## 5. 510(k) Summary

AUG 16 2007

**SUBMITTER:**

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341

Contact: Christine Ford, Regulatory Affairs Specialist
phone (610) 596-2367 fax (610) 266-4962

**DEVICE NAME:**

Omnifix® Syringes, Omnican® and Omnifix Insulin Syringes

**COMMON OR USUAL NAME:**

Piston Syringes, Insulin syringes

**DEVICE CLASSIFICATION:**

Piston Syringe
Class II, CFR Title 21 § 880.5860

**PREDICATE DEVICES:**

B. Braun Injekt® Piston Syringe (K063280)

NIPRO disposable hypodermic syringes with or without needle (K051574)

BD Ultra Fine II, Micro Fine and Short Needle Insulin Syringes (K955235 and K024112)

**DESCRIPTION:**

The Omnifix piston syringes consist of a graduated hollow barrel and a movable plunger with a plunger tip. One end of the barrel has a male connector (nozzle), which permits attachment to a female connector (hub). Both luer lock and luer slip nozzles are available, with centric and eccentric configurations. The Omnifix syringes will be available in 1 mL, 2 mL, 2.5 mL, 3 mL, 5 mL, 10 mL, 20 mL, 30 mL, and 50 mL volume sizes, and as a 1 mL insulin syringe. The Omnican insulin syringes have an integrated needle bonded to the nozzle end of the syringes and are graduated in units of insulin. The Omnican insulin syringes will be available in sizes of 0.5 mL and 1 mL, and with a 30 gauge needle in lengths of 8 mm and 12 mm.

**INTENDED USE:**

The Omnifix piston syringes are intended to be used to inject fluid into, or withdraw fluids from, the body. The Omnican and Omnifix insulin syringes are intended for subcutaneous injection of insulin.

**SUBSTANTIAL EQUIVALENCE:**

The Omnifix® piston syringes and Omnican® and Omnifix insulin syringes have the same intended use, operation, and similar design and materials as the stated predicate devices, the B. Braun Injekt piston syringe, the NIPRO disposable hypodermic syringes with or without needle, and the BD Ultra Fine II, Micro Fine and Short Needle Insulin Syringes. Biocompatibility and functional testing have been performed to verify the safety and effectiveness of the Omnifix and Omnican syringes. There are no differences between the predicate and proposed devices that raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2007

Ms. Christine Ford
Regulatory Affairs Specialist
B. Braun Medical Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109

Re: K071459
Trade/Device Name: B. Braun Omnifix® Piston Syringes
B.Braun Omnican® and Omnifix® Insulin Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 24, 2007
Received: May 25, 2007

Dear Ms. Ford:

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.

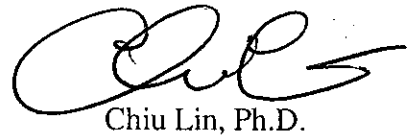
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 4. Indications for Use Statement



510(k) Number (if known): K071459

Device Names: B. Braun Omnican® and Omnifix® Insulin Syringes

Indications For Use:

The B. Braun Omnican® and Omnifix® Insulin Syringes are intended for subcutaneous injection of insulin.

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K071459

## 4. Indications for Use Statement



510(k) Number (if known): K071459

Device Names: B. Braun Omnifix® Piston Syringes

Indications For Use:

The B. Braun Omnifix® Piston Syringes are intended to be used to inject fluid into, or withdraw fluids from, the body.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K071459