K052773

JAN 2 4 2006

7.0 510(k) Summary

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 596-2367

Contact: Christine Ford, Regulatory Affairs Specialist

DEVICE NAME: B. Braun 0.2 micron filter

COMMON OR USUAL NAME: 0.2 micron filter

DEVICE CLASSIFICATION: Class II per Code of Federal Regulation, Title 21, §880.5860, Piston Syringe, product code FMF .

PREDICATE DEVICE: B. Braun PTFE Syringe Filter, K952918

DESCRIPTION: The B. Braun 0.2 micron Filter consists of a female luer taper, a filter assembly which contains a 0.2 micron nylon filter, a bottom cover and a male luer taper. A syringe is intended to be attached to the female luer taper end of the filter. A drug solution may then be drawn through the filter into the syringe. The filter is then removed and the resulting filtered solution may be used for patient administration. Conversely, the syringe may be filled with a drug solution prior to attachment of the filter. The filter is intended to retain particulates when the drug solution is expelled. Currently, drug compatibility testing has been completed for use of the filter with acetylcholine chloride solutions. Use of the filter with other solutions has not been tested.

INTENDED USE: The B. Braun 0.2 micron Filter is intended to filter particulates from drug solutions when attached to a syringe prior to patient administration.

SUBSTANTIAL EQUIVALENCE: The B. Braun 0.2 micron Filter has the same intended use, operation and function as stated for the B. Braun PTFE Syringe Filter (K952918). There are no differences 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

JAN 2 4 2006

Ms. Christine Ford
Regulatory Affairs Specialist
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

Re: K052773
Trade/Device Name: B. Braun 0.2 Micron Filter
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: January 10, 2006
Received: January 12, 2006

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.

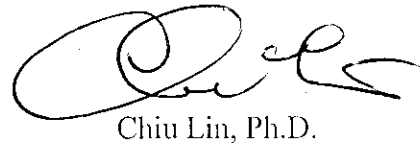
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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

K052773

2.0 Indications for Use Statement

510(k) Number (if known): _____

Device Name: B. Braun 0.2 micron Filter

Indications For Use: The B. Braun 0.2 micron Filter is intended to filter particulates from drug solutions when attached to a syringe prior to patient administration.

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)

[illegible]
[illegible] of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(Division Sign-Off)
510(k) Number K052773