DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 18,2014

Becton, Dickinson and Company
C/O Mr. Daniel Olivier
Certified Compliance Solutions, Inc.
President
11665 Avena Place, Suite 203
San Diego, CA 92128

Re: K141474
Trade/Device Name: BD Intelliport System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: PHC, FPA
Dated: December 15, 2014
Received: December 16, 2014

Dear Mr. Olivier:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141474

Device Name
BD Intelliport System

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 areas. 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

Submitter:	Becton, Dickinson and Company
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Contact person:	Daniel Olivier
Phone number:	(858) 675-8200
Fax number:	(858) 675-8201

Date prepared:	September 14, 2014
Trade name:	BD Intelliport System
Common name:	Intelliport System
Product Code, Primary:	PHC, Infusion Safety Management Software
Regulation:	21 CFR 880.5725, Infusion Pump, Class II
Product Code, Secondary:	FPA, Set, Administration, Intravascular
Regulation:	21 CFR 880.5440, Intravascular Administration Set, Class II

Substantial equivalence claimed to: DocuSys Anesthesia Information and Digital-Drug Management System

Description:
The BD Intelliport System is used for automated documentation of medication, concentration, dose, volume and time of each IV injection for when intravenous bolus injections of medication are given to a patient.

During treatment, the clinician connects an intelligent injection port, called the Intelliport device, to a patient's fluid-delivery line and performs standard drug-delivery activities. The health practitioner injects the drug; the Intelliport reads the 2-D barcode adhered to the syringe containing the drug such as Becton Dickinson syringe K110771. This barcode contains the drug name and concentration. As the drug is injected, the Intelliport measures the volume of the injected drug and the time the drug was administered. Once the drug has been administered, the Intelliport transmits all of the information to an electronic record maintained by the Computer.

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 events in the pre-op, intra-op, and PACU areas. 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.

Technological Characteristics
The BD Intelliport System is substantially equivalent to the predicate Device, the DocuSys Anesthesia Information and Digital-Drug Management System.

	BD Intelliport System	**DocuSys Anesthesia Information & Digital-Drug Management System**
Manufacturer	Becton Dickinson	DocuSys
510(k)	NA	K062388
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 events in the pre-op, intra-op, and PACU areas. 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 DocuSys Anesthesia Information and Digital-Drug Management System offers anesthesia a comprehensive record keeping system with advanced patient safety features. The clinician begins interacting with the system through the electronic anesthesia pre-operative assessment in which patient data relative to anesthesia is recorded. Electronic documentation of the patient's allergies and home medications allows for proactive adverse drug event screening when the patient is in the operating room prior to anesthesia delivering drugs. The DocuSafe electronic anesthesia information system allows the clinician to record anesthesia related events in the pre-op, intra-op, and PACU areas. The DocuSafe software receives physiologic data from various patient monitoring devices. Clinicians enter drug information onto the anesthesia record in one of two methods: a) manually selecting the drug from a list of drugs in the formulary, or b) through the use of DocuSys' optional digital-Drug Management System. If the optional d-DMS is used, the clinician may scan a barcode affixed to a Syringe Label Cradle or use DocuJet to record the drug delivery. A

	BD Intelliport System	DocuSys Anesthesia Information & Digital-Drug Management System
		Formulary Reference module, managed by pharmacy, contains drug specific information used for documenting drugs on the anesthesia record, performing ADE checks, and submitting medication utilization information for billing purposes. The DocuRx pharmacy component of the digital-Drug Management System provides for pre-screening of medications that are ordered by anesthesia to check for any potential adverse drug events. It also provides a methodology for narcotics tracking through its comprehensive medication tracking and wasting feature. Each component of the Anesthesia Information and Digital-Drug Management System plays an integral part in standardizing medication administration techniques and documentation.
Allergy data	Provides notice of patient allergies	Provides notice of patient allergies
Drug interactions	NA	Adverse drug event screening
Medication history record	Provides a record of drug delivery related events	Provides a record of drug delivery related events
Drug formulary	Provides drug formulary to select drugs to be delivered	Provides drug formulary to select drugs to be delivered
Drug delivery	Pre-filled syringe that has a barcode attached to register drug delivered	Pre-filled syringe that has a barcode to register drug delivered and volume
Measuring drug delivery	Measures volume of the injected drug using an ultrasonic sensor	Measures the syringe plunger displacement
Accuracy of drug delivery	± 5% for bolus volumes > 1.0 mL to 55 mL ± 20% for bolus volumes of 0.4 to 1.0 mL (at nominal conditions)	Calculated as a percent of total syringe volume not volume of drug delivered so not used for comparison.
Formulary database	Provides ability to edit drug formulary	Provides a Formulary Reference module
Narcotics tracking	Provides database for tracking narcotics	Provides database for tracking narcotics
External data interface	Provides interface to hospital information system	Provides interface to hospital information system

Substantial Equivalence Discussion

The BD Intelliport System is substantially equivalent to the DocuSys Anesthesia Information and Digital-Drug Management System based on indications for use and comparison of functional

capabilities. Both devices are intended to provide the healthcare professional with an electronic record of “anesthesia related events.” The BD Intelliport System provides an automated record of the name, concentration, dose, volume of the drug injected into the patient, as well as the time of the injection. Features common to both systems include:

- Medication history record: name, concentration, dose, volume of the drug injected into the patient as well as the time of the injection
- Allergy Alerts
- Drug Formulary

The minor differences between the BD Intelliport System and the DocuSys Anesthesia Information and Digital-Drug Management System do not raise new questions of safety or effectiveness. These differences will be discussed in turn.

The DocuSys Anesthesia Information and Digital-Drug Management System provides adverse drug event screening such as notification of potential drug – drug interactions. This feature is not provided by the BD Intelliport System. Failure to provide this feature does not raise safety or efficacy concerns as this screening is currently performed in the hospital setting.

The drug-delivery accuracy of the DocuSys Anesthesia Information and Digital-Drug Management System is ±3%. However, this accuracy measurement is always calculated based on the total syringe volume not the volume of drug delivered to the patient. As stated in the DocuSys *Summary Data for DocuJet II Accuracy*, “If a user delivers a bolus injection of 2ml using a 20ml syringe and the DocuJet records 2.2ml on the record, that is not considered a discrepancy of 10%. The discrepancy is based on the Nominal Syringe Volume and therefore would be calculated as 0.2ml/20ml, a 1% discrepancy.” The term discrepancy, in this case, is tantamount to accuracy. The accuracy of the BD Intelliport System is ± 5% for bolus volumes from 1.0 mL to 55 mL and ± 20% for bolus volumes from 0.4 to 1.0 mL at nominal conditions. This measurement is based on the volume of the drug delivered.

A performance test comparison of the accuracy of the DocuSys Anesthesia Information and Digital-Drug Management System could not be performed as this product is no longer marketed and not available.

Testing of the BD Intelliport System syringe delivery is conducted in accordance with the bolus delivery requirements as defined in IEC 60601-2-24 (Particular requirements for the safety of infusion pumps and controllers). The accuracy of drug delivery for the BD Intelliport System does not raise safety or efficacy concerns as this accuracy is in line with the accuracy currently achieved through manual activation of a syringe.

Test Summary

The performance testing for the BD Intelliport System includes software unit testing and code reviews (verification), system validation testing, and testing to compliance standards for electrical and electromagnetic safety. Traceability has been documented between the system specification to validation test protocols. Validation test procedures also address the user interface, user manual descriptions, usability, wireless communication and general performance including volume delivery accuracy.

Conclusion:
The performance of the BD Intelliport System is substantially equivalent to that of the DocuSys Anesthesia Information and Digital-Drug Management System and raises no safety or effectiveness issues and performs as well or better than the predicate device.