June 20, 2025

Becton Dickinson
Tim Wade
Associate Director, Regulatory Affairs
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K243062
Trade/Device Name: BD Intelliport System; BD Intelliport Reader (516230); BD Intelliport Sensor (516229); BD Intelliport Gateway (516232); BD Intelliport Mount (516233); BD Intelliport Charger (516231)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PHC, FPA
Dated: May 23, 2025
Received: May 23, 2025

Dear Tim Wade:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

for Kyran R. Gibson -S

Shruti Mistry
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243062

Device Name

BD Intelliport System;
BD Intelliport Reader (516230);
BD Intelliport Sensor (516229);
BD Intelliport Gateway (516232);
BD Intelliport Mount (516233);
BD Intelliport Charger (516231)

Indications for Use *(Describe)*

The BD Intelliport™ System is an automated record keeping system that incorporates patient safety features that are aligned with hospital patient records and protocols. The system is comprised of an injection port and software that enables the identification, measurement, alerting and documentation of the administration of medications to patients.
The BD Intelliport™ System allows the clinician to record anesthesia-related medication administration events during pre-procedure, intra-procedure and recovery phase. The system is indicated for use by healthcare professionals in a hospital or medical center setting with patients who are receiving manually administered bolus intravenous injections as part of their care to facilitate documentation of the medications.

The BD Intelliport™ System is intended for patients with body weights >20 kg.

Do not use the BD Intelliport™ System with blood, blood products, biologics, or chemotherapeutics.

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.

BD Intelliport™ System
510(k) Summary
21 CFR 807.92

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 is as follows:

Submitter Information:

Becton Dickinson (BD)
One Becton Drive
Franklin Lakes, NJ USA 07417
Contact Person: Tim Wade, Associate Regulatory Affairs Director
Tel: 602.830.5330

Date Prepared:

June 17, 2025

Subject Device:

Device Trade Name	BD Intelliport™ System
510(k) Number	K243062
Regulation Number	21 CFR 880.5725 21 CFR 880.5440
Classification Product codes:	PHC, FPA
Device Classification Name	Infusion Safety Management Software; Set, Administration, Intravascular
Review Panel	General Hospital

Predicate Device:

Device Trade Name	BD Intelliport™ System
510(k) Number	K182092
Regulation Number	21 CFR 880.5725 21 CFR 880.5440
Classification Product codes:	PHC, FPA
Device Classification Name	Infusion Safety Management Software; Set, Administration, Intravascular
Review Panel	General Hospital

Device Description

BD Intelliport™ System integrates into an intravenous line and automatically captures information about the anesthesia medications administered to the patient. It wirelessly transmits anesthesia medication administration information to the patient's Electronic Medical Record (EMR) via hospital server applications (Gateway software). The BD Intelliport™ System provides core technologies that enable key functions of the system:

- Medication Identification: Informs clinician of medication and concentration along with any informational notifications such as patient allergy and expired medication reminders. This occurs when syringes with the correct type of RFID encoded label are attached.

- Dose Measurement: Measures volume of drug administered to the patient through the system, then calculates dose weight.

- Automatic Charting: Wirelessly transmits measured doses to the EMR.

The following are the main system components:

- BD Intelliport™ Injection Site which is comprised of the following two components:
    - BD Intelliport™ Sensor
    - BD Intelliport™ Reader
- BD Intelliport™ Mount (optional accessory)
- BD Intelliport™ 2-Bay Charger (accessory)
- BD Intelliport™ Gateway

Indications for Use:

The BD Intelliport™ System is an automated record keeping system that incorporates patient safety features that are aligned with hospital patient records and protocols. The system is comprised of an injection port and software that enables the identification, measurement, alerting and documentation of the administration of medications to patients.

The BD Intelliport™ System allows the clinician to record anesthesia-related medication administration events during pre-procedure, intra-procedure and recovery phase. The system is indicated for use by healthcare professionals in a hospital or medical center setting with patients who are receiving manually administered bolus intravenous injections as part of their care to facilitate documentation of the medications.

The BD Intelliport™ System is intended for patients with body weights >20 kg.

Do not use the BD Intelliport™ System with blood, blood products, biologics, or chemotherapeutics.

Comparison to Predicate Device:

The subject BD Intelliport System has the following similarities to the predicate BD Intelliport System (K182092):

- Same intended use
- Same patient population and users
- Same fundamental scientific technology
- Same mechanism of action
- Same sterility assurance levels
- Similar materials

The subject and predicate devices have the following differences:

- Improved flow algorithm
- Modified indications for use
- Modifications to system components and design
- RFID reading capability
- Updated Cybersecurity profile

A detailed comparison of technological characteristics is provided in the table below:

Attribute	Subject Device (BD Intelliport System)	Predicate Device (K182092– BD Intelliport System)	Significance to Substantial Equivalence
Intended Use/ Indications for Use			
Intended Use	The BD Intelliport System is intended to automate the record keeping of bolus intravenous injections.	The BD Intelliport system is intended to automate the record keeping of bolus intravenous injections.	Identical
Indications for Use	The BD Intelliport system is an automated record keeping system that incorporates patient safety features that are aligned with hospital patient records and protocols. The system is comprised of an injection port and software that enables the identification, measurement, alerting and documentation of the administration of medications to patients. The BD Intelliport system allows the clinician to record anesthesia-related medication administration events during pre-procedure, intra-procedure, and recovery phase. The system is indicated for use by healthcare professionals in a hospital or medical center setting with patients who are receiving manually administered bolus intravenous injections as part of their care to facilitate documentation of the medications.	The BD Intelliport system is an automated record keeping system that incorporates patient safety features that are aligned with hospital patient records and protocols. The system is comprised of an injection port and software that enables the identification, measurement, alerting and documentation of the administration of medications to patients. The BD Intelliport system allows the clinician to record anesthesia-related medication administration events during preop, intra-op, and PACU. The system is indicated for use by healthcare professionals in a hospital or medical center setting with patients who are receiving manually administered bolus intravenous injections as part of their care to facilitate documentation of the medications.	Different The indications for use remain unchanged between the subject device and the predicate device except for the change from preop, intra-op, and PACU to pre-procedure, intra- procedure and recovery phase to clarify that the subject device can be used in different use environments, by qualified clinicians as substantiated by the human factors testing. The removal of the contraindication "The BD Intelliport System is not intended for use with refrigerated medications (excluding cefazolin)" is appropriately substantiated by the verification and validation testing.

Attribute	Subject Device (BD Intelliport System)	Predicate Device (K182092– BD Intelliport System)	Significance to Substantial Equivalence
	The BD Intelliport™ system is intended for patients with body weights >20 kg. Do not use the BD Intelliport™ System with blood, blood products, biologics, or chemotherapeutics.	The BD Intelliport™ system is intended for patients whose body weights are >20kg. The BD Intelliport™ system is not intended for use with blood, blood products, biologics, or chemotherapeutics. The BD Intelliport™ system is not intended for use with refrigerated medications (excluding cefazolin).	
Technology and Design			
Components	• Intelliport Injection Site which consists of: o Intelliport Reader o Intelliport Sensor • Intelliport Gateway (software) • Intelliport 2-Bay Charger (accessory) • Intelliport Mount (optional accessory)	• Intelliport Injection Site which consists of: o Intelliport Base o Intelliport Sensor • Intelliport Tablet • Intelliport Radio • Intelliport Gateway (software) • Intelliport 5-Bay Charger (accessory)	Different Modifications have been made to the subject device design to allow for improved user interaction. Additional offering of optional mount accessory.
Syringe reading capability	RFID labeled drug syringes	2D Barcode labeled drug syringes	Different Both devices utilize electronically encoded medication syringes. Differences have been qualified through verification testing.
Compatible Accessories	• 1 mL-30 mL luer lock syringes • Intravenous (IV) administration tubing and IV extension sets and accessories having luer lock connectors.	• 1 mL-60 mL luer lock syringes • Intravenous (IV) administration tubing and IV extension sets and accessories having luer lock connectors.	Different The subject device has limited the size of luer lock syringes within the range of the predicate devices. Differences have been qualified through verification and human factors testing.

Attribute	Subject Device (BD Intelliport System)	Predicate Device (K182092– BD Intelliport System)	Significance to Substantial Equivalence
Flow Algorithm	Algorithm calculates velocity based on transit time, the speed of sound of the material and the fluid path length	Algorithm calculates velocity based on transit time, the speed of sound of the material and the fluid path length	Different The fundamental design of the algorithm between the predicate and subject devices is the same. The subject device calculations have been updated to allow for broader range of drugs, including refrigerated medications. This has been qualified through verification testing.
Injection Site: Sensor			
Physical/ Mechanical Specifications (Sensor)	Fluid Connection: 2 ports, BD Luer-Lok™ connector Port: 3-way stopcock with integrated BD SmartSite™ needle free valve Useful Life: >24hrs to 30 days Sensor Dead Volume: ≤0.12 mL following injection. Port Capacity: 120 Injections	Fluid Connection: 1 ports, BD Luer-Lok™ type fitting Port: BD Q-Syte™ needle free valve Useful Life: >24hrs to 30 days Sensor Dead Volume: <0.3 mL Port Capacity: 100 Injections	Different Differences in tolerances and dimensions between the subject device and predicate device are made to accommodate improved design features. Design verification and validation testing demonstrates that the subject device performs as intended.
Injection Site: Reader			
Function	Reader decodes drug information from sensor, displays information on screen, and communicates drug information to the gateway. Serves as user interface for clinician.	Tablet decodes drug information from sensor, displays information on screen, and communicates drug information to the gateway. Serves as user interface for clinician.	Identical Although the tablet component has been changed to the reader their function is identical.

Attribute	Subject Device (BD Intelliport System)	Predicate Device (K182092– BD Intelliport System)	Significance to Substantial Equivalence
Computing Platform Operating Systems	Modified proprietary embedded software	Proprietary embedded software	Different The updated operating systems have been qualified through software, cybersecurity and design verification activities.
Volume measurement accuracy	± 10% (for volumes >1.0 mL) ± 0.2mL (for volumes 0.4 – 1.0 mL)	± 10% (for volumes >1.0 mL) ± 0.2mL (for volumes 0.4 – 1.0 mL)	Identical
Volume Measurement Resolution	Uniform increments of 0.5 mL	Uniform increments of 0.5 mL	Identical
Volume Measurement Performance Window	Average Push Speed: 10ml/min to 400 ml/min Volume Range: 0.5ml to 30ml	Average Push Speed: 10ml/min to 400 ml/min Volume Range: 0.5ml to 60ml	Different The subject device lowers the upper limit of the volume range from 60ml to 30ml. This change has been qualified through verification and human factors testing.
Notifications	Includes Drug Name and Concentration Visual and auditory notification on the screen Alerts for allergy, antibiotic dosing reminder, and expired medication alerts	Includes Drug Name and Concentration Alerts for allergy and antibiotic dosing reminder Visual and auditory notification on the screen	Different Addition of expired medication alerts has been qualified through design verification and validation testing.
Dose History List	Contains doses sent to the EMR Contains doses missing drug name and concentration Contains doses flagged with a potential volume error message	Contains doses sent to the EMR Contains doses missing drug name and concentration Contains doses flagged with a potential volume error message	Identical

Attribute	Subject Device (BD Intelliport System)	Predicate Device (K182092– BD Intelliport System)	Significance to Substantial Equivalence
Charger (Hardware)			
Specifications	Storage Capacity: 2 Readers Input Voltage: 100-240 VAC, 50 – 60Hz Output Voltage: 5V Output Current: 3A	Storage Capacity: 5 Bases Input Voltage: 100-240 VAC, 50 – 60 Hz Output Voltage: 5V Output Current: 4A	Different The updated charger has been qualified as part of design verification activities.
Gateway (Software)			
EMR connectivity	Send/receive medication data to/from EMR	Send/receive medication data to/from EMR	Identical
Encoded drug table (EDT)	306 drugs on ISDT (Intelliport System Drug Table)	161 drugs on EDT (Encoded Drug Table)	Different The subject device algorithm has been updated to allow for additional drugs to be qualified as part of design verification testing.
Provisioning	Semi-automated method to provision the device on network	Manual method to provision the device on network	Different The subject device has been updated to provide a semi-automated way of connecting to Wifi to improve use of the system and has been qualified through software testing.
System			
Software Documentation Level	Enhanced documentation level	Major level of concern – Class C	Identical The level of concern/documentation level is the same between the predicate and subject devices.

Attribute	Subject Device (BD Intelliport System)	Predicate Device (K182092– BD Intelliport System)	Significance to Substantial Equivalence
Biocompatibility	Biocompatible per ISO 10993-1 Sensor: Externally communicating medical device with blood path, indirect patient contact. Prolonged contact (>24 hr to 30 days) Reader: Direct contact with intact skin. Prolonged contact (>24 hours to 30 days) Mount & Charger: No patient contact	Biocompatible per ISO 10993-1 Sensor: Externally communicating medical device with blood path, indirect patient contact. Prolonged contact (>24 hr to 30 days) Base: Direct contact with intact skin. Prolonged contact (>24 hours to 30 days) Charger: No patient contact	Identical Both devices share common contact duration and type of intended tissue contact for the Injection system (reader and sensor). The biological evaluation, conducted in accordance with ISO10993-1, demonstrated that the subject device (sensor and reader) is biocompatible for its intended use.
Electrical Safety & Electromagnetic Compatibility	Conformity to IEC 60601-1 IEC 60601-2	Conformity to IEC 60601-1 IEC 60601-2	Identical The updated design of the subject device has been tested for electrical safety and electromagnetic compatibility.
Sterilization	Sensor: Sterile, Single Use, e-beam, SAL 10^{-6} Reader: Non-sterile, Reusable Mount: Non-sterile, Reusable Charger: Non-sterile, Reusable	Sensor: Sterile, Single Use, Ethylene Oxide, SAL 10^{-6} Base: Non-sterile, Reusable Tablet: Non-sterile, Reusable Charger: Non-sterile, Reusable	Different Both devices have components delivered sterile or non-sterile and both are sterilized using FDA established methods. The sterility of the subject is supported by sterilization validation testing.

Performance Testing

To demonstrate substantial equivalence of the subject device to the predicate device, non-clinical testing was conducted. Using FDA Guidance, recognized consensus standards, and internal requirements the following tests were conducted on the subject device:

- Sensor Testing
  - Bolus volume measurement accuracy
  - Sensor barcode scan
  - Sensor flow rate
  - Sensor readiness
  - Sensor detect
  - Detachment force of sensor from reader
  - Sensor tensile and leak testing
  - Syringe attachment and detachment detection
  - Smartvalve detection
  - Sensor IV Port ISO 80369-7 Testing
  - Smartsite™ 80369-7 Testing
  - Particulate Testing per USP 788 & ISO 8536-4

- Reader Testing
  - Cleaner compatibility
  - Charging initiation
  - Audio test
  - User reader touchscreen interaction
  - Decoding barcode symbology
  - Sensor detect
  - Reader Sensor Barcode Scan
  - Smartvalve Detection
  - Syringe attachment and detachment detection
  - Reader syringe decoding coverage test
  - Reader false read
  - Decoding response time
  - Wifi functionality
  - Dose transmission time
  - Bolus volume measurement under operating environmental conditions
  - Battery charging test

- Mount Testing
  - Positive indication upon injection site attachment
  - Retention force of injection site to mount
  - Usage life

- Charger Testing
    - Charger stays in place during use
    - One handed insertion and removal
    - Charge bay keyed for installation
    - Bay powered when reader installed
    - Output current
    - Operating temperature
    - Cleaning chemical compatibility
    - LED light indicator
    - Reader screen visibility
    - Verify charger does not scratch reader
    - Dimensions/weight
    - Surface temperature limits
    - Reverse input polarity protection
    - Wear resistance
    - Drop test
    - Power supply cord length
- Software validation & cybersecurity assessment
- Reprocessing/cleaning validation
- Electromagentic Compatibility, Wireless, and Electrical, Mechanical, and Thermal (EMT) Safety Testing
- Biocompatibility
- Packaging Testing

Human Factors Evaluation

A human factors evaluation, including formative and summative usability studies were conducted to assess critical tasks completed by intended device users while operating the device. Testing was conducted in accordance with FDA guidance "Applying Human Factors and usability Engineering to medical devices" (2016). The results of the studies and the analysis of residual risk, show that the use-related risks associated with the Intelliport™ System have been mitigated to acceptable levels and support that the subject device does not raise different questions of safety or effectiveness.

Conclusion

The subject device, the BD Intelliport™ System, has met all predetermined acceptance criteria for the non-clinical and human factors testing conducted in accordance with relevant FDA guidance, recognized consensus standards, and internal requirements. The differences in

technological characteristics do not change the intended use of the device and the testing conducted supports the technology changes do not raise different questions of safety or effectiveness when compared to the predicate device. Therefore, the subject device is considered substantially equivalent to the predicate BD Intelliport™ System.