September 28, 2023

Becton Dickinson Infusion Therapy Systems, Inc.
Amy Moore
Senior Regulatory Affairs Specialist
9450 S State St
Sandy, Utah 84070

Re: K230865
Trade/Device Name: PIVO™ Pro Needle-free Blood Collection Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: August 25, 2023
Received: August 28, 2023

Dear Amy Moore:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Porsche Bennett
For David Wolloscheck, Ph.D.
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)*
K230865

Device Name
PIVO™ Pro Needle-free Blood Collection Device

Indications for Use *(Describe)*

The PIVO™ Pro Needle-free Blood Collection Device attaches to a peripheral IV catheter system for use to obtain venous blood specimens into a vacuum tube or syringe from adult and pediatric patients, including those with difficult intravenous access who may have small, fragile, and/or non-palpable veins.

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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K230865 510(k) Summary (21 CFR §807.92)

PIVO™ Pro Needle-free Blood Collection Device

Submitter Information	Submitter Name:	Becton Dickinson Infusion Therapy Systems Inc.
	Submitter Address:	9450 South State Street, Sandy, Utah 84070
	Contact Person:	Amy Moore, Sr. Regulatory Affairs Specialist
	Email Address:	amy.moore@bd.com
	Phone Number:	(801) 522-5000
	Date of Preparation:	September 28, 2023
Subject Device	Trade Name:	PIVO™ Pro Needle-free Blood Collection Device
	Common Name:	Blood Collection Device
	510(k) Reference:	K230865
	Regulation Number:	21 CFR §862.1675
	Regulation Name:	Blood Specimen Collection Device
	Regulatory Class:	II
	Product Code:	JKA
	Classification Panel:	General Hospital
Predicate Device	Trade Name:	PIVO™ Needle-free Blood Collection Device
	Common Name:	Blood Collection Device
	510(k) Reference:	K193569
	Regulation Number:	21 CFR 862.1675
	Regulation Name:	Blood Specimen Collection Device
	Regulatory Class:	II
	Product Code:	JKA
	Classification Panel:	General Hospital
Reason for Submission	The purpose of this submission is to notify the FDA of the introduction of PIVO™ Pro Needle-free Blood Collection Device, allowing for compatibility with a peripheral IV catheter with NearPort™ IV Access and addition of a patient population statement to the Indications for Use.	
Device Description	The PIVO™ Pro Needle-free Blood Collection Device is a sterile, single use needle-free collection device that attaches to a peripheral intravascular catheter (IV) system. The device is comprised of an inner flow tube with a slider, proximal flexible tube	

	with female Luer, outer housing, and winged clip on the distal end. The winged clip attaches to the IV system. The female Luer attaches to an evacuated tube holder or syringe. The inner flow tube is then advanced to collect a blood sample. Once complete, the inner flow tube is retracted, and the device is removed from the IV. The device is available in three sizes: 20GA, 22GA, and 24GA IV compatible. The device is compatible with the corresponding IV gauge and larger IV catheters. The PIVO™ Pro Needle-free Blood Collection Device is compatible with peripheral IV catheters and extension sets with NearPort™ IV Access.
Indications for Use (21 CFR § 807.92(a)(5))	The PIVO™ Pro Needle-free Blood Collection Device attaches to a peripheral IV catheter system for use to obtain venous blood specimens into a vacuum tube or syringe from adult and pediatric patients, including those with difficult intravenous access who may have small, fragile, and/or non-palpable veins.
Technological Characteristics	Technological characteristics of the subject device are substantially equivalent to the predicate device. The subject PIVO™ Pro Needle-free Blood Collection Device achieves its intended use based on the same technology and principles of operation as the predicate device. A comparison of the subject and predicate device technological characteristics is provided in the table below.

Attribute	SUBJECT (K230865) PIVO™ Pro Needle-free Blood Collection Device	PREDICATE (K193569) PIVO™ Needle-free Blood Collection Device	Comparison & Discussion
Classification	21 CFR 862.1675 Class II JKA – Blood Specimen Collection Device	21 CFR 862.1675 Class II JKA – Blood Specimen Collection Device	Same
Indications for Use	The PIVO™ Pro Needle-free Blood Collection Device attaches to a peripheral IV catheter system for use to obtain venous blood specimens into a vacuum tube or syringe from adult and pediatric patients, including those with difficult intravenous access who may have small, fragile, and/or non-palpable veins.	The PIVO™ device is attached to a peripheral IV catheter for use as a direct blood draw device into a vacuum tube or a syringe.	Minor grammatical wording changes with no change to meaning. Addition of a patient population statement, with specific reference to pediatric patients and patients with DIVA (difficult intravenous access) which are subsets of 'General Use' and do not introduce new risks not normally associated with the general use of the subject device. Therefore, modifications, do not raise

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Attribute	SUBJECT (K230865) PIVO™ Pro Needle-free Blood Collection Device	PREDICATE (K193569) PIVO™ Needle-free Blood Collection Device	Comparison & Discussion
			new or different questions of safety or effectiveness.
Intended Use	Venous blood draw	Venous blood draw	Same
Patient Interface	Separately placed commercially available peripheral IV catheter	Separately placed commercially available peripheral IV catheter	Same
PIV Attachment	Clip-to-Connect	Clip-to-Connect	Same
Blood Collection Attachment	Female Luer to Blood Transfer Device or Syringe	Female Luer to Blood Transfer Device or Syringe	Same
Blood Control Mechanism	Cap on female luer and clamp on flexible tubing	Cap on female luer and clamp on flexible tubing	Same
Tubing	Transparent Flexible	Transparent Flexible	Same
Primary Components Material Composition			
ISO 10993-1 Biocompatibility Contact Type and Duration	Body Contact: Externally communicating device Contact: Circulating blood Contact Duration: Limited (A) (<24 hrs)	Body Contact: Externally communicating device Contact: Circulating blood Contact Duration: Limited (A) (<24 hrs)	Same
Housing	Polycarbonate	Polycarbonate	Same
Inner Flow Tube	Polyimide	Polyimide	Same
Proximal Tubing	Vestamid	Vestamid	Same
Luer	Nylon	Nylon	Same
Slider (Pusher)	Nylon	Nylon	Same
Winged Clip	Polycarbonate	Polycarbonate	Same
Clamp	Nylon	HDPE	Same
Color	Pink Blue Yellow	Pink Blue Yellow	Same
Compatible PIV Sizes	The device is available in three sizes: 20 GA, 22 GA, and 24 GA IV compatible. The device is compatible with the corresponding IV gauge and larger IV catheters.	14 GA – 24 GA	Clarification only. Both the predicate and subject devices are available in three sizes: 20GA, 22GA and 24 GA IV compatible, as indicated on the product label. The subject and predicate devices are compatible with the

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Attribute	SUBJECT (K230865) PIVO™ Pro Needle-free Blood Collection Device	PREDICATE (K193569) PIVO™ Needle-free Blood Collection Device	Comparison & Discussion
			corresponding IV gauge and larger IV catheters. For example, a 20GA IV compatible subject or predicate device can be used with a 20GA or larger IV catheter (e.g., 18GA). The clarification does not change the use of the device or device specifications and, therefore, does not raise new or different questions of safety or effectiveness.
Proximal Tubing	Transparent Flexible	Transparent Flexible	Same
Inner Flow Tube (Distal Tubing) Length	20 GA = 155.28 mm 22 GA = 155.28 mm 24 GA = 132.68 mm	20 GA = 141.2 mm 22 GA = 141.2 mm 24 GA = 141.2 mm	The results of design validation and verification testing demonstrate that the modifications to the subject device perform as intended and do not raise new or different questions of safety or effectiveness.
Outer Diameter (OD) of Inner Flow Tube (Distal Tubing)	20 GA = 0.709 mm max 22 GA = 0.543 mm max 24 GA = 0.400 mm max	20 GA = 0.709 mm max 22 GA = 0.543 mm max 24 GA = 0.400 mm max	Same
Wall Thickness of Inner Flow Tube (Distal Tubing)	20 GA = 0.709 mm 22 GA = 0.0635 mm 24 GA = 0.0575 mm	20 GA = 0.709 mm 22 GA = 0.0635 mm 24 GA = 0.0575 mm	Same
Sample collection	Device attaches to female luer of PIV system, tube inserted into PIV, blood is drawn through tube into a blood transfer device	Device attaches to female luer of PIV system, tube inserted into PIV, blood is drawn through tube into a blood transfer device	Same
Packaging Material	Tyvek/PET OR Nylon/Nylon	Tyvek/PET OR Nylon/Nylon	Same
Complete Retraction	Yes	Yes	Same

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Attribute	SUBJECT (K230865) PIVO™ Pro Needle-free Blood Collection Device	PREDICATE (K193569) PIVO™ Needle-free Blood Collection Device	Comparison & Discussion
Sterilization Method	Gamma	Gamma	Same
Single Use Only	Yes	Yes	Same

Summary of Performance Tests

Performance tests completed on the subject devices were limited to those tests required to support a determination of substantial equivalence to the predicate device. A risk analysis was conducted to assess the impact of the proposed modifications to the predicate device. When technological characteristics between the subject and predicate devices were found to be identical, results of performance testing conducted on the predicate devices were applied to the subject device. The performance tests listed below were conducted to ensure that the subject device meets predetermined design requirements:

1) Compliance Testing
   - Biocompatibility (ISO 10993-1)
     - Body contact: Externally communicating device
     - Contact: Circulating blood
     - Contact duration: Limited (A) (<24 hrs)
   - Packaging Testing (ASTM D4169)
   - Sterilization Validation (ISO 11137-1)
2) BD Internal Studies
   - Catheter Gauge Compatibility
   - Extension Length
   - Catheter Perforation
   - Insertion
   - Alignment
   - Atraumatic Tip
   - Flow Rate
   - Hemolysis
   - Pusher Pull Force
   - Blood Leak
   - Pressure Leak
   - Vacuum Leak
3) Packaging verification testing per *ISO 11607-1 Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems*

	4) Usability testing per *Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff*, issued February 2016 Per design control requirements specified in 21 CFR 820.30, the subject device met all predetermined acceptance criteria for the above-listed performance tests, demonstrating substantial equivalence to the predicate devices. Clinical studies are not required to demonstrate substantial equivalence to the predicate device.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and results of performance testing, the subject PIVO™ Pro Needle-free Blood Collection Device has been demonstrated to be substantially equivalent to the predicate PIVO™ Needle-free Blood Collection Device.