November 13, 2019

Piper Access, LLC
℅ Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K191976
Trade/Device Name: Piper GO-IO Intraosseous Infusion System
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI
Dated: September 5, 2019
Received: September 17, 2019

Dear Mark Job:

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,

Alan 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191976

Device Name

Piper GO-IO® lntraosseous Infusion System

Indications for Use *(Describe)*

The Piper GO-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.

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.

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K191976

510(k) Summary
21 CFR 807.92(a)

Applicant

Name:	Piper Access, LLC
Address:	3981 South 700 East Suite #15 Salt Lake City, UT 84107
Ph:	801-210-2886
Manufacturer Contact:	Jay Muse, President and CEO
Email:	Jay.muse@piperaccess.com
Application Correspondent:	Jacob Lee
Email:	Jacob.Lee@bd.com
Date prepared:	November 08, 2019

Subject Device

Trade Name:	Piper GO-IO® Intraosseous Infusion System
Common Name:	Intraosseous Infusion System
Classification Name:	Hypodermic single lumen needle
Class:	II
Regulation:	21 CFR 880.5570
Product Code:	FMI
Panel:	General Hospital

Predicate Device

510(k):	K141117 (Clearance Date July 8, 2014)
Trade Name:	EZ-IO® Intraosseous Infusion System
Manufacturer:	Arrow/Teleflex Medical
Common Name:	Intraosseous Infusion System
Classification Name:	Hypodermic single lumen needle
Class:	II
Regulation:	21CFR 880.5570
Product Code:	FMI
Panel:	General Hospital

Reason for Submission

This is a new device.

Subject Device Description

The Piper GO-IO® Intraosseous Infusion System provides clinicians and emergency personnel with access to the intraosseous space for resuscitation and lifesaving fluid delivery for up to 24 hours. The Piper GO-IO® Intraosseous Infusion System consists of the following:

- a single use hypodermic needle (with needle safety cap),
- a powered or manual driver to assist with needle insertion,
- an extension set, and;
- an adhesive-backed securement dressing.

For insertions using the powered driver, the hypodermic needle includes a needle hub that mates with a stylet connected to a drive adapter hub. The drive adapter hub includes a magnetic insert that attaches to the powered driver prior to needle insertion. The Piper GO-IO® Powered Driver is a hand-held, battery-powered device with a rechargeable lithium battery used to assist in the insertion of the subject device needle through the bone cortex. The assembly of the hypodermic needle and stylet with connected drive adapter hub is referred to as the needle set.

For insertions using the manual driver, the needle and the needle hub mate with a stylet in the same way as the needle set that is used with the powered driver, except the stylet is integrated into the handle of the manual driver instead of a drive adaptor hub (i.e. the manual driver needle assembly does not include a drive adapter hub).

The stylet was designed to include a passive safety feature to protect the placer from sharps injury. After the needle is inserted, the stylet is separated from the needle and needle hub. Upon separation of the stylet from the needle hub, the passive safety feature is released onto the stylet tip and can be safely discarded into a sharps container. Following needle insertion, the securement dressing can be applied to secure the needle hub to the skin. An extension set is available for access to the needle hub to support fluid exchange.

The subject device Piper GO-IO® Intraosseous Infusion System will be offered in needle set (for use with the powered driver) and manual driver needle kit configurations. Each kit configuration will include a securement dressing and an extension set.

Intended Use

The Piper GO-IO® is intended to provide clinicians and emergency personnel with access to the intraosseous space.

Indications for Use

The Piper GO-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.

Technological Characteristics

The technological characteristics of the subject Piper GO-IO® Intraosseous Infusion System are substantially equivalent with respect to the basic design and function as compared to the predicate EZ-IO® Intraosseous Infusion System. The differences between the subject and predicate devices are not critical to the intended use of the device and do not raise different questions of safety and effectiveness.

The following table provides a comparison of the technological characteristics between the subject and predicate device in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.

Subject and Predicate Device Comparison Table		
Attribute	**Piper GO-IO® Intraosseous Infusion System (Subject Device)**	**EZ-IO® Intraosseous Infusion System (Predicate)**
510(k)	Subject of this Premarket Notification	K141117
Product Code	Same as predicate	FMI
Intended Use	Same as predicate	Intended to provide clinicians and emergency personnel with access to the intraosseous space.
Indications for Use	Same as predicate with the exception of the subject device brand name	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.
Target Patient Population	Same as predicate	Adults and Pediatrics
Anatomical Insertion Site	Same as predicate	Adults: Proximal tibia, distal tibia, proximal humerus Pediatrics: Proximal tibia, distal tibia, proximal humerus, distal femur
Primary IO System Components	Same as predicate with the exception of the subject stylet, which includes a passive safety sharps prevention feature	• Hypodermic Needle w/Stylet • Needle Safety Cap • Securement Dressing • Extension Set • Powered Driver • Manual Driver
Needle: Dwell Time	Same as predicate	24 hours or less
Needle: Use	Same as predicate	Single Use
Needle Lengths	15mm (3-39kg) 25mm (>3kg) 45mm (>40kg)	15 mm (3-39kg) 25 mm (3kg and over) 45 mm (40kg and over)

Subject and Predicate Device Comparison Table		
Attribute	**Piper GO-IO® Intraosseous Infusion System (Subject Device)**	**EZ-IO® Intraosseous Infusion System (Predicate)**
Needle: Outer Diameter	Same as predicate	15 gauge
Needle: Materials	Same as predicate	304 Stainless Steel
Needle: Tip Design	Touhy/Huber Style Needle Tip	Faceted Tip
Needle: Depth Markers	Same as predicate	Depth markers every 1 cm
Needle: Hub Material	Same as predicate	Medical grade polycarbonate
Needle: Hub Connection	Same as predicate	Standard Luer Lock
Stylet: Materials	Same as predicate	Stainless Steel
Stylet: Sharps Injury Prevention Feature	Includes a stylet tip safety feature	Does not include a sharps prevention feature on the stylet
Drive Adapter Hub: Materials	Same as predicate	Polycarbonate and stainless steel
Inclusion of a Needle Protective Cover	Yes, includes a cover made of polypropylene	Yes, includes a cover made of unknown material
Needle Set Sterilization Method & SAL	Same as predicate	EO, 10^{-6}
Manual Driver Attachment	Manual driver handle with integrated stylet mates with internal lumen of needle and needle hub attaches to manual driver	Manual handle attaches to needle set (i.e. assembly of needle and stylet) with magnet
Manual Driver Component Materials	Handle: ABS Stylet: Stainless Steel (304)	Handle: Polycarbonate Stylet: The manual handle does not include an integrated stylet
Manual Driver Sterilization Method	Same as predicate	EO
Manual Driver SAL	Same as predicate	10^{-6}
Powered Driver Features	Same as predicate	Cordless, Battery-powered
Powered Driver Use	Same as predicate	Reusable
Powered Driver Materials	Copolyester	Polycarbonate
Powered Driver Energy Source	Rechargeable Lithium Batteries	Lithium Batteries

Subject and Predicate Device Comparison Table		
Attribute	**Piper GO-IO® Intraosseous Infusion System (Subject Device)**	**EZ-IO® Intraosseous Infusion System (Predicate)**
Powered Driver Battery Light Indicator	4 battery light indicators to represent battery charge level	One battery light indicator
Powered Driver Needle Attachment	Same as predicate	Magnetic
Powered Driver Cleaning Method	Same as predicate	High level disinfectant
Powered Driver: Type of protection against electric shock	Internally Powered and Class II	Internally Powered
Powered Driver: Degree of protection against electric shock	Same as predicate	Type BF applied part
Powered Driver: Degree of protection against ingress of water	IP33, Spraying water and solid foreign body protection (objects >2.5mm diameter)	IPX0 Ordinary Protection
Means to Insert Needle	Same as predicate	Manual or Powered Driver
General Method of Insertion	Same as predicate	Push needle through soft tissue until it contacts bone. Confirm depth markings. Insert needle set through bone until change in pressure is felt or to desired depth. Remove stylet. Connect IV extension set.
Degree of safety or application in the presence of a flammable anesthetic mixture:	Not intended for use in an oxygen rich environment	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide

Subject and Predicate Device Comparison Table		
Attribute	**Piper GO-IO® Intraosseous Infusion System (Subject Device)**	**EZ-IO® Intraosseous Infusion System (Predicate)**
Expected Service Life (Powered Driver)	Expected service life is approximately 400 insertions. Service life expectancy is dependent on actual usage (bone density and average insertion time), storage, and frequency of testing.	The predicate device is warranted to a service life of 500 insertions. Service Life expectancy is dependent on actual usage (bone density and average insertion time), storage, and frequency of testing.
Electromagnetic Immunity and Emissions (IEC 60601-1-2)	Same as predicate	Complies with standard
Maximum RPM	Same as predicate	1587 or less

Performance Testing

The following tables identify the performance tests completed on the subject device system, including the standard followed for each test.

Needle Set Kit and Manual Driver Kit Performance Tests	Standard Followed
Needle Outer Diameter (OD)	ISO 9626: 2016
Effective Needle Length	ISO 7864: 2016
Needle Lubricity	ISO 7864: 2016
Needle Cleanliness	ISO 9626: 2016
Needle to Hub Assembly Tensile	Internal Protocol/Standard
Stylet to Drive Adapter Hub Tensile	Internal Protocol/Standard
Needle and Stylet Disassembly Force	ISO 23908: 2011
Safety Activation	FDA Guidance for Sharps Injury Prevention Features & ISO 23908: 2011
Stylet Safety Override (force to failure)	ISO 23908: 2011
Securement Dressing – Pinch Force	Internal Protocol/Standard
Securement Dressing – Peel Strength	Internal Protocol/Standard
Securement Dressing – Liner Removal	Internal Protocol/Standard
Manual Driver Hub to Stylet Tensile	Internal Protocol/Standard
Cannula Needle Resistance to Corrosion	ISO 9626: 2016
Cannula Needle Surface Finish	ISO 7864: 2016
Needle Surface Finish and Visual Appearance	ISO 9626: 2016
Needle Hub Luer	ISO 594-1: 1986 and ISO 594-2: 1998
Needle Hub Cleanliness	ISO 7864: 2016
Needle Point	ISO 7864: 2016
Needle Resistance to Breakage	ISO 9626: 2016
Needle Stiffness	ISO 9626: 2016
Gravity Flow Rate	Internal Protocol/Standard
Liquid Leak Needle Hub	Internal Protocol/Standard
Limits for Acidity or Alkalinity (Needle)	ISO 7864: 2016
Limits for Extractable Metals (Needle)	ISO 7864: 2016
Depth Markings	Internal Protocol/Standard
Chemical Resistance	Internal Protocol/Standard
Needle Durability	Internal Protocol/Standard
Manual Drilling	Internal Protocol/Standard
Packaging Integrity and Seal Strength	ISO 11607-1:2006 ASTM F88/F88M: 2015 ASTM F1886/F1886M: 2016 ASTM F1929: 2015
Sharps Injury Prevention Feature (in Simulated Clinical Use)	FDA Guidance for Sharps Injury Prevention Features & ISO 23908: 2011

Powered Drill Performance Tests	Standards Followed
Needle Set Coupling	Internal Protocol/Standard
Battery Capacity/Indicator	Internal Protocol/Standard
Battery Usable Life	Internal Protocol/Standard
Battery Indicator / State of Charge	Internal Protocol/Standard
Drill High Temperature Shut Down	Internal Protocol/Standard
Use Life	Internal Protocol/Standard
Duty Cycle	Internal Protocol/Standard
Motor Stall/Stuck Shutoff	Internal Protocol/Standard
Usability	IEC 60601-1-6: 2013
Electrical Safety and Electromagnetic Compatibility	• ANSI AAMI ES60601-1:2005/(R)2012, A1:2012, C1:2009/(R)2012, A2:2010/(R)2012 • IEC 60601-1-2: 2014 • IEC 60601-1-12: 2014 • IEC 62133: 2012
Firmware Verification and Validation	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Sterilization, Packaging, and Shelf-Life	Standard Followed
Sterilization Validation/Adoption	ISO 11135:2014
Packaging/Shelf-Life Validations	ISO 11607-1 AMD 1: 2014 ASTM F88/F88M: 2015 ASTM F1886/F1886M: 2016 ASTM F1929: 2015
Residuals	ISO 10993-7: 2008
Bacterial Endotoxin	USP <85> USP <161>

A biocompatibility evaluation was conducted on the subject device per *ISO 10993-1:2009*, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process*. According to the evaluation, the biological tests in the table below were conducted.

Biological Endpoint	Standard Followed
Cytotoxicity	ISO 10993-05: 2009
Sensitization	ISO 10993-10: 2010
Irritation/Intracutaneous Reactivity	
Acute Systemic Toxicity	ISO 10993-11: 2006
Material Mediated Pyrogenicity	
Hemocompatibility	ISO 10993-4: 2017

Summary of Substantial Equivalence

The subject device, Piper GO-IO® Intraosseous Infusion System, has the same intended use and the same fundamental scientific technology as the predicate device, EZ-IO Intraosseous Infusion System. The results of performance and biological tests conducted on the Piper GO-IO® Intraosseous Infusion System met all predetermined acceptance criteria and demonstrated that the different technological characteristics of the subject device do not raise different questions of safety and effectiveness. Based on the intended use, technological characteristics, performance and biological test results, the Piper GO-IO® Intraosseous Infusion System can be considered substantially equivalent to the cited predicate device.