Becton, Dickinson, and Company
Rahul Ram
Senior Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K182092
Trade/Device Name: BD Intelliport System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: PHC
Dated: August 1, 2018
Received: August 3, 2018

Dear Rahul Ram:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sarah Mollo

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K182092

Device Name
BD Intelliport System, Version 1.2

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 in the pre-op, 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.

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).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

BD Intelliport™ Medication Management System, Version 1.2

1 Introduction

As per 21 CFR 807.92, this document is a “510(k) Summary,” a summary basis for a determination of substantial equivalence of the BD Intelliport Medication Management System, Version 1.2, to the cited predicate device (the BD Intelliport System, cleared under K141474).

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Franklin Lakes, NJ 07417
Tel: 201.847.6800
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2 Submission Administrative Details

510(k) Type:	Traditional
Device Trade Name:	BD Intelliport™ Medication Management System, Version 1.2
Device Common Name:	Automated Medication Record Keeping System
Applicant:	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417, USA
Primary Contact:	Rahul Ram Senior Staff Regulatory Affairs Specialist BD Medical – Medication and Delivery Solutions Tel: +1 (201) 847-4712 Fax:+1 (201) 847-5307 Email: rahul.ram@bd.com
Alternate Contact:	John Roberts Associate Director, Regulatory Affairs BD Medical – Medication and Delivery Solutions Tel: +1 (201) 847-4760 Fax: + 1 (201) 847-5307 Email: john.w.roberts@bd.com
Classification Regulation:	21 CFR 880.5725
Classification:	Class II
Panel:	General Hospital
Product Codes:	PHC, FPA
Legally Marketed Predicate Device:	K141474 (BD Intelliport System)

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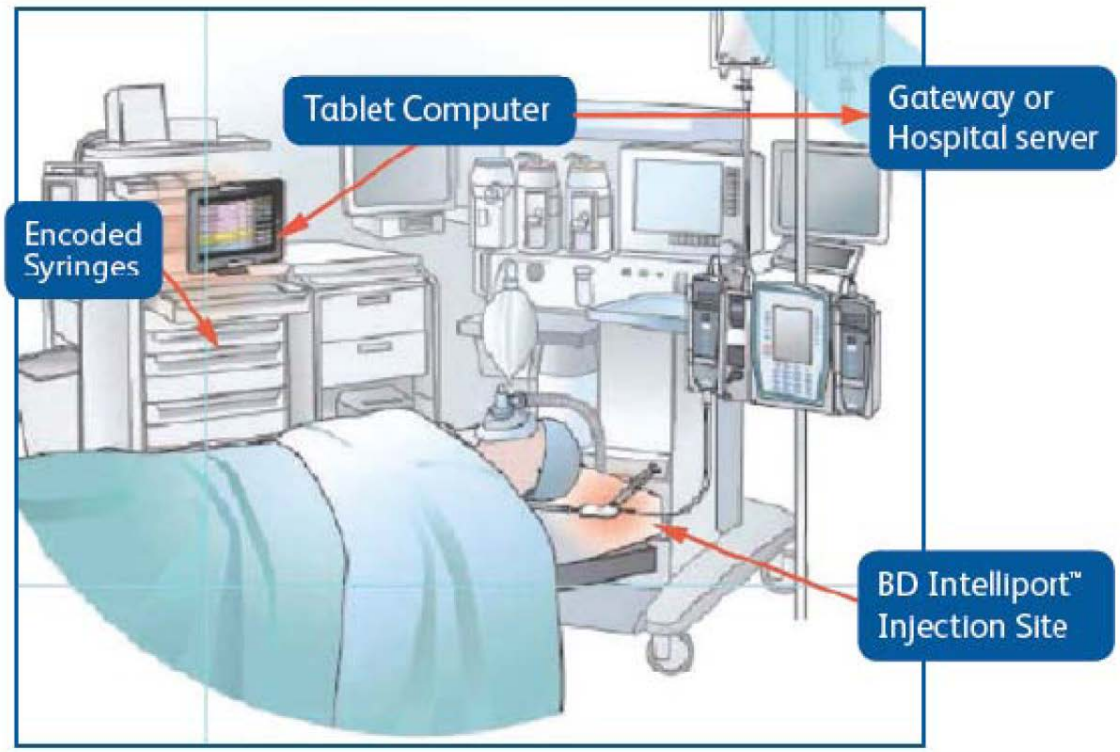
3 Summarized Device Description



Like the cited predicate device, the BD Intelliport Medication Management System, Version 1.2 is a system of hardware and software components that measures the delivered volume of intravenous (IV) bolus medications associated with anesthesia-related, medication administration events in the pre-op, intra-op, and PACU, and provides automated documentation of medication identity, concentration, dose, delivered volume, and delivery timestamp to the hospital electronic medical record (EMR) system. There are two modes: EMR mode and Standalone mode. Standalone mode allows for printing dose history reports, but is not connected to an EMR

The device is organized by three subsystems, each of which includes several physical/software components:

- Injection Site subsystem
- Tablet subsystem
- Gateway subsystem

The Injection Site subsystem is composed of two physical components (the Base and the ultrasonic Sensor) and the software residing inside the Base. The Tablet subsystem is composed of one physical component (the Tablet) and the software residing inside the Tablet. The Gateway subsystem consists of the Gateway

software and the hospital server hardware on which the Gateway software resides. The device also includes an accessory for charging up to five Bases simultaneously.

During treatment, the clinician connects an intelligent injection port (the Injection Site) to a patient's fluid-delivery line and performs standard drug-delivery activities. The clinician injects the drug using BD Luer Lok, 1-60ml size syringes only, and then flushes with a separate normal, saline syringe. Flushing after each administration ensures all medication is administered to patient since there is a 0.334 ml dead space.

The device can be used with both encoded and non-coded syringes. If an encoded syringe is used, the device reads the two-dimensional barcode adhered to the syringe. The barcode contains information about the content in the syringe including the drug name and concentration. If a noncoded syringe is used, then the end user is prompted by the Tablet software to pick the drug name and concentration from the Encoded Drug List (EDL). When an encoded syringe is first connected to the device, the name of the drug is read back to the clinician and an allergy alert will trigger on the Injection Site base if the patient is allergic to the medication based on the patient's allergies record in their EHR (electronic health record). As the drug is injected, the device measures the volume of the injected drug via an ultrasonic sensor and records the time the drug was administered. Drug delivery information is stored and inserted into the patient's EHR by way of the Tablet and Gateway software in the EMR mode and available for printing in the Standalone mode.

4 Indications for Use

The indications for use statement of the BD Intelliport Medication Management System, Version 1.2 is the following:

> 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 in the pre-op, 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.*
>
> *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.*

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The BD Intelliport™ system is not intended for use with refrigerated medications (excluding cefazolin)

5 Technological Characteristics

The BD Intelliport Medication Management System, Version 1.2 is a modified version of the predicate device, the BD Intelliport System (cleared under K141474). The following is a list of differences between the two devices:

- Modification of the volume measurement algorithm to improve accuracy and precision, in addition to specification changes
- Change volume measurement accuracy specification from 5% and 10%, and provide “Enter Dose” message for any drugs outside of the 10% specification
- Increase the number of drugs in the Edited Drug List from 70 drugs to 161 drugs
- Addition of new error message and software popup screen at start up
- Update labeling to clarify dead space specification (0.334 mL)
- Add mandatory template login password
- Add default enabled audio at beginning of each case, and after care transition
- Resolution of software bugs
- Incremental improvements to improve reliability
- Removal of software features to simplify clinical workflow (i.e., removal of the orders and infusion features)
- Addition of features related to technician maintenance (i.e., the introduction of remote services (RSS) and remote technician login)
- Modification of the format whereby volume measurements are presented to the user (i.e., measurements are now rounded to the nearest 0.5 mL, to align with standard dosing units in clinical practice).
- Minor dimensional and production tolerance changes, as well electronic layout updates of various physical components

6 Substantial Equivalence

The following table provides a comparison of technological characteristics between the predicate and subject device:

Characteristic	Predicate Device	Subject Device	Comments
Manufacturer	Becton Dickinson & Company	Becton Dickinson & Company	Identical

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Characteristic	Predicate Device	Subject Device	Comments
Base	Attaches to Sensor to provide communication to Tablet, measures dose volume based upon Sensor raw data	Attaches to Sensor to provide communication to Tablet, measures dose volume based upon Sensor raw data	Physically identical, firmware updates (see *below*)
Sensor	Provides medication fluid path and raw data for dose volume measurement	Provides medication fluid path and raw data for dose volume measurement	Identical
Tablet	Provides dose history user interface and communication to Gateway	Provides dose history user interface and communication to Gateway	Physically identical, software updates (see *below*)
Gateway	Provides for connection to EMR (EMR mode only) and storage of dose history information	Provides for connection to EMR (EMR mode only) and storage of dose history information	Equivalent – software updates (see *below*)

The following table provides a comparison of Base firmware technological characteristics between the predicate and subject device:

Characteristic	Predicate Device	Subject Device	Comments
Volume measurement accuracy	± 5% (for volumes >1.0 mL) ± 20% (for volumes 0.4 – 1.0 mL)	± 10% (for volumes >1.0 mL) ± 0.2mL (for volumes 0.4 – 1.0 mL)	Equivalent – the specification of the subject device enforces a narrower distribution of measurements than that of the predicate device
Potential volume error message logic	Subject device includes more messages to indicate potentially inaccurate volume measurements than the predicate device, and improved logic for “bubble” messages		Equivalent – reduces the risk related to inaccurate volume measurements

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The following table provides a comparison of Tablet software technological characteristics between the predicate and subject device:

Characteristic	Predicate Device	Subject Device	Comments
Allergy alerts	Visual and auditory notification on the screen	Visual and auditory notification on the screen	Identical
Potential volume error messages	Subject device includes more messages to indicate potentially inaccurate volume measurements than the predicate device, and improved logic for “bubble” messages		Equivalent – reduces the risk related to inaccurate volume measurements
Untested drug “Enter Dose” messages	Not available in predicate device	Available in subject device for untested drugs	Equivalent – reduces the risk related to inaccurate volume measurements

The following table provides a comparison of Gateway software technological characteristics between the predicate and subject device:

Characteristic	Predicate Device	Subject Device	Comments
EMR connectivity	Send/receive medication data to/from EMR	Send/receive medication data to/from EMR	Equivalent
Encoded drug table (EDT)	70 drugs on EDT	161 drugs on EDT	Equivalent – medication identity feature verified; volume measurements are provided only for tested drugs

7 Non-Clinical Performance Testing

Bench and software verification (unit-level, integration-level, system-level) testing was conducted to ensure that the BD Intelliport Medication Management System, Version 1.2 meets system requirements and is as safe and as effective as the predicate device.

Environmental boundary testing of water was performed between 15° C and 29° C, 20% and 85% relative humidity (non-condensing), and 84 kPa to 101 kPa.

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Testing was performed to ensure that the device volume measurements meet the volume accuracy specification with real drugs. Testing was conducted on a set of drugs commonly used in Anesthesia, bracketed based upon speed of sound and solvent/dissolved solids composition. Testing of Cefazolin was performed at 4^0C.

Software testing demonstrated compliance with the following FDA guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, dated May 2005
- General Principles of Software Validation *Guidance for Industry and FDA Staff, dated* January 2002
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Draft Guidance for Industry and Food and Drug Administration Staff DRAFT GUIDANCE This draft guidance document is being distributed for comment purposes only, dated October 2018.

8 Simulated Human Use Testing

Both formative and summative usability human factors testing studies were conducted. These studies assessed the behavior of intended device users in operating the device and performing critical tasks. The results of the testing showed that intended users can safely operate the device, and that any residual risk related to potential use errors is acceptable.

Testing was completed in compliance with Guidance for Industry and FDA Staff, Applying Human Factors and Usability Engineering to Medical Devices, dated February 2016

9 Conclusion

Based upon the results of the non-clinical performance testing and simulated human use testing conducted and associated activities, the BD Intelliport Medication Management System, Version 1.2 is as safe and as effective as the cited predicate device, the BD Intelliport System (cleared under K141474).