busse
Hospital Disposables

K093970

510(k) Summary

AUG 06 2010

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: December 17, 2009

Product Trade Name: Busse Epidural Catheter Kit

Common Name: Epidural Catheter

Classification Name: Class II, 21 CFR 868.5120, Product code BSO

Predicate Device: Micor Conduction Catheter, K001717, Micor Inc.

Device Description: The Epidural Catheter kit consists of clear tubing with a black radiopaque stripe, a Thread assist guide, a Connector Gasket, and a Tuohy Borst adapter catheter connection. All inserted in a Polyethylene bag. The catheter is marked at 5 cm from the tip with 1 cm increments up to 20 cm. The 10 cm mark is indicated by two marks, the 15 cm by three marks, and the 20 cm by four marks.

The Catheter will be available 20 Gauge, with a nominal length of 36 inches. It will be available in open tip or closed tip with 3 eyes. As an extra safety feature, the tip of the catheter is incorporated with a marking to assure the completed catheter has been removed.

Intended Use: The epidural catheter is intended for administration of local anesthetics into epidural space. Busse recommends the removal and/or replacement of the catheter every 72 hours.

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Technological Characteristics: The design of the proposed Catheter is the same as the predicate device, except for the minor changes in the material used. The material does not effect the performance of the device, as attached testing demonstrate.

Summary of Testing: All materials used in the fabrication of the epidural catheter were evaluated through biological qualification safety tests.
The biocompatibility tests performed were:

1. Kligman Maximization Test
2. Intracutaneous Injection Test
3. Systemic Injection Test
4. Rabbit Pyrogen Test
5. L929 Mem Elution Test
6. Hemolysis Test
7. Subacute Toxicity

These materials have met the testing requirements and were found to be acceptable for the intended use.

Summary of Performance Testing: Busse Epidural Catheter has been tested for the following performance tests:

1. Liquid Leakage
2. Kink Test
3. Flow Rate
4. General Tensile Testing
5. Pull Test

These materials have met the testing requirements and were found to be acceptable for the intended use.

Conclusion: 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.

Official Correspondent: Muhamad Ansari (Signature)

Muhamad Ansari (printed name)

Title: Director of Regulatory Affairs

Date: 6/24/10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Muhamad Ansari
Director of Regulatory Affairs
Busse Hospital Disposables
75 Arkay Drive
Hauppauge, New York 11788

AUG 06 2010

Re: K093920
Trade/Device Name: Busse Hospital Disposable Epidural Catheter Kit
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: July 29, 2010
Received: July 30, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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

K093920

AUG 0 6 2010

510(k) Number (if known): _____

Device Name: Busse Hospital Disposable Epidural Catheter Kit.

The epidural catheter kit is intended for administration of local anesthetics into epidural space. Busse recommends the removal and/or replacement of the catheter every 72 hours.

(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

510(k) Number: K093920

Prescription Use____X____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)