K110771

MAY 13 2011

510(K) Summary of Safety and Effectiveness

Date Prepared: 16 March 2011

1. **Submitted By:**

John Roberts
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2. **Device Name:**

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

3. **Predicate Device:**

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

4. **Device Description:**

The modified BD Single Use, Hypodermic Syringe is a three-piece single use, hypodermic syringe with a 6% (Luer) connector in 1ml Luer Slip, 3ml and 5ml Luer Lok and Luer Slip syringe sizes. The syringe assembly consists of a plastic barrel with a graduated scale, a synthetic rubber stopper, and a plastic plunger rod. The changes to the modified device from the predicate include a new synthetic stopper material and a new silicone based stopper lubricant formulation. The syringe performance characteristics are equivalent to the predicate device. The BD Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.

The modified BD Single Use, Hypodermic Syringe are provided sterile, by either EO or an Irradiation sterilization method, in a syringe only configuration or with a pre-attached or side-by-side hypodermic needle.

5. **Intended Use**:

The BD Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.

6. **Technological Characteristics:**

The principal device of this 510(k) premarket notification is the result of a design change to the predicate device (K980987) conducted in accordance with Quality System Regulations, 21 CFR 820. The BD Single Use, Hypodermic Syringe is Substantially Equivalent to the predicate device, given that:

a) The BD Single Use, Hypodermic Syringe has the same intended use as the predicate device
b) The BD Single Use, Hypodermic Syringe operates under the same operating principle as the predicate device
c) The BD Single Use, Hypodermic Syringe barrel and plunger rod use an identical design and identical materials as the predicate device
d) The BD Single Use, Hypodermic Syringe and the predicate device meet the requirements for manual use and use with power-driven pumps as defined by ISO 7886-1 and ISO 7886-2 respectively.
e) The BD Single Use, Hypodermic Syringe and the predicate device component materials comply with ISO 10993 as applicable to the intended use of the device
f) The BD Single Use, Hypodermic Syringe and the predicate device are sterilized to an SAL of 10^{-6} via an EtO or Irradiation sterilization process
g) The BD Single Use, Hypodermic Syringe are assembled and packaged at the same manufacturing location utilizing the same equipment as the predicate device
h) The BD Single Use, Hypodermic Syringe demonstrated equivalent performance to the predicate device during design verification testing.

6. **Performance:**

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

Design Verification testing included the following:

Performance Characteristic	Test Performed	Acceptance Criteria
Functional Testing		
Sustaining Force	Determination of forces required to operate plunger ISO 7886-1 – Annex G	Per ISO 7886-1
Break-Out Force	Determination of forces required to operate plunger ISO 7886-1 – Annex G	Per ISO 7886-1
Pump Sticktion / Force	Determination of forces required to move the piston ISO 7886-2 – Annex C	Per ISO 7886-2
Stopper Seal	Water Leakage Test ISO 7886-1 – Annex D	Per ISO 7886-1
Autoclavability	Water Leakage Test ISO 7886-1 – Annex D After Syringe autoclave for 15mins at 270°F	Per ISO 7886-1
Chemical Testing (Extractables)		
Zinc Lead, Tin, Iron	ISO 7886-1	Per ISO 7886-1
Cadmium	ISO 7886-1	Per ISO 7886-1
pH shift	ISO 7886-1	Per ISO 7886-1
Biocompatibility Testing		
Cytotoxicity	ISO10993-5:1999	Non-Toxic
Hemolysis	ISO10993-4:2002/A:2006	Non-Toxic
Acute Systemic Toxicity	ISO10993-11:2006	Non-Toxic
Intracutaneous Reactivity	ISO10993-10:2002/A1:2006	Non-Irritant
Murine Local Lymph Node Assay	ISO10993-10:2002/A1:2006	Non-Sensitizer
Pyrogenicity	ISO10993-11:2006	Non-Pyrogenic

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

Mr. John Roberts
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MAY 13 2011

Re: K110771
Trade/Device Name: BD Single Use, Hypodermic Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: April 19, 2011
Received: April 21, 2011

Dear Mr. Roberts:

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,

for

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
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110771

Device Name: BD Single Use, Hypodermic Syringe

Indications for Use:

The BD Single Use, Hypodermic Syringe is intended for use by health care professionls for general purpose fluid aspiration/injection.

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)

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Richard C. Chapman 5/12/11

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

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