K082297

busse
Hospital Disposables

DEC 0 9 2008

510(k) Summary

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: August 6, 2008

Product Trade Name: Busse Surgical Drapes

Common Name: Surgical Drapes

Classification Name: Surgical Drapes
Class II, 21 CFR 878.4370, Product code KKX

Predicate Device: 3M Company, Drapes, K031287

Device Description: Surgical drapes are intended to provide protection from microbial and other contamination. There are various sizes, with & without fenestration, and with & without adhesive strip/patch.

Intended Use: A Surgical Drape is a protective patient covering, such as to isolate a site of surgical incisions from microbial and other contamination.

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Technological Characteristics/Substantial Equivalence:

The surgical drapes are generally identical to 3M Surgical Drapes in design, material & intended use.

Summary of Testing:

All materials used in the fabrication of the surgical drapes 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

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 generally 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

DEC 0 9 2008

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

Re: K082297
Trade/Device Name: Busse Surgical Drape I
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: November 13, 2008
Received: November 18, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 S. Lin, Ph. D
Division 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 Statement

510(k) Number (if known): K082297

Device Name: Busse Surgical Drape I

Indication for Use: The Busse Surgical Drape is intended for external use only and is used is as a protective patient covering, such as to isolate a site of surgical incisions from microbial and other contamination. They are provided sterile using ethylene oxide.

Prescription Use ____ AND/OR Over-The-Counter Use X
(Per 21 CFR 801Subpart D) (Per 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE 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: K082297