510(K) Summary of Safety and Effectiveness

1. **Submitted By:**

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2. **Device Name:**

Trade Name:	BD Emerald™ Single Use Hypodermic Syringe
Common Name:	Piston Syringe
Classification Name:	Syringe, Piston
Classification:	Class II, 21 CFR 880.5860

3. **Predicate Device:**

Trade Name(s):	Becton Dickinson Single Use Hypodermic Syringe
Manufacturer:	Becton, Dickinson and Company
510(k) Number(s):	K980987 and K110771

4. **Device Description:**

The BD Emerald™ Single Use, Hypodermic Syringe is a three-piece sterile, single use, hypodermic syringe with a 6% Luer taper tip that is provided in the following syringe sizes: 2ml, 3ml, 5ml, and 10ml. All sizes will be available with either a Luer Slip or Luer Lock tip and may be packaged as a syringe only, or syringe and needle combination.

The syringe assembly consists of a lubricated polypropylene barrel with a graduated scale, a resin stopper, and a polypropylene plunger rod. The polypropylene syringe barrel incorporates a male 6% (Luer) connector, and is connectable to a compatible female 6% (Luer) connector. The needle assembly consists of a lubricated stainless steel needle attached to a polypropylene hub with epoxy.

5. **Intended Use:**

The BD Emerald™ Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose aspiration and injection of fluids.

6. **Technological Characteristics:**

The principle device of this 510(k) premarket notification is the result of material, design, and labeling changes to the predicate devices (K980987 and K110771) which were conducted in accordance with Quality System Regulations, 21 CFR 820.

The BD Emerald™ Single Use Hypodermic Syringe is Substantially Equivalent to the predicate devices, given that both the principle and predicate devices:

- have the same intended use
- operate under the same operating principle
- meet the requirements for manual use as defined by ISO 7886-1
- have materials that comply with ISO 10993 as applicable to the intended use of the device
- are sterilized to a Sterility Assurance Level (SAL) of 10^{-6}
- demonstrate equivalent performance during design verification testing.

7. **Testing:**

The results of Design Verification tests demonstrate that the BD Emerald™ Single Use, Hypodermic Syringe performed in an equivalent manner to the predicate devices and is safe and effective when used as intended.

Performance Testing:

The BD Emerald™ Single Use Hypodermic Syringe have been designed and successfully tested to meet the applicable requirements outlined in ISO 7886-1, Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use. The needles that may be included with the syringe meet the applicable requirements outlined in ISO 7864, Sterile Hypodermic Needles for Single Use and ISO 9626, Stainless Steel Needle Tubing for the Manufacture of Medical Devices.

Biocompatibility Testing:

The BD Emerald™ Single Use Hypodermic Syringe and needles have been designed and successfully tested to meet the applicable requirements outlined in ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a Risk Management Process.

Sterilization and Shelf-life Testing:

The BD Emerald™ Single Use Hypodermic Syringe and needles have been designed and successfully tested to meet the applicable requirements outlined in ISO 11135-1, Sterilization of Healthcare Products – Ethylene Oxide Sterilization Process for Medical Devices.

8. **Substantial Equivalence:**

The vast similarities of the BD Emerald™ Single Use Hypodermic Syringe to the predicate devices support the substantial equivalence in intended use, function and basic composition. The testing to voluntary standards provides additional evidence that the BD Emerald™ Single Use Hypodermic Syringe is substantially equivalent to the predicate devices in terms of safety, efficacy and performance.

The differences between the BD Emerald™ Single Use Hypodermic Syringe and the predicate devices do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Kara McKee
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Becton Dickinson
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Franklin Lakes, New Jersey 07417

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Re: K113241
Trade/Device Name: BD Emerald™ Single Use Hypodermic Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: November 1, 2011
Received: November 2, 2011

Dear Ms. McKee:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

Indications for Use Statement

510(k) Number (if known): K113241

Device Name: BD Emerald™, Single Use, Hypodermic Syringe

Indications for Use:

The BD Emerald™ Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose aspiration and injection of fluids.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 11/30/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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