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Hospital Disposables

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SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
NEEDLE STICK BLOCK

Regulatory Affairs Contact:	Muhamad Ansari Busse Hospital Disposables PO Box: 11067 75 Arkay Dr. Hauppauge NY 11788
Telephone:	631-435-4711 Ext: 254
Fax:	631-435-2849
Date Summary prepared:	Sept 23, 2005
Date Summary Revised:	February 27, 2006
Product Trade Name:	Needle Stick Block
Common Name:	needle, hypodermic, single lumen.
Classification:	Class II, 21 CFR 880.5570, FMI
Predicate Device:	SharpsAway Disposal Cup
Description:	Sterile/ Latex Free/ Needle Stick Block The proposed Needle Stick Block was created to help prevent needle sticks by providing a means of moving used sharps from procedure and hold it temporarily until procedure is completed to then be disposed off in a sharps container.
Intended Use:	The Needle Stick Block is a single needle holder to be used after the needle is removed from the patient and until it can be properly disposed, therefore, aiding in the prevention of needle stick injuries. The Needle Stick Block is a safety device designed to help the health care facilities to minimize the risk of needle sticks. Busse Hospital Disposable intent to sell this device individually and as part of safety trays in which needle is involved. The intended use will remain the same whether is sold individually or as part of a tray.

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510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE
NEEDLE STICK BLOCK

Summary of tests performed to prove the substantial equivalence of the Needle Stick Block with the predicate device:

A) Determination of puncture resistance of the foam insert for both devices.
B) Determination of puncture resistance of vessel wall for Needle Stick Block and SharpsAway predicate device.
C) Test to show that once inserted, Needle Stick Block with foam insert exerts enough resistance to retain needle for at least one hour under normal circumstances.
D) Simulate use study by experienced medical experts (at least 1 year experience with handling needles using the predicate instrument)
    1. Same intended use
    2. Same features

Technological Characteristics [21 CFR 807.92(a)(6)]
The subject device has the same Technological Characteristics as a legally marketed predicate device.

Conclusion [21 CFR 807.92(b)(3)]
The above statements are accurate representations of the device Busse intents to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted.

Manufacturer: Busse Hospital Disposables.

Official Correspondent: _____ (Signature)

Muhamad Ansari (printed name)
Title: Director of Regulatory Affairs
Date: 3/2/06

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2006

Mr. Muhamad Ansari
Director of Regulatory Affairs
Busse Hospital Disposables, Incorporated
75 Arkay Drive
P.O. Box 11067
Hauppauge, New York 11788

Re: K052843
Trade/Device Name: Needle Stick Block
Regulation Number: 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: II
Product Code: FMI
Dated: February 27, 2006
Received: March 7, 2006

Dear Mr. Ansari:

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 (301) 594-4618. 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/dsma/dsmamain.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

K052843

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INDICATIONS FOR USE

510(k) Number (if known): K052843

Device Name: Needle Stick Block.

Indication for Use: The Needle Stick Block is a single needle holder to be used after the needle is removed from the patient and until it can be properly disposed, therefore, aiding in the prevention of needle stick injuries

Prescription Use____x_____ (Per 21 CFR 801Subpart D)

AND/OR

Over-The-Counter Use____ (Per 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] General Hosp...
[illegible] Dental Devices

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