busse
Hospital Disposables

K061737

SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
BUSSE LOSS OF RESISTANCE SYRINGE

DEC 18 2006

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 Revised:	Sept 20^{h}, 2006
Product Trade Name:	Busse Loss of Resistance Syringe
Common Name:	Loss of Resistance Syringe.
Classification Name:	Conduction Anesthetic
Classification:	Class II, 21 CFR 868.5140
Product Code:	CAZ
Predicate Device:	B-D Loss of Resistance Syringe – (K925902)
Device Description:	The Busse Loss of Resistance Syringe is a single use device, which is sold as sterile individually packaged and sterile packaged inside a kit/procedure tray. The syringe will be available in luer lock and luer slip tip.
Intended Use:	The Busse Loss of Resistance Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use. The loss of Resistance Syringe is not intended for injection or aspiration. The syringe will be sold sterile individually packaged, and as part of a sterile kit.

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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 and Hemolysis – Rabbit Blood Test.
These materials have met the testing requirements and were found to be acceptable for the intended use.

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.
Based on all the testing and comparison Busse believes the subject device is substantially equivalent to the predicate device
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: 9/21/10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Muhamad Ansari
Director of Regulatory Affairs
Robert Busse & Company, Incorporated
Corporate Offices
P.O. Box 11067
Hauppauge, New York 11788

DEC 18 2006

Re: K061737
Trade/Device Name: Busse Loss of Resistance Syringe
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: November 20, 2006
Received: November 22, 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): K061737

Device Name: Busse Loss of Resistance Syringe.

Indication for Use: The Busse Loss of Resistance Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use. The loss of Resistance Syringe is not intended for injection or aspiration. The Syringe will be sold sterile individually packaged, and as part of a sterile kit.

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)

Mark Weiss for Ann Graham

...of Anesthesiology, General Hospital,
...ion Control, Dental Devices

K061737