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

July 8, 2016

Becton, Dickinson and Company
Mr. Matthew Trachtenberg
Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07666

Re: K151870
Trade/Device Name: BD U-500 Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 5, 2015
Received: July 6, 2015

Dear Mr. Trachtenberg:

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

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)*
K151870

Device Name
BD U-500 Insulin Syringe

Indications for Use *(Describe)*
The BD U-500 Insulin Syringe is intended for the subcutaneous injection of U-500 insulin for patients requiring more than 200 units per day.

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

Submitted By: Matthew S. Trachtenberg
Staff Regulatory Affairs Specialist, BD Medical
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201 847 6337
Fax: 201 847 5307

Date Prepared: March 29, 2016

Device Name:

Trade Name:	BD U-500 Insulin Syringe
Common Name:	U-500 Insulin Syringe
Classification:	Class II device; 21 CFR 880.5860, Piston Syringe
Product Code:	FMF (Syringe, Piston)

Legally marketed predicate device(s) to which substantial equivalence is being claimed:
K024112 – BD Insulin Syringe

Reason for Submission
To introduce the new BD U-500 Insulin Syringe that comprises modifications to an existing device with new packaging, labeling, and indications for use.

Device Description:
The U-500 Insulin Syringe is a standard single use 0.5mL plastic syringe intended for the injection of U-500 insulin into the subcutaneous tissue. It features a 31G needle and 6 mm needle length with unique U-500 scale markings on the syringe barrel. The U-500 syringe also features a green needle shield and a green U-500 symbol. It is a single use, sterile, nontoxic syringe. The fluid path of the syringe is sterile and non-pyrogenic.

Indications for Use:
The BD U-500 Insulin Syringe is intended for the subcutaneous injection of U-500 insulin for patients requiring more than 200 units per day.

Comparison with Predicate Devices:
The BD U-500 Insulin Syringe has a similar intended use and operational principle as its predicate device for the subcutaneous injection of insulin. It also shares several similarities in technology compared to its predicate device consisting of a barrel, a movable plunger, the needle, and needle cover. These syringes are Gamma sterilized and are for single use only.

The only differences between the subject device and the predicate device are the syringe barrel scale markings, the color of the needle shield (green) and the packaging graphics. Each scale mark line on the U-500 Insulin Syringe measures 5 units of U-500 insulin due to the 5-times concentrated U-500 insulin product. Caution should be observed in the measurement of dosage to avoid overdose. The green needle shield, green U-500 symbol on the syringe, and the syringe packaging graphics are designed to match the color of the U-500 insulin vial labeling.

Feature	Subject Device: BD U-500 Insulin Syringe	Predicate Device: BD Insulin Syringe – Ultra-Fine™ and Ultra-Fine™ II
510(k) Number	K151870	K024112
Manufacturer	BD	BD
Syringe Type	Insulin	Insulin
Intended Use	For the subcutaneous injection of U-500 insulin for patients requiring more than 200 units per day.	For subcutaneous injection of insulin.
Principle of Operation	Piston Syringe	Piston Syringe
Specific Drug Use	U-500 Insulin	U-100 Insulin
Needle (Cannula) Cover Color	Green	Orange
Needle (Cannula) Gauge	31G	30G and 31G
Scale Marking	5 unit lines	1 unit lines
Needle (Cannula) Length	6mm	6mm, 8mm, and 12.7mm
Single Use Only	Yes	Yes
Non-Pyrogenic	Yes	Yes
Sterile	Yes	Yes
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}

Testing:
BD has performed non-clinical performance testing to demonstrate substantial equivalence to the predicate device. This testing includes the following:

- Device material biocompatibility per ISO 10993-1, Biological evaluation of medical devices;
- Device functional performance at time-zero and shelf-life per ISO 8537, Sterile single-use syringes, with or without needle, for insulin. This includes Volumetric Accuracy; both what was described within the standard, and an evaluation at the lowest selectable dose.
    - At volumes < half of nominal capacity (including the lowest selectable dose), volumetric accuracy shall be within ± [1.5% of nominal capacity + 2% of expelled volume].
    - At volumes ≥ half of nominal capacity, volumetric accuracy shall be ± 5%.
- Human factor evaluations per ANSI/AAMI/IEC 62366-1 Medical devices –Application of usability engineering to medical devices;
- Device sterilization per ISO 11737 Sterilization of Medical Devices;
- U-500 Insulin Stability; and
- Extractables and Leachables Testing.

Results of testing demonstrated the BD U-500 Insulin Syringe device met requirements for its intended use.

Conclusion:
The analysis and testing performed demonstrate that the BD U-500 Insulin Syringe device is substantially equivalent to its predicate device.