

K081446

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitted By:**

JUL 17 2008

Pasquale Amato, RAC, CQA
Senior Regulatory Affairs Specialist

Becton, Dickinson and Company
BD Medical Surgical Systems
1 Becton Drive MC 237
Franklin Lakes, NJ 07417

Phone: 201-847-4513
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2. **Device Name:**

Trade Name: BD Spinal Needle

Common Names: Spinal Needle

Classification Name: Needle, Conduction, Anesthetic w/wo Introducer

Classification: Class II

3. **Predicate Device:**

BD Spinal Needle
BD Precisionglide Needle
BD Hypoint Needle
Manufactured by: Becton, Dickinson and Company

4. **Device Description:**

The BD Spinal needle consists of a non-lubricated stainless steel cannula attached to the needle hub using an epoxy adhesive. When appropriate for the procedure, this needle includes a stylet. This stylet consists of non-lubricated stainless steel. The stainless steel stylet is attached to the stylet handle using an epoxy adhesive. The needle assembly is protected with a polypropylene shield. The Spinal needle is packaged appropriately for either sterile or non-sterile, single use, purposes.

5. **Intended Use:**

An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.

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6. **Technological Characteristics:**

The BD Spinal Needle and the predicate device have the same identical technological characteristics and perform equivalently.

7. **Substantial Equivalence:**

Based on comparison of the device features, materials, intended use and performance, the BD Spinal Needle has shown to be substantially equivalent to the commercially available predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Pasquale Amato, RAC, CQA
Senior Regulatory Affairs Specialist
Becton, Dickinson and Company
BD Medical Surgical Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417

JUL 17 2008

Re: K081446

~~Trade/Device Name: BD Spinal Needle~~

Regulation Number: 21 CFR 868.5150

Regulation Name: Anesthesia Conduction Needle

Regulatory Class: II

Product Code: BSP

Dated: May 21, 2008

Received: May 22, 2008

Dear Mr. Amato:

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.

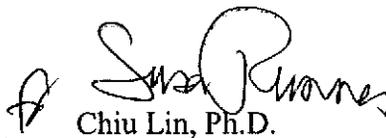
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Indications for Use

510(k) Number (if known): 15081446

Device Name: BD Spinal Needle

Indications For Use:

An anesthesia conduction needle is a device used to inject local anesthetics into a patient to ~~provide regional anesthesia.~~

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

W. Mary for M. Husband

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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