DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 27, 2016

Becton, Dickinson and Company
Ms. Priyanka Apte
Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K161170
Trade/Device Name: BD Eclipse™ Hypodermic Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 22, 2016
Received: April 28, 2016

Dear Ms. Apte:

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,

Tina Kiang -S

for 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)*
K161170

Device Name
BD Eclipse™ Hypodermic Needles

Indications for Use *(Describe)*
The BD Eclipse™ Hypodermic Needle is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse Hypodermic Needle is compatible for use with standard luer-lock syringes.

The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/ syringe combination.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

Submitted By: Priyanka Apte
Regulatory Affairs Specialist
Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417
Phone: (201)847-4608
Fax: (201)847-5307

Date Prepared: May 27, 2016

Subject Devices:	Trade Name:	BD Eclipse™ Hypodermic 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 Devices:	Trade Name:	BD Eclipse™ Hypodermic Needle
	510(k) Reference:	K010188
	Common Name:	Hypodermic Single Lumen Needle
	Classification:	Class II, 21 CFR §880.5570, Hypodermic Single Lumen Needle
	Product Code:	FMI: Needle, Hypodermic, Single Lumen

Device Description
The BD Eclipse™ Hypodermic Needle is a device that is composed of a typical hypodermic needle with a one piece hub/adapter and pivoting cover that is connected to the adapter. The pivoting cover can be manually rotated forward after use allowing for secure encapsulation of the needlepoint making the product safe for disposal. These needles have a regular, short or intradermal bevel type. The needle assembly is protected with a polypropylene shield.

The Eclipse™ Hypodermic Needles are offered in a variety of gauge sizes (18-30 gauge) and needle length (½'' - $1^{1/2}$''). The needle hub is color-coded to the appropriate gauge needle per ISO 6009.

The BD Eclipse™ Hypodermic Needle hub incorporates a female 6% (Luer) connector which can be used with a compatible male 6% (Luer) connector. The BD Eclipse™ Hypodermic Needle is not to be used with luer-slip syringe as the needle may become disengaged from the syringe when activating the safety cover. This product is single use and provided sterile.

The change described in this submission is the replacement of current silicone based HCFC-containing needle lubricant with silicone based HCFC-free lubricant.

Intended Use
The BD Eclipse™ Hypodermic Needle is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse Hypodermic Needle is compatible for use with standard luer-lock syringes.

The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

Technological Characteristics
The subject BD Eclipse™ Hypodermic Needles are equivalent to that of the predicate BD Eclipse™ Hypodermic Needles in intended use, fundamental scientific technology, operating principles, product design, and performance characteristics.

Device Characteristics	Subject Device BD Eclipse™ Hypodermic Needle (K161170)	Predicate Device BD Eclipse™ Hypodermic Needle (K010188)
Manufacturer	Becton, Dickinson and Company	Becton, Dickinson and Company
Intended Use	The BD Eclipse™ Hypodermic Needle is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse Hypodermic Needle is compatible for use with standard luer-lock syringes. The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.	The BD Eclipse™ Hypodermic Needle is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse Hypodermic Needle is compatible for use with standard luer-slip and luer-lock syringes. The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.
Operating Principle	BD Eclipse™ Hypodermic Needles are devices that are composed of a typical hypodermic needle with a one piece hub/adapter and pivoting cover that is connected to the adapter. The device consists of a mechanism that covers the needle point after use	BD Eclipse™ Hypodermic Needles are devices that are composed of a typical hypodermic needle with a one piece hub/adapter and pivoting cover that is connected to the adapter. The device consists of a mechanism that covers the needle point after use
Materials	Hub: Polypropylene Cannula: Stainless Steel Cannula Lubricant: HCFC-free silicone Needle/Safety Shield:	Hub: Polypropylene Cannula: Stainless Steel Cannula Lubricant: HCFC containing silicone Needle/Safety Shield:

	Polypropylene	Polypropylene
Packaging	Blister Pouch Shelf Carton Case Carton	Blister Pouch Shelf Carton Case Carton
Specification	Needle Length: ½'' - $1^{1/2}$'' Needle Gauge: 18-30 Gauge Bevel: Regular, Short, Intradermal Hub Color: Per ISO 6009	Needle Length: ½'' - 2" Needle Gauge: 18-25 Gauge Bevel: Regular, Short, Intradermal Hub Color: Per ISO 6009
Functional Testing	Hub/Needle Bond Strength: Met internal BD specification Needle Penetration Test: Met internal BD specification Needle Shield Removal Forces: Met internal BD specification Leak Testing: Per ISO 594-2	Hub/Needle Bond Strength: Met internal BD specification Needle Penetration Test: Met internal BD specification Needle Shield Removal Forces: Met internal BD specification Leak Testing: Per ISO 594-2
Sterilization	Per ISO 11135	Per ISO 11135
SAL Level	SAL 10^{-6}	SAL 10^{-6}
Shelf Life	5 Years	5 Years
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1

Performance Data

Additional length /gauge size have been validated per design validation/verification activities which included cannula pull out forces to ensure hub/cannula bonding, activation/unlocking forces, impact resistance to ensure safety mechanism of a needle and a ship test to ensure needle/safety shield integrity. 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 Eclipse™ Hypodermic Needle evaluated using 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 Test, Hub/Needle Bond Strength, Leak Testing and Needle Shield Removal Forces were performed to demonstrate that the subject device met BD's internal predetermined acceptance criteria.

The results of these activities mentioned in 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.

Substantial Equivalence

The subject BD Eclipse™ Hypodermic Needle has the same intended use, fundamental scientific technology and operating principles when compared to the predicate BD Eclipse™ Hypodermic Needle and is substantially equivalent to its legally marketed predicate K010188.

Conclusion

The BD Eclipse™ Hypodermic Needles have been verified to meet the established performance criteria above. The results of design verification testing demonstrate that the BD Eclipse™ Hypodermic Needles perform as intended and perform as well as the legally marketed predicate device.