K091258

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitted By:**

Pasquale Amato, RAC, CQA
Senior Regulatory Affairs Specialist

OCT - 9 2009

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

Phone: 201-847-4513
Fax: 201-847-5307

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 25G
BD Spinal Needle 27G
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 insert molding process. 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 insert molding process. 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.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

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BD Medical Surgical
1 Becton Drive MC237
Franklin Lakes, New Jersey 07417

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Re: K091758
Trade/Device Name: BD Spinal Needle 27G
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: September 10, 2009
Received: September 16, 2009

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division 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):

Device Name: BD Spinal Needle 27G

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____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

L Schultz

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

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