March 22, 2021

Teleflex Medical
Rachel Rehl
Regulatory Affairs Specialist
3015 Carrington Mill Blvd.
Morrisville, North Carolina 27560

Re: K202492
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: February 19, 2021
Received: February 23, 2021

Dear Rachel Rehl:

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,

For Rumi Young
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202492

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

For patients ≥12 years old, use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established.

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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K202492 510(k) SUMMARY

EZ-IO Intraosseous Vascular Access System
MR Conditional Safety Status Labeling

1. Submitter Information

Name: Teleflex Medical
Address: 3015 Carrington Mill Blvd.
Morrisville, NC 27560 USA
Contact Person: Rachel Rehl
Telephone Number: (919)433-2588
Email: rachel.rehl@teleflex.com

Date Prepared: August 28, 2020

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 Vascular Access System (K180395)

4. Device Description and Clinical Operation

Device Description

The EZ-IO Intraosseous Vascular Access System previously cleared with K180395 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).

Clinical 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. At least one depth marker on the cannula 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 cannula firmly seated in the bone. The stylet is then separated and removed from the cannula by turning the stylet hub counterclockwise leaving the catheter with a standard Luer lock hub securely seated in the bone. The cannula Luer lock permits attachment of the provided EZ-Connect, standard syringes or other IV tubing for administration of medications and fluids.

5. 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

For patients ≥ 2 years old, use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established.

6. Technological Characteristics and Substantial Equivalence

The proposed device is identical to the predicate device described in K180395 in design, materials of construction, functional performance, principles of operation, manufacturing, packaging, sterilization, and shelf life.

The only change is the labeled MR Conditional Safety Status. Table 5-1 below provides a comparison of the proposed and predicate devices.

Table 5-1: Substantial Equivalence Comparison to Predicate

	Proposed Device EZ-IO Intraosseous Vascular Access System (MR Conditional Safety Status Labeling)	Predicate Device K180395 EZ-IO Intraosseous Vascular Access System	Comparison
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 For patients ≥12 years old, use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established.	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	Wording updated for clarity but the indications for use are the same.
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, 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.	Same

	Proposed Device EZ-IO Intraosseous Vascular Access System (MR Conditional Safety Status Labeling)	Predicate Device K180395 EZ-IO Intraosseous Vascular Access System	Comparison
Target Population	Adult and pediatric patients who are in need of vascular access.	Adult and pediatric patients who are in need of vascular access.	Same
Where Used	Pre-hospital, In hospital, Acute care	Pre-hospital, In hospital, Acute care	Same
Anatomical Sites Used	• Proximal Tibia • Proximal Humerus • Distal Tibia • Distal Femur in pediatric population	• Proximal Tibia • Proximal Humerus • Distal Tibia • Distal Femur in pediatric population	Same
Needle/Cannula Design	• 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	Same
Needle Set Guidelines	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	Same
Depth Control	Positioning marks at 5 mm and 10 cm apart to provide visual reference points Tactile feedback for change of pressure	Positioning marks at 5 mm and 10 mm apart to provide visual reference points Tactile feedback for change of pressure	Same
Sterile single use components and accessories	• 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	Same
Sterility of single use components and accessories	Ethylene Oxide	Ethylene Oxide	Same
Shelf life of single use components and accessories	4 Years	4 Years	Same

	Proposed Device EZ-IO Intraosseous Vascular Access System (MR Conditional Safety Status Labeling)	Predicate Device K180395 EZ-IO Intraosseous Vascular Access System	Comparison
Biocompatibility	Biocompatible materials used (per ISO 10993-1 prolonged contact duration).	Biocompatible materials used (per ISO 10993-1 prolonged contact duration).	Same
MR Safety Status	MR Conditional	MR Unsafe	Update to MR Safety Status as described in submission.

7. Non-clinical Testing

Non-clinical testing was conducted as the basis of the MR Conditional safety status claims that are proposed in this 510(k). The testing is listed in Table 5-2 below. Summaries of the testing are provided as well. The test article was the 45 mm needle.

Table 5-2: Non-Clinical Testing

Testing	Summary
MRI Testing, Exponent, 2020	This study evaluated the MRI compatibility of the EZ-IO Needle Set in regard to radiofrequency (RF)-induced heating in 1.5 T and 3 T clinical scanners. The evaluation was conducted using methodologies prescribed in ASTM F2052, ASTM F2213, ASTM F2182, and ASTM F2119 as a guide. The evaluation concluded that the EZ-IO Needle Set should be labeled as MR Conditional and included labeling guidelines in the report.

8. Conclusions

The conclusions drawn from the non-clinical tests inform the MRI labeling that is proposed in this 510(k). As there is no change to the device itself, we can conclude that the device is substantially equivalent to the predicate 510(k) K180395.