K072247

## 5. 510(k) Summary

NOV 0 8 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:** Sterican Needles

**COMMON OR USUAL NAME:** Hypodermic Single Lumen Needles

**DEVICE CLASSIFICATION:** Hypodermic Single Lumen Needles
Class II, CFR Title 21 § 880.5570

**PREDICATE DEVICE:** BD Precision Glide™ Needles (BD Single Lumen Needle, Syringe, and Blood Collection Set), K021475

**DESCRIPTION:** The hypodermic needles are comprised of a metal tube that is sharpened at one end, and at the other end is bonded to a female connector (hub), which is designed to attach to a male connector, such as a syringe. The needles will be available in gauge sizes of 18 G through 27 G, and in lengths ranging from ½ inch to 4 ¾ inches.

**INTENDED USE:** The Sterican hypodermic needles, when attached to a male connector, are intended to be used to inject fluid into, or withdraw fluids from, parts of the body below the surface of the skin.

**SUBSTANTIAL EQUIVALENCE:** The Sterican hypodermic needles have the same intended use, operation, similar materials of construction, and are similar in design to the predicate device, the BD Precision Glide™ Needles, covered under K021475 (Single Lumen Needle, Syringe, and Blood Collection Set). Biocompatibility and functional testing have been performed to verify the safety and effectiveness of the Sterican needles. There are no differences between the predicate and proposed needles 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

NOV 0 8 2007

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

Re: K072247
Trade/Device Name: Sterican Hypodermic Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: August 09, 2007
Received: August 13, 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,

Neil R. P. Ogden for

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

K072247

## 4. Indications for Use Statement



510(k) Number (if known): _____

Device Name: Sterican Hypodermic Needles

Indications For Use:

The Sterican hypodermic needles, when attached to a male connector, are intended to be used to inject fluid into, or withdraw fluids from, parts of the body below the surface of the skin.

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)

Anthony D. Watson

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

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