March 4, 2021

Bard Access Systems, Inc. (BAS) [Wholly-owned subsidiary of BD]
Connor Dahl
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K203193
Trade/Device Name: BD Intraosseous Infusion System
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MHC
Dated: January 29, 2021
Received: February 1, 2021

Dear Connor Dahl:

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
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)*
K203193

Device Name
BD Intraosseous Infusion System

Indications for Use *(Describe)*
The BD 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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K203193

510(k) Summary for BD Intraosseous Infusion System

21 CFR 807.92(a)

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part(I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based on is presented in the following table:

General Provisions	Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly-owned subsidiary of BD]
	Submitter Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Connor Dahl Regulatory Affairs Specialist
	Telephone Number:	801.522.5834
	Fax Number:	801.522.5425
	Date of Preparation:	1/26/2021
Subject Device	Trade Name(s):	BD Intraosseous Infusion System
	Common Name:	Interosseous Infusion System
	Classification Name:	Hypodermic single lumen needle
	Class:	2
	Regulation Number:	21 CFR 880.5570
	Product Code:	MHC
	Classification Panel	General Hospital
Predicate Device	Predicate Trade Name:	Piper GO-IO® Intraosseous Infusion System
	Classification Name:	Intraosseous Infusion System
	Class:	2
	Product Code:	FMI
	Regulation Number:	21 CFR 880.5570
	Premarket Notification #:	K191976
	Manufacturer:	Piper Access, LLC
	Classification Panel:	General Hospital

Device Description	The BD 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 BD 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 BD Intraosseous Infusion System is an easy-grip, 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 BD 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 BD Intraosseous Infusion System is intended to provide clinicians and emergency personnel with access to the intraosseous space.
Indications for Use	The BD 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 BD Intraosseous Infusion System are substantially equivalent with respect to the basic design and function as compared to the predicate Piper GO-IO® Intraosseous Infusion System. The technological characteristics between the subject and predicate devices are the same, with the exception of the addition of the 35 mm and 55 mm needle lengths under review in this submission. The technological differences listed below were evaluated using industry consensus standards, validation, and as defined in the risk assessment. Therefore, the differences in technological characteristics between the subject and predicate devices do not raise new or different questions of safety or effectiveness.

The following table provides a comparison between the subject and predicate devices.

Attribute	Subject Device – BD Intraosseous Infusion System	Predicate Device – Piper GO-IO® Intraosseous Infusion System
Owner	Bard Access Systems, Inc.	Piper Access, LLC
Classification	Same as predicate	FMI – 21 CFR 880.5570
510(k) Status	Subject of this Premarket Notification	K191976 – Concurrence date November 13, 2019
Intended Use	Same as predicate	Intended to provide clinicians and emergency personnel with access to the intraosseous space.
Indications for Use	The BD 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.	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.
Commercial Name	BD Intraosseous Infusion System	Piper GO-IO® Intraosseous Infusion System
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 • The previously cleared Securement Dressing and Power Driver are not under review in this submission	• Hypodermic Needle w/Stylet • Needle Safety Cap • Securement Dressing • Powered Driver

			• Manual Driver
	Needle: Dwell Time	Same as predicate	24 hours or less
	Needle: Use	Same as predicate	Single Use
	Needle Lengths	Needle lengths with corresponding tissue depth recommendations: • 15mm (0-10 mm tissue depth) • 25mm (0-20 mm tissue depth) • 35mm (10-30 mm tissue depth) • 45mm (20-40 mm tissue depth) • 55mm (30-50 mm tissue depth)	Needle lengths with corresponding patient weight recommendations: • 15mm (3-39kg) • 25mm (>3kg) • 45mm (>40kg)
	Needle: Outer Diameter	Same as predicate	15 gauge
	Needle: Materials	Same as predicate	304 Stainless Steel
	Needle: Tip Design	Same as predicate	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	Same as predicate	Includes a stylet tip safety feature
	Drive Adapter Hub: Materials	Same as predicate	Polycarbonate and stainless steel

	Inclusion of a Needle Protective Cover	Same as predicate	Yes, includes a needle cover made of polypropylene
	Needle Set Sterilization Method & SAL	Same as predicate	Ethylene Oxide, 10^{-6}
	Manual Driver Attachment	Same as predicate	Manual driver handle with integrated stylet mates with internal lumen of needle and needle hub attaches to manual driver
	Manual Driver Component Materials	Same as predicate	Handle: ABS Stylet: Stainless Steel
	Manual Driver Sterilization Method and SAL	Same as predicate	Ethylene Oxide, 10^{-6}
	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.

Safety & Performance Tests

The following performance tests were conducted in determining substantial equivalence of the BD Intraosseous Infusion System to the predicate Piper GO-IO® Intraosseous Infusion System:

Needle Set Kit and Manual Driver Kit Performance Tests	Standard Followed
Needle Outer Diameter (OD)	ISO 9626: 2016 and Internal Protocol/Standard
Needle Length	Internal Protocol/Standard
Needle Lubricity	ISO 7864: 2016
Needle Quality, Surface Finish, and 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	Internal Protocol/Standard	
	Safety Activation	FDA Guidance for Sharps Injury Prevention Features & ISO 23908: 2011	
	Stylet Safety Override (force to failure)	ISO 23908: 2011	
	Manual Driver Hub to Stylet Tensile	Internal Protocol/Standard	
	Needle Resistance to Corrosion	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 and Internal Protocol/Standard	
	Gravity Flow Rate	Internal Protocol/Standard	
	Liquid Leak Needle Hub	Internal Protocol/Standard	
	Limits for Acidity or Alkalinity (Needle)	ISO 9626: 2016 / ISO 7864: 2016	
	Limits for Extractable Metals (Needle)	ISO 7864: 2016	
	Depth Markings	Internal Protocol/Standard	
	Insertion Force	Internal Protocol/Standard	
	Needle Bone Retention – Needle Point OD	Internal Protocol/Standard	
	Packaging Integrity and Seal Strength	ISO 11607-1:2006 ASTM F88/F88M: 2015 ASTM F1886/F1886M: 2016 ASTM F1929: 2015	
	Device Usability/Simulated Use	Internal Protocol/Standard	

Sharps Injury Prevention Feature (Simulated Clinical Use)	FDA Guidance for Sharps Injury Prevention Features & ISO 23908: 2011

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
Sterilant 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

Technological Comparison to Predicate Device	The subject device, BD Intraosseous Infusion System, has the same intended use and the same fundamental scientific technology as the predicate device, Piper GO-IO® Intraosseous Infusion System. The main difference between the subject device is the addition of the 35 mm and 55 mm needle lengths as compared to the predicate device needle lengths. This technological difference was assessed by the performance of verification testing to applicable test standards and the performance of additional user validation to address the acceptability and risks associated with the new subject device needle lengths. The results of the user validation, performance (verification and validation testing) and biological tests conducted on the BD 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 BD Intraosseous Infusion System can be considered substantially equivalent to the cited predicate device.
Summary of Substantial Equivalence	Based on the risk management activities and testing, the subject BD Intraosseous Infusion System has been demonstrated to be substantially equivalent to the cited predicate device.