Becton, Dickinson and Company
% John Smith
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K181730
Trade/Device Name: BD Vacutainer® Eclipse™ UltraFill™ Blood Collection Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: February 1, 2019
Received: February 1, 2019

Dear Mr. Smith:

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 B. Mollo -S

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)*
k181730

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

Indications for Use *(Describe)*
The BD Vacutainer® Eclipse™ UltraFill™ 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 needle is designed with an attached safety shield, which can be activated to cover the needle immediately after puncture to provide protection from accidental needle sticks.

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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K181730 510(k) SUMMARY

BD Vacutainer® Eclipse™ UltraFill™ Blood Collection Needle

Submitter

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Contact Person: Eileen Hiller, Senior Staff Regulatory Affairs Specialist

Date Prepared: March 1, 2019

Name of Device: BD Vacutainer® Eclipse™ UltraFill™ Blood Collection Needle

Common or Usual Name: Blood collection needle

Classification Name: Hypodermic Single-Lumen Needle

Classification Regulation: 21 C.F.R. § 880.5570

Regulatory Class: II

Product Code: FMI

Classification Panel: General Hospital

Predicate Device: BD Vacutainer® Eclipse™ Blood Collection Needle (K982541)

Device Description

The BD Vacutainer® Eclipse™ Blood Collection Needle consists of a double-ended hollow stainless steel cannula, a threaded polystyrene hub, a sleeve that interrupts blood flow between filling multiple tubes, a polystyrene collar, and a safety shield which can be activated to cover the needle immediately after venipuncture to protect against accidental needle sticks. The device is available in two versions: non-integrated holder and Pre-Attached Holder. The Pre-Attached model features a pre-attached needle holder, whereas the non-integrated model requires the user to obtain a compatible holder.

The device is single-use and supplied sterile. The stainless steel cannula and silicone cannula lubricants are classified as externally communicating with limited (≤24 hours) duration contact; all other device components have limited (≤24 hours) duration surface contact with intact skin of the health care professional user and the patient. Once the vein has been accessed by puncturing with the intravenous end of the cannula, the healthcare professional will begin the blood collection process by placing evacuated blood collection tubes on the cannula's non-patient end, where the sleeve acts as a non-return valve and allows for more than one tube to be used to collect blood from the vein puncture.

Intended Use / Indications for Use

The BD Vacutainer® Eclipse™ UltraFill™ 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 needle is designed with an attached safety shield, which can be activated to cover the needle immediately after venipuncture to provide protection from accidental needle sticks.

Comparison with Predicate Device

The BD Vacutainer® Eclipse™ UltraFill™ Blood Collection Needle has the same intended use and principles of operation, and similar indications for use and technological characteristics, as the previously cleared BD Vacutainer® Eclipse™ Blood Collection Needle (K982541). The subject device has the same intended use as the predicate, namely multiple-sample blood collection via venipuncture. Its indications for use are also substantively the same: the device is indicated for use in clinical environments where venipuncture is performed. The minor differences in the wording of the indications for use statement—namely, the inclusion of language specifying that the device is 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—are for enhanced clarity; they do not affect the device's diagnostic/therapeutic use or raise new questions of safety or effectiveness as compared to the predicate, because they do not alter how the device is used in any way.

Venous flow through the inner diameter of the cannula into attached blood collection tubes is the technological principle for both the subject and predicate devices. The subject and predicate devices are based on the following same technological elements:

- Same overall design, including safety shield feature and use of a holder
- Same cannula material, geometry and gauge (Outer Diameter)
- Same method of use and very limited duration of contact (≤ 3 min.) with patient's blood

The primary technological differences between the subject and predicate devices are an increase in the cannula's inner diameter (ultra-thin wall versus thin wall), and introduction of a Pre-Attached Holder configuration with corresponding packaging as another option for the health care practitioner and added more detail and clarifications to the labeling. Minor differences in certain component materials/suppliers have been appropriately verified not to impact device performance. A table comparing the key features of the subject and predicate devices is provided below.

In addition, the minor differences in technological characteristics do not raise any new types of safety or effectiveness questions. Furthermore, performance data (design verification testing) demonstrates that the modified device is as safe and effective as the cited predicate. Thus, the BD Vacutainer® Eclipse™ UltraFill™ Blood Collection Needle is substantially equivalent to its predicate device.

	Subject Device: BD Vacutainer® Eclipse™ UltraFill™ Blood Collection Needle	Predicate Device: BD Vacutainer® Eclipse™ Blood Collection Needle (K982541)	Discussion / Comment
Regulation Number	21 C.F.R. § 880.5570	21 C.F.R. § 880.5570	Same
Classification Name	Needle, Hypodermic, Single-Lumen	Needle, Hypodermic, Single-Lumen	Same
Regulatory Class	Class II	Class II	Same
Product Code	FMI	FMI	Same
Intended Use / Indications for Use	The BD Vacutainer® Eclipse™ UltraFill™ 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 needle is designed with an attached safety shield, which can be activated to cover the needle immediately after venipuncture to provide protection from accidental needle sticks.	The BD Vacutainer® 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 protection from accidental needle sticks.	The indications for use have been updated for enhanced clarity
Sterility	Gamma Irradiation to SAL of 10^{-6}		Same
Single Use?	Yes		Same
Cannula Material	304 Stainless Steel		Same
Cannula Lubricants	Silicone-based oils		Same
Needle Wall Thickness	Ultra-Thin Wall (UTW)	Thin Wall (TW)	The needle wall thickness has been decreased to increase the inner-diameter of the needle for faster fill time.
Needle Length	1 ¼ inch		Same
Safety Shield Activation Method	User activates with the thumb after venipuncture, shield "pivots" around the hinge, locking into place at the needle base and at the cannula		Same
Shelf Life	5 years (Eclipse™ UltraFill™); 3 years (Eclipse™ UltraFill™ Pre-Attached)	5 years	Same

Performance Data

Design verification and validation were performed to ensure that the Eclipse™ UltraFill™ Needle meets its performance specifications and demonstrates equivalence to the specified predicate device.

- Samples of venous blood obtained with the BD Vacutainer® Eclipse™ UltraFill™ Blood Collection Needle were assessed to verify performance as measured by analytical indicators of hemolysis.

- Simulated use assessment was conducted to validate the performance of the safety shield feature of the BD Vacutainer® Eclipse™ UltraFill™ Needle.

- Mechanical verification testing was performed to assess product characteristics including mechanical integrity, penetration force, tube fill time, cannula pull force, safety shield activation force, safety shield override force (snag resistance), sleeve function, 3 point stiffness, resistance to breakage, and external blood splatter. The results confirmed that the 21- and 22-gauge BD Vacutainer® Eclipse™ UltraFill™ Blood Collection Needles meet pre-established functional design requirements and that the changes incorporated in the subject device as compared to the predicate do not impact the product's ability to be used safely and perform as intended.

The device complies with the following recognized consensus standards:

- ISO 23908, *Sharps Injury Protection – Requirements and Test Methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*
- ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices (including amendment I: 2001)*
- AAMI/ANSI/ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- ISO 11137-1, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
- ISO 11737-1, *Sterilization of health care products — Microbiological methods, Part 1: Estimation of the population of microorganisms*
- ISO 11737-2, *Sterilization of health care products — Microbiological methods, Part 2: Tests for sterility performed in the validation of sterilization process*
- ISO 10993-2, *Biological evaluation of medical devices – Part 2: Animal welfare*
- ISO 10993-3, *Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- ISO 10993-4, *Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
- ISO 10993-5, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-6, *Biological evaluation of medical devices – Part 6: Tests for local effect after implantation*

- ISO 10993-10, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- ISO 10993-12, *Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*
- ISO 10993-13, *Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices*
- ISO 10993-15, *Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys*
- ISO 10993-17, *Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances*
- ISO 10993-18, *Biological evaluation of medical devices – Part 18: Chemical characterization of materials*
- ISO 6009, *Hypodermic needle for single use – Color coding for identification*
- IEC 62366-1, *Medical devices – Part 1: Application of usability engineering to medical devices*

Conclusion

The testing performed demonstrates the BD Vacutainer® Eclipse™ UltraFill™ Blood Collection Needle is substantially equivalent to its predicate device.