catheter through the cortex of the bone to a desired depth within the bone marrow to facilitate intraosseous infusion of desired fluids and medications for vascular access. All system materials are biocompatible. Needle sets are single-use and composed of 304 stainless steel with polycarbonate hubs and available in 15 mm (for patients 3-39 kg); 25 mm (for patients 3 kg or over) and 45 mm (for patients 40 kg or over) lengths. Black lines on the needle set serve as depth markers. The reusable cordless driver/drill is powered by lithium batteries with a battery-power indicator light. An extension tubing set accessory, the EZ-Connect, is included with every needle set. The EZ-Connect contains a needleless connector system and Luer lock adapter. An optional dressing, the EZ-Stabilizer, is an accessory to the EZ-IO Vascular Access System. It is designed as a securement device with an adhesive backing that is placed over an EZ-IO Needle

to keep the needle securely anchored to the patient; and is recommended in the Instructions for use (IFU).

The following is a summary of the device operation: Clinicians locate anatomical landmarks and clean the insertion site. Using the cordless driver with needle set attached, the needle set is pressed through the soft tissue to the outer cortex of the bone. Depth markers on the catheter must be visible prior to powering the driver to ensure adequate needle length for proper placement within the medullary space. Clinicians then squeeze the driver trigger and apply moderate, steady pressure. The trigger is released when a sudden "give" or "pop" is felt, which indicates entry into the medullary space; the needle set will not always be inserted to the hub. After insertion of the needle set, the driver unit is detached from the needle set, leaving the stylet and catheter firmly seated in the bone. The stylet is then separated and removed from the catheter by turning the stylet hub counterclockwise leaving the catheter with a standard Luer lock hub securely seated in the bone. The catheter Luer lock permits attachment of the provided EZ-Connect, standard syringes or other IV tubing for administration of medications and fluids.

5. <u>Indications for Use</u>

For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent, or medically necessary cases for up to 24 hours. Insertion sites:
ADULTS (≥22 years old): proximal humerus, proximal tibia, distal tibia
PEDIATRICS (≤21 years old): proximal humerus, proximal tibia, distal tibia, distal femur

Use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established. Insertion sites:
ADULTS (≥22 years): proximal humerus, proximal tibia, distal tibia
PEDIATRICS (≥12 years through 21 years old): proximal humerus, proximal tibia, distal tibia, distal femur

6. <u>Technological Characteristics and Substantial Equivalence</u>

The proposed device is identical to the predicate device described in K141117 in design, materials of construction, functional performance, principles of operation, manufacturing, packaging, sterilization, and shelf life. They are also identical in target population and environment of use.

The only change is the labeled indications to allow for up to 48 hour use when alternate intravenous access is not available or reliably established.

The table below provides a comparison of the proposed and predicate devices.

	Proposed Device EZ-IO Intraosseous Vascular Access System (Expansion of indication for up to 48 Hour Use)	**Predicate Device - K141117** EZ-IO Intraosseous Infusion System
Indications for Use	For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent, or medically necessary cases for up to 24 hours. Insertion sites: ADULTS (≥22 years old): proximal humerus, proximal tibia, distal tibia PEDIATRICS (≤21 years old): proximal humerus, proximal tibia, distal tibia, distal femur Use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established. Insertion sites: ADULTS (≥22 years): proximal humerus, proximal tibia, distal tibia PEDIATRICS (≥12 years through 21 years old): proximal humerus, proximal tibia, distal tibia, distal femur	The EZ-IO Intraosseous Infusion System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.
Contraindications	• Fracture in target bone. • Previous, significant orthopedic procedure at the site, prosthetic limb or joint. • IO access (or attempted IO access) in targeted bone within past 48 hours. • Infection at the area of insertion. • Excessive tissue (severe obesity) and/or absence of adequate anatomical landmarks.	• Fracture in target bone • Previous significant orthopedic procedure at the site (IO access in past 48 hours, prosthetic limb or joint) • Infection at area of insertion • Excessive tissue and/or absence of adequate anatomical landmarks.
Target Population	SAME: Adult and pediatric patients who are in need of vascular access.	Adult and pediatric patients who are in need of vascular access.
Where Used	SAME: Pre-hospital, In hospital, Acute care	Pre-hospital, In hospital, Acute care
Anatomical Sites Used	SAME: Proximal Tibia	Proximal Tibia

	Proposed Device EZ-IO Intraosseous Vascular Access System (Expansion of indication for up to 48 Hour Use)	**Predicate Device - K141117** EZ-IO Intraosseous Infusion System
	Humeral Head (proximal humerus) Distal Tibia Distal Femur in pediatric population	Humeral Head (proximal humerus) Distal Tibia Distal Femur in pediatric population
Needle/Cannula Design	SAME: Sterile, single use Hubs: polycarbonate and color additive Stylet/catheter: Stainless Steel Faceted tip Standard Luer connection 15 mm; 25 mm; 45 mm 15 gauge (0.071”, 1.8 mm) Needle Cover: Polypropylene	Sterile, single use Hubs: polycarbonate and color additive Stylet/catheter: Stainless Steel Faceted tip Standard Luer connection 15 mm; 25 mm; 45 mm 15 gauge (0.071”, 1.8 mm) Needle Cover: Polypropylene
Needle Set Guidelines	SAME: Available Needle Sets: 15 mm: 3-39 kg 25 mm: 3 kg or over 45 mm : 40 kg or over	Available Needle Sets: 15 mm: 3-39 kg 25 mm: 3 kg or over 45 mm : 40 kg or over
Depth Control	SAME: Positioning marks at 5 cm and 10 cm apart to provide visual reference points Tactile feedback for change of pressure	Positioning marks at 5 cm and 10 cm apart to provide visual reference points Tactile feedback for change of pressure
Sterile single use components/accessories	SAME: EZ-IO Needle Sets EZ-Connect Extension Set EZ-IO Patient Wristband NeedleVISE 1-port Sharps Block EZ-Stabilizer Dressing	EZ-IO Needle Sets EZ-Connect Extension Set EZ-IO Patient Wristband NeedleVISE 1-port Sharps Block EZ-Stabilizer Dressing
Sterility of single use components/accessories	SAME: Ethylene Oxide	Ethylene Oxide
Shelf life of single use	SAME: 4 Years	4 Years

	Proposed Device EZ-IO Intraosseous Vascular Access System (Expansion of indication for up to 48 Hour Use)	**Predicate Device - K141117** EZ-IO Intraosseous Infusion System
components/accessories		
Biocompatibility	Biocompatible materials used (per ISO 10993-1 prolonged contact duration).	Biocompatible materials used (per ISO 10993-1 limited contact duration).

7. Nonclinical Testing

Biocompatibility testing for prolonged (>24 hours to ≤ 30 days) contact duration was completed on the proposed device materials in accordance with the FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (issue date June 16, 2016) as appropriate for the contact type for each component:

- EZ-IO Needle Set: External communicating device; blood path indirect and tissue/bone/dentin contact, prolonged duration.
- EZ-Connect extension tubing set: External communicating device; blood path, indirect contact; prolonged duration.
- EZ-Stabilizer dressing: Surface device, intact skin contact; prolonged duration.

Biocompatibility of the materials of construction were previously reviewed in K141117 for limited duration (≤24 hours). The materials have not changed for the proposed device, but the contact duration, for the purpose of biocompatibility testing is changed to prolonged (>24 hours to ≤30 days) contact to account for the 48 hour dwell time. Testing addressing the ISO 10993-1 requirements for prolonged contact was conducted.

The performance testing of the predicate K141117 remains applicable to the proposed device. Performance requirements for the EZ-IO components relate to physical parameters such as tensile strength, torsion strength, bend strength, leak and burst pressure. These performance tests are not dependent upon factors of time or number of occurrences of an action or event. The device materials are unchanged and there is no additional risk or change to the materials' physical properties when subjected to 48 hour use compared to 24 hour use. Therefore, the information supporting performance of the device for up to 24 hour use in the predicate K141117 also applies to the proposed device. No new performance testing is required.

8. Clinical Data

A US single-site, prospective clinical IDE trial was performed to study use of the EZ-IO Intraosseous Vascular Access System for up to 48 hours indwelling time; the primary study endpoint was the absence of serious complications resulting from intraosseous (IO) catheter retention over a 48-hour period.

The study participants were either healthy or health-compromised adult volunteers with mild to moderate renal disease (NHANES Stage 1 to 3) and/or controlled diabetes (HbA1C ≤8). There were 121 evaluable subjects enrolled in the study; 79 were in the healthy subset, 39 were in the diabetes only subset, and 3 in the diabetes with renal insufficiency subset. Placement site was randomized with 61 proximal tibia and 60 proximal humerus insertions. Subjects were infused with 0.9% sodium chloride at a rate

of 100 mL/hr for the initial eight hours then a rate of 30 mL/hr. Pain control during the study was managed with a slow infusion of preservative and epinephrine-free lidocaine before initial flush, and analgesics. An IO aspirate culture was obtained before catheter removal, followed by an x-ray of the site. After 30 days, subjects returned for examination and repeat x-ray.

Three subjects were discontinued from the 48-hour procedural portion of the study: one with pain and left arm swelling after 10 hours; and two adverse events (AE) between 30-32 hours, swelling secondary to extravasation; and leaking at the hub of the device and accidental dislodgement. Four subjects withdrew following IO needle insertion before 48 hours due to inability to control pain or pain and fever.

Study follow-up was performed at 30 days. There were no serious AEs or complications, or unexpected AEs reported for any of the subjects randomized into the study. AEs determined to be related and/or possibly related to the device included: pain, swelling; elevated white blood cell counts and neutrophils; skin demarcation/ scar; fever; local skin allergy; and vasovagal response during initial insertion.

Under the conditions of the study, IO access can be maintained for 48 hours without significant risk of serious adverse events. Pain associated with catheter dwell and infusion can be well-managed, and a slow infusion of 30 mL/hour maintains patency for 48 hours.

Based on limitations of the study as compared to the expected actual use of the device during the 24-48-hour period as well as the limitations of clinical literature regarding IO use for 24-48 hours, the Indications for Use statement restricts the use of the device beyond 24 hours (and only up to 48 hours) to when alternate intravenous access is not available or readily established and only in patients ≥12 years of age. In addition, specific "CAUTION" statements were added to the Instructions for Use to inform clinicians that patients with comorbidities may have an increased risk for complications, and that the risks may increase as the device remains in place a longer period of time. Other "CAUTION" statements state the importance of frequent monitoring of the intraosseous site and infusion.

9. Conclusions

The EZ-IO Intraosseous Vascular Access System is substantially equivalent to the predicate device.