July 25, 2023

Teleflex Medical
Rachel Rehl
Regulatory Affairs Team Lead
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K231924
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: June 29, 2023
Received: June 30, 2023

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,

CAPT Alan M. Stevens
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.

Submission Number *(if known)*

K231924

Device Name

EZ-IO Intraosseous Vascular Access System

Indications for Use *(Describe)*

INDICATIONS FOR USE:
For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent or medically necessary cases up to 24 hours. For patients ≥ 12 years old, 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 old): proximal humerus, proximal tibia, distal tibia
PEDIATRICS (≤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.

Special 510(k) SUMMARY

EZ-IO Intraosseous Vascular Access System
Sterile G3 Driver

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: 29 June 2023

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 880.557)

3. Predicate Device

EZ-IO Intraosseous Vascular Access System (K202492)

4. Device Description and Clinical Operation

Device Description

The EZ-IO Intraosseous Vascular Access System previously cleared with K202492 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. For patients ≥ 12 years old, the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established.

ADULTS (≥22 years old)

- Proximal humerus
- Proximal tibia
- Distal tibia

PEDIATRICS (≤21 years old)

- Proximal humerus
- Proximal tibia
- Distal tibia
- Distal femur

6. **Technological Characteristics and Substantial Equivalence**

The proposed device is identical to the predicate device described in K202492 in design, materials of construction, functional performance, principles of operation, manufacturing, packaging, sterilization, and shelf life.

The only change is the change to the sterility of the EZ-IO Power Driver. **Table 1** below provides a comparison of the proposed and predicate devices.

Table 1: Substantial Equivalence Comparison to Predicate

	Proposed Device EZ-IO Intraosseous Vascular Access System (Sterile Driver)	**Predicate Device – K202492** 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. For patients ≥ 12 years old, 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 old) • Proximal humerus • Proximal tibia • Distal tibia PEDIATRICS (≤21 years old) • Proximal humerus • Proximal tibia • Distal tibia • Distal femur	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.	Combined the verbiage above and below the insertion sites into one paragraph. No change to indication for use statement.
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
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	• Proximal Tibia • Proximal Humerus	Same

	Proposed Device EZ-IO Intraosseous Vascular Access System (Sterile Driver)	**Predicate Device – K202492** EZ-IO Intraosseous Vascular Access System	**Comparison**
	• Distal Tibia • Distal Femur in pediatric population	• Distal Tibia • Distal Femur in pediatric population	
EZ-IO Power Driver Design	• Housing: Cycoloy, Sabic P/N C6200-6T5D007, Maroon • Drive Shaft: 304 Stainless Steel • Driver Shaft Seal: Trosta, Black Shore 58A Ethylene Propylene Diene Monomer (EPDM) with metal insert (1008 Steel) • Gasket: HD Urethane Foam Tape, Korel 8000, Shore A • Magnet Bonding: Loctite 603 • Trigger Cover: Thermoplastic Elastomer, Shore 25 A, Black • Label: Facestock: Matte Radiant White Polyester, Adhesive: Permanent #300 Acrylic, Liner: Densified Kraft, Ink: Black • Trigger Guard: Cycoloy, Sabic P/N C6200-BK1005, Black • Lanyard: Buna-N, Hard, Dash Number 42 • Batteries: Manganese Dioxide Lithium Batteries, CR2	• Housing: Cycoloy, Sabic P/N C6200-6T5D007, Maroon • Drive Shaft: 304 Stainless Steel • Driver Shaft Seal: Trosta, Black Shore 58A Ethylene Propylene Diene Monomer (EPDM) with metal insert (1008 Steel) • Gasket: HD Urethane Foam Tape, Korel 8000, Shore A • Magnet Bonding: Loctite 603 • Trigger Cover: Thermoplastic Elastomer, Shore 25 A, Black • Label: Facestock: Matte Radiant White Polyester, Adhesive: Permanent #300 Acrylic, Liner: Densified Kraft, Ink: Black • Trigger Guard: Cycoloy, Sabic P/N C6200-BK1005, Black • Lanyard: Buna-N, Hard, Dash Number 42 • Batteries: Manganese Dioxide Lithium Batteries, CR2	Same
Sterility of EZ-IO Power Driver	• Sterile Driver: Ethylene Oxide (SAL 10^{-6}) and • Non-Sterile	• Non-Sterile	The proposed device will be an ethylene oxide sterilized version of the currently marketed product. The current non-sterile version will still be available
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	• Sterile, single use • Hubs: polycarbonate and color additive • Stylet/catheter: Stainless Steel • Faceted tip • Standard Luer connection 15 mm; 25 mm; 45 mm	Same

	Proposed Device EZ-IO Intraosseous Vascular Access System (Sterile Driver)	**Predicate Device – K202492** EZ-IO Intraosseous Vascular Access System	**Comparison**
	• 15 gauge (0.071", 1.8 mm) • Needle Cover: Polypropylene	• 15 gauge (0.071", 1.8 mm) • Needle Cover: Polypropylene	
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 mm 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
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 Conditional	Same

7. Non-Clinical Performance Testing

The following assessments and tests were performed to demonstrate substantial equivalence:

- Packaging Verification Testing
- EZ-IO Power Driver RPM and Insertion Testing
- EZ-IO Power Driver Useful Life Testing
- ASTM F1886/F1886M-16 – Package Integrity Visual Inspection
- ASTM F2096-11 (2019) – Package Integrity Bubble Leak Testing
- ISO 11607-1:2019 – Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11135:2014 – Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 10993-1: 2018 – Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

The EZ-IO Power Driver meets the acceptance criteria of the bench testing as well as met the acceptance criteria of the functional testing previously established for the predicate device. The results of the bench tests demonstrate that the EZ-IO Power Driver is as safe and effective as the predicate device.

8. Conclusions

The intended use of the EZ-IO Intraosseous Vascular Access System is the same as the predicate device. The addition of a sterile version of the EZ-IO Power Driver was shown to be substantially equivalent through non-clinical performance testing. There were no changes to the device itself, therefore we can conclude that the device is substantially equivalent to the predicate 510(k) K202492.