K093909

busse
Hospital Disposables

MAY - 6 2010

Summary of Safety and Effectiveness

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:	April 16, 2010
Product Trade Name:	Busse Surgical Drapes IV
Common Name:	Surgical Drapes
Classification Name:	Surgical Drapes Class II, 21 CFR 878.4370, Product code KKX
Predicate Device:	KC Surgical Drapes, K083234, Kimberly Clark Corp.
Device Description:	Surgical drapes described in this submission are one piece, single use, designed to provide an absorbent sterile barrier & 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. They are provided sterile using ethylene oxide.
Technological Characteristics:	The subject device has the same Technological Characteristics as a legally marketed predicate device
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. Cytotoxicity: Agar Overlay (L929) 2. Sensitization: Buehler Method 3. Irritation: Primary Skin (ISO)

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4. Flammability Test
5. Lint 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: _____ (Signature)

Muhamad Ansari _____ (printed name)

Title: Director of Regulatory Affairs

Date: 4/27/10

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

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

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Re: K093909
Trade/Device Name: Busse Surgical Drape IV
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: April 27, 2010
Received: April 29, 2010

Dear Mr. Muhamad 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. 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

INDICATION FOR USE STATEMENT

510(k) Number (if known): K093909

Device Name: Busse Surgical Drape IV

Indication for Use:

Busse Surgical Drape IV is intended to be used 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: k093909