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K012584

SEP - 6 2001

BD

Indispensable to human health

Summary of Safety and Effectiveness for the BD Durasafe™ Plus! Epidural Lock CSE Needle Set/Kit

1 BD Contact person:

Pasquale Amato
Regulatory Compliance Coordinator
BD Medical Surgical – Mail Code 226
1 Becton Drive
Franklin Lakes, NJ 07417-1880
Phone (201) 847- 4513
Fax (201) 847- 4855

2 Device Name: BD Durasafe™ Plus! Epidural Lock CSE Needle Set/Kit

3 Predicate Device(s):

3.1 BD Durasafe™ Variable Extension Combined Spinal Epidural (CSE) Needle Set/Kit K945497.

4 Intended Uses: The BD Durasafe™ Plus! Epidural Lock CSE Needle Set/Kit is used to perform the combined spinal/epidural (CSE) anesthesia procedure.

5 Device Description and Comparison:

A comparison between the modified BD Durasafe™ Plus! Epidural Lock CSE Needle Set/Kit and existing BD Durasafe™ Variable Extension Combined Spinal Epidural (CSE) Needle Set/Kit is provided in the table below:

COMPONENT / CHARACTERISTIC	CSE (EXISTING DESIGN)	CSE (MODIFIED DESIGN)
Cannula	Stainless Steel	Stainless Steel
Needle Hub	Polypropylene	Polypropylene
Stylet	Polypropylene	Polypropylene

COMPONENT / CHARACTERISTIC	CSE (EXISTING DESIGN)	CSE (MODIFIED DESIGN)
Color Additive	Pink/Gray	Pink/Gray
Gasket	None	Isobutyl Rubber
Needle Shield	Polyethylene	Polyethylene
Locking Mechanism	Slide/Grip Lock	Pinch Lock
Sterilization Process	ETO	ETO

6 Equivalence determination:

The modified BD Durasafe™ Plus! Epidural Lock CSE Needle Set/Kit is substantially equivalent in product function and intended use to the existing unmodified predicate device. The BD Durasafe™ Plus! Epidural Lock CSE Needle Set/Kit exhibits the following similarities as detailed below:

- Same intended use
- Similar confirmation of needle placement
- Same range of needle gauge sizes
- Similar insertion technique
- Same materials
- Same sterilization process

In summary the modified BD Durasafe™ Plus! Epidural Lock CSE Needle Set/Kit described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2001

Mr. Pasquale Amato
BD Medical Surgical
1 Becton Drive
Franklin Lakes, NJ 07417

Re: K012584
BD Durasafe™ Plus! Epidural Lock CSE Needle Set/Kit
Regulation Number: 868.5140/868.5150
Regulation Name: Anesthetic Conduction Kit/Anesthesia Conduction Needle
Regulatory Class: II (two)
Product Code: 73 CAZ/BSP
Dated: August 9, 2001
Received: August 10, 2001

Dear Mr. Amato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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.

In addition, we have determined that your device kit contains Povidine Iodine Solution and Xylocaine (Lidocaine) 1 percent which are subject to regulation as drugs.

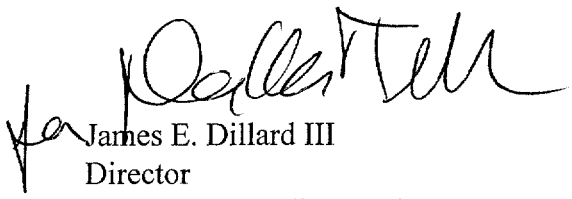
Our substantially equivalent determination does not apply to the drug component[s] of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component[s]. For information on applicable Agency requirements for marketing this [these] drug[s], we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your 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 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained 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/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number: not known at this time

Device Name: BD Durasafe™ Plus! Epidural Lock CSE Needle Set/Kit

Indications for Use: The BD Durasafe™ Plus! Epidural Lock CSE Needle Set/Kit is used to perform the combined spinal/epidural (CSE) anesthesia procedure.

Division of Cardiovascular & Respiratory Devices
510(k) Number K012584

prescription use ✓