K091377

JUL - 2 2009

510(K) Summary of Safety and Effectiveness

1. **Submitted By:**

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Tel: 201 847 4570
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2. **Device Name:**

Trade Name: BD Flu+ Syringe

Common Name: Piston Syringe

Classification Name: Syringe, Piston

3. **Predicate Device:**

Trade Name: BD SoloShot IX Syringe
Manufacturer: Becton, Dickinson and Company
510(k) Number: K042934

4. **Device Description:**

The BD Flu+ is a two-piece single use, sterile syringe with an integral needle. It allows for a variable dose up to 1 ml to be aspirated and injected. It is intended for general-purpose aspiration and injection of fluids from a vial or ampoule. The BD Flu+ syringe has been designed for low dead space to reduce medication waste.

The BD Flu+ Syringe is a 1.0mL maximum dosage with 0.5mL and 1.0mL barrel marking and 0.25mL incremental markings. The Flu+ syringe is assembled with a pre attached needle in the following gauges and sizes

Needle Gauge	Color Coding (ISO-6009) Plunger Rod Color
23G (0.6mm) x 1 inch (25mm)	Blue
25G (0.5mm) x 5/8 inch (16mm)	Orange
25G (0.5mm) x 1inch (25mm)	Orange

Plunger Rod is color coded to comply with the ISO 6009 for needle gauge sizes.

5. **Intended Use**:

The BD Flu+ Syringe is intended for the aspiration and injection of the influenza vaccine.

6. **Technological Characteristics:**

The Modified Device, the subject of this 510(k), The BD Flu+ Syringe was modified by removing the stainless steel clip and modifying the barrel scale markings (variable dose). The Modified Device is manufactured of the same materials, has the same intended use and SAL of 10^{-6} as the Predicate Device.

6. **Performance:**

Design Verification tests were performed based on the risk analysis performed, and the results of these tests demonstrate that the BD Flu + Syringe performed in an equivalent manner to the predicate device and is safe and effective when used as intended.

The Modified Device is manufactured of identical materials and has the same intended use as the Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Eileen Hiller
Manager of Regulatory Affairs
Becton Dickinson and Company
BD Medical Surgical
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K091377
Trade/Device Name: BD Flu + Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: June 26, 2009
Received: June 30, 2009

Dear Ms. 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. 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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K091377

Device Name: BD Flu+ Syringe

Indications for Use:

The BD Flu+ Syringes are intended for the aspiration and injection of the influenza vaccine.

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)

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

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