August 20, 2018

Becton, Dickinson and Company
Eileen Hiller
Senior Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K170824
Trade/Device Name: BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: July 19, 2018
Received: July 19, 2018

Dear Eileen Hiller:

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,

Tina Kiang -S

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)*
K170824

Device Name
BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle

Indications for Use *(Describe)*
The BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle is a sterile, single use, medical device specifically intended to be used by trained healthcare professionals in accordance with the instructions for use for the collection of multiple blood samples into evacuated blood collection tubes, for the purpose of in vitro diagnostic testing. The device incorporates a flash technology to indicate venous access and a hinged safety shield. In the activated position, the safety shield protects against an accidental needle stick injury during normal handling and disposal.

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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510(k) Summary

K170824

Submitted By:	Eileen Hiller Senior Staff Regulatory Affairs Specialist Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 Phone: (201)847-4570 Email: Eileen_Hiller@BD.com	

Date Prepared:	August 20, 2018	
Subject Devices:	Trade Name:	BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle
	Common Name:	Hypodermic Single Lumen Needle
	Classification:	Class II, 21 CFR § 880.5570, Hypodermic Single Lumen Needle
	Product Code:	FMI: Needle, Hypodermic, Single Lumen
Predicate Device:	Trade Name:	BD Vacutainer® Eclipse™ Blood Collection Needle
	510(k) Reference:	K982541
	Common Name:	Hypodermic Single Lumen Needle
	Classification:	Class II, 21 CFR § 880.5570, Hypodermic Single Lumen Needle
	Product Code:	FMI: Needle, Hypodermic, Single Lumen

1. Device Description

The BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle is a sterile, single use, straight blood collection needle intended to be used by a trained Healthcare Worker (HCW) for conducting venipuncture. The device consists of a stainless steel cannula bonded into the front needle hub which is the intravenous (IV) end that is inserted into the patient's vein and non-patient (np) cannula that is inserted into a holder. Blood collection tubes are inserted for venous blood collection. The device contains an additional blood flash visibility feature to provide the HCW with confirmation that the vein has been accessed.

After blood collection, when the needle is removed from a vein, a drop of blood may form at the IV patient end of the needle. This droplet may cause blood splatter during activation of the safety shield. The Eclipse™ Signal™ Blood Collection Needle minimizes the size of the blood droplet and by design, draws the blood into the lumen of the needle and away from the healthcare professional.

The Eclipse™ Signal™ BCN has the same pivoting safety shield as the predicate Eclipse™ BCN. The device has a pivoting safety shield which is designed to be activated using a single-handed technique and gives an audible confirmation of the safety lock engagement. The shield locks

over and covers the needle after use, protecting the healthcare worker from an accidental needle stick injury.

The needles are manufactured in specific diameters and lengths. The color of the IV shield indicates the needle gauge (green shield for the 21G needle and black shield for the 22G needle).

The purpose of this Traditional 510(k) is to expand the product family with an additional safety blood collection needle with a flash visibility feature. The premarket notification also includes other small modifications to the needle hub, needle cannula, integrated holder and safety shield. The BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle has the same intended use, operating principles and performance and scientific technology as the predicate device.

There are two variants of Eclipse™ Signal™ Blood Collection Needle (BCN) and a total of 4 models.

- BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle, 21G and 22G
- BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle with Integrated Holder, 21G and 22G.

2. Intended Use

The BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle is a sterile, single use, medical device specifically intended to be used by trained healthcare professionals in accordance with the instructions for use for the collection of multiple blood samples into evacuated blood collection tubes, for the purpose of in vitro diagnostic testing. The device incorporates a flash technology to indicate venous access and a hinged safety shield. In the activated position, the safety shield protects against an accidental needle stick injury during normal handling and disposal.

3. Technological Characteristics

The principal BD Vacutainer® Eclipse™ Signal ™ Blood Collection Needles are equivalent to the predicate BD Vacutainer® Eclipse™ Blood Collection Needles in intended use, fundamental scientific technology, operating principles, product design, and performance characteristics.

Device Characteristics	Principal Device BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle (K170824)	Predicate Device BD Vacutainer® Eclipse™ Blood Collection Needle (K982541)
Manufacturer	Becton, Dickinson and Company	Becton, Dickinson and Company
Intended Use	The BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle is a sterile, single use, medical device specifically intended to be used by trained healthcare professionals in accordance with the instructions for use for the collection of multiple blood samples into evacuated blood collection tubes, for the purpose of	The VACUTAINER® Brand Eclipse™ Blood Collection Needle is a sterile, multiple sample, single-use device for blood collection. The needle is designed with an attached safety shield, which can be activated to cover the needle immediately after venipuncture to provide

	in vitro diagnostic testing. The device incorporates a flash technology to indicate venous access and a hinged safety shield. In the activated position, the safety shield protects against an accidental needle stick injury during normal handling and disposal.	protection from accidental needle sticks.
Operating Principle	BD Vacutainer® Eclipse™ Signal™ Blood Collection Needles are devices that are composed of two piece stainless steel cannula mounted into a two piece hub/adapter and pivoting safety shield to cover the needle after removal from the vein. This device also has a flash chamber for vein access confirmation.	BD Vacutainer® Eclipse™ Blood Collection Needles are devices composed of one piece stainless steel cannula mounted into a one piece hub/adapter and pivoting safety shield to cover the needle after removal from the vein.
Materials	Cannula- stainless steel Hub- polycarbonate Porous Plug- polyethylene Safety Shield-polypropylene Rubber Sleeve- synthetic rubber Holder (integrated model)-polypropylene Lubricant- silicone	Cannula- stainless steel Hub- polystyrene Safety Shield-polypropylene Rubber Sleeve- synthetic rubber Holder (integrated model)-polypropylene Lubricant- silicone
Packaging	Protective Shields or Foil Seal Shelf Carton Case Carton IFU	Protective Shields or Blister Pouch Shelf Carton Case Carton IFU
Specification	Needle Length: 1.0 inch Needle Gauge: 21 or 22 Gauge Diameter – extra thin wall Bevel: 3 bevel Hub Color: Per ISO 6009	Needle Length: 1 ¼ inch Needle Gauge: 21 or 22 Gauge Diameter – thin wall Bevel: 3 bevel Hub Color: Per ISO 6009

4. Performance Data

Performance data was collected to ensure the modifications to the blood collection needle were not impacted by the addition of the flash chamber and related components in the blood fluid path. Performance studies include examining the specimen for hemolysis and specimen quality.

The results of all these tests either met the predetermined acceptance criteria and BD's internal specification or performed to the standard.

Modifications proposed to BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle were evaluated using a risk management plan. This risk assessment process is performed in accordance with ISO14971. Biocompatibility testing included cytotoxicity (per ISO10993-5),

hemolysis (per ISO10993-4), acute systemic toxicity (per ISO10993-11), intracutaneous reactivity (per ISO10993-10), sensitization (per ISO10993-10), pyrogenicity (per ISO 10993-11) and chemical extractable analysis (per ISO 10993-18). The results were acceptable according to ISO 10993-1.

Design Verification activities such as Needle Penetration, Hub/Needle Bond Strength, Leak Testing and Needle Shield Removal Forces, Flash Reliability, Activation Force and Holder Detachment and Splatter Testing were performed to demonstrate that the subject device met BD's internal predetermined acceptance criteria.

The results of these activities mentioned in the table above (Risk Management, Biocompatibility and Design Verification activities) either met BD's internal specification or performed according to the standard. Thus these activities demonstrated that the subject device is substantially equivalent to the predicate device.

5. Substantial Equivalence

The BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle is substantially equivalent to the legally marketed predicate device, BD Vacutainer® Eclipse™ Blood Collection Needle (K982541) in intended use, principles of operation, technology, design, materials and performance.

Specifically, the BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle and predicate device have the same intended use, namely single-patient, multiple-sample blood collection by health care professionals. The minor differences in the wording of the subject device's indications statement are for enhanced clarity and to reflect the updated flash technology; they do not alter the diagnostic/therapeutic purpose of the device or raise any new types of safety or effectiveness questions, as they do not alter how the device is used as compared to the predicate. Similarly, the minor differences in technological characteristics between the two devices do not raise any new questions of safety or effectiveness, with the additional flash feature not altering the subject device's blood collection functionality.

6. Conclusion

The BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle has been verified to meet the established performance criteria above. The results of the design verification testing demonstrate that the BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle performs as intended and performs as well as the legally marketed predicate device.