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K061394

SUMMARY

SEP - 6 2006

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
SPECIALTY NEEDLE

Regulatory Affairs Contact:	Muhamad Ansari Busse Hospital Disposables PO Box: 11067 75 Arkay Dr. Hauppauge NY 11788
Telephone:	631-435-4711 Ext: 254
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Date Summary prepared:	May 16, 2006
Product Trade Name:	Specialty Needles (Spinal Needle, Pencil Point Spinal Needle, Epidural Needle)
Common Name:	Anesthesia Conduction Needle.
Classification:	Class II, 21 CFR 868.5150
Product Code:	BSP
Predicate Device:	Exel Spinal Needle – (K895771)
Device Description:	Anesthesia conduction needles consist of different styles. All the needles consist of a plastic hub connected to a stainless steel cannula. Some of the needles have stylets made of the same steel whereas others have stylets made of plastic. Some of the needles have wings which can be attached to the hub for more stability depending on user procedure. The needles have been categorized as following: 1. Spinal Needles (Quincke) 2. Pencil Point Spinal Needle (Whitacre) 3. Epidural Needles (Tuohy & Hustead)

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The differences between the styles of needles are the tip of the needle, which is either pencil-point-tip (Whitacre), curved and sharp needle (Touhy), sharp needle tip (Quincke).

Needle Style	Gage Size Range	Length Range
Spinal Needle (Quinke)	18g to 25g	1 ½" to 6"
Pencil Point Spinal Neede (Whitacre)	18g to 25g	1 ½" to 6"
Epidural Needle (Tuohy, & Hustead)	16g to 25g	1 ½" to 6"

These needles will be provided as sterile, single use, disposable devices. They will be packaged individually or included in regional anesthesia trays.

Intended Use: Specialty needles (Spinal Needle, Pencil Point Needle, and Epidural Needle) are intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Summary of Testing: All materials used in the fabrication of the specialty needles were evaluated through biological qualification safety tests. The biocompatibility tests performed were L929 Men Elution Test, Kligman Maximization Test, Intracutaneous Injection Test, Systemic Injection Test, Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay
These materials have met the testing requirements and were found to be acceptable for the intended use.

Summary of tests performed to prove the substantial equivalence of the Specialty Needles with the predicate device:

1. Same intended use
2. Same material
3. Same flow rate
4. Same bonding strength

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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: Muhamad Ansari (Signature)

Muhamad Ansari (printed name)
Title: Director of Regulatory Affairs
Date: 5/16/06

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2006

Mr. Muhamad Ansari
Director of Regulatory Affairs
Busse Hospital Disposables, Incorporated
75 Arkay Drive
P.O. Box 11067
Hauppauge, New York 11788-0920

Re: K061394
Trade/Device Name: Specialty Needles
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: August 25, 2006
Received: August 28, 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 (240) 276-0120. 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,

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): _____

Device Name: Specialty Needles.

Indication for Use: specialty needles – Spinal Needle, Pencil Point Needle, and Epidural Needle – are intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.

Prescription Use____x_____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801Subpart D) (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)

...on Sign-Off)
...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number: K061394