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Hospital Disposables

K070465

SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
BUSSE EPIDURAL CATHETER

Regulatory Affairs Contact: Muhamad Ansari
Busse Hospital Disposables
PO Box: 11067
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JUL 19 2007

Date Summary Prepared: February 8th 2007

Product Trade Name: Busse Epidural Catheter

Common Name: Epidural Catheter

Classification Name: Anesthesia Conduction Catheter

Classification: Class II, 21 CFR 868.5120

Product Code: BSO

Predicate Device: Micor – Conduction Catheter – (K001717)

Device Description: The Busse Epidural Catheter is a single use device, which is sold as sterile individually packaged and sterile packaged inside a kit/procedure tray.

Intended Use: The Epidural Catheter is intended for administration of local anesthetics into the epidural space. Busse recommends the removal and/or replacement of the catheter every 72 hours.
The epidural catheter will be sold sterile individually packaged, and as part of a sterile kit.
The Catheter will also be sold as a non-sterile product to kit packers, who then may sterilize the catheter as part of a kit.

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510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

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 L929 Men Elution Test, Kligman Maximization Test, Intracutaneous Injection Test, Systemic Injection Test, Salmonella Typhimurium; and Escherichia Coli Reverse Mutation Assay, Hemolysis – Rabbit Blood, 14 Day Repeat Dose Intravenous Toxicity Study (Sub – Chronic), Intramuscular Implantation Test – ISO
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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2007

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

Re: K070465
Trade/Device Name: Busse Epidural Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: July 6, 2007
Received: July11, 2007

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 (301) 443-6597 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): K070465

Device Name: Busse Epidural Catheter.

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

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070465