K093835

# 510(k) Summary

FEB - 4 2011

| | |
|---|---|
| **Regulatory Affairs Contact** | **Ms. Mary Mejaes**<br>**BAM Corporation Ltd.**<br>**Unit 1706 Tower 2, Grand Central Plaza**<br>**No. 138 Shatin Rural Committee Rd.**<br>**Shatin, Hong Kong** |
| **Telephone:** | **852-2314-1300** |
| **Fax:** | **852-2314-1317** |
| **Email:** | **mary@bam-corp.com** |
| **Date Summary Prepared:** | **June 23, 2010** |
| **Common Name:** | **BAM Standard Surgical Gown**<br>**BAM Reinforced Surgical Gown**<br>**BAM Ultra-Reinforced Surgical Gown** |
| **Classification Name:** | **Surgical Gowns**<br>**Class 2, 21 CFR 878: 4040, Product FYA** |
| **Predicate Device:** | **Kimberly Clark Ultra Surgical Gown**<br>**Kimberly Clark Ultra Film Reinforced Surgical Gown** |
| **Device Description:** | **BAM Standard, Reinforced and Ultra Reinforced Surgical Gowns are full-length, nonwoven SMS polypropylene gowns. They are constructed with hook and loop neck closures and tie waist closures. The BAM Standard Surgical Gown has an extra layer of SMS fabric reinforcement in the sleeves and BAM Reinforced Surgical Gown has an extra layer of fabric in critical areas. The Ultra Reinforced Gown has an extra layer of film Reinforced fabric in the critical areas for higher Barrier protection. BAM Standard and Reinforced Surgical Gowns meet the requirements for the Association for the Advancement of Medical Instrumentation (AAMI) Level 3** |

| | |
|---|---|
| | **Requirements for liquid barrier performance. The BAM Ultra Reinforced Surgical Gown fully meets the requirements of AAMI Level 4 Liquid barrier requirements for Critical areas. The BAM Standard, Reinforced and Ultra-Reinforced and their predicates are provided sterile or non-sterile and for single use.** |
| **Intended Use** | **BAM Surgical Gowns are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids and particulate material.** |
| **Substantial Equivalence** | **BAM Standard, Reinforced and Ultra Reinforced Surgical Gowns are substantially equivalent to the predicate, Kimberly Clark Ultra Surgical Gown and Kimberly Clark Ultra Reinforced Surgical Gowns in intended use, design, materials and biocompatibility attributes. BAM Standard, Reinforced and Ultra Reinforced Surgical Gowns and their predicates are provided for single use and either Sterile or Non- sterile.** |

| Product | Aspect | Comparison |
|---|---|---|
| BAM Standard, Reinforced and Ultra Reinforced Surgical Gowns | Basic Intended Use | Same as Kimberly Clark Ultra and Ultra Reinforced Surgical Gowns |
| BAM Standard, Reinforced and Ultra Reinforced Surgical Gowns | Material Used | SMS, Same as Kimberly Clark Ultra and Ultra Reinforced Surgical Gowns |
| BAM Standard, Reinforced and Ultra Reinforced Surgical Gowns | Sterility | Same as Kimberly Clark Ultra and Ultra Reinforced Surgical Gowns both sterile by EtO or non-sterile |
| BAM Standard, Reinforced, Ultra Reinforced Surgical Gowns | Testing | Same barrier testing and AAMI barrier classification levels as Kimberly Clark Ultra and Ultra Reinforced Surgical Gowns. |

| | |
|---|---|
| **Summary of Testing** | **BAM Standard and Reinforced Surgical Gowns have been tested in compliance with the requirements of AAMI Level 3 liquid barrier performance requirements of ANSI/AAMI PB70 :2003 " Liquid barrier performances and classification of protective apparel and drapes intended for use in healthcare facilities." The critical zones of BAM Ultra Reinforced Surgical Gowns have been tested in compliance with Level 4 liquid barrier performance requirements of ANSI/AAMI PB70:2003.**<br><br>**In addition BAM Standard, Reinforced and Ultra Reinforced Surgical Gowns have been tested and meet the requirements for Class 1, "normal flammability" in accordance with 16 CFR Part 1610. These devices also meet The requirements for biocompatibility per ISO 10993-10** |
| **Conclusion** | **The above statements are true representations of the Standard, Reinforced and Ultra Reinforced Surgical Gowns BAM Corporation Ltd. intends to market that believes the subject devices are substantially equivalent to the predicate devices. All data and information in the premarket notification are truthful and accurate and no material fact has been omitted.** |

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

Ms. Mary Mejaes
Director of Official Cerrespondent
BAM Corporation Limited
Unit 1706, Tower 2, Grand Central Plaza, No. 138
Shatin Rural Committee Road
Shatin N.T. Hong Kong

FEB - 4 2011

Re: K093835
Trade/Device Name: BAM Standard, Reinforced and Ultra Reinforced Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: January 3, 2011
Received: January 5, 2011

Dear Ms. Mejaes:

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,

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

510(k) Number: K093835

Device Name: BAM STANDARD, REINFORCED AND ULTRA REINFORCED SURGICAL GOWNS

Indications For Use:

BAM STANDARD, REINFORCED AND ULTRA REINFORCED SURGICAL GOWNS are sterile, single use, blue SMS Surgical Gowns intended to protect surgical patients and operating room personnel from the transfer of micro-organisms, body fluids and particulate material. The BAM STANDARD and REINFORCED SURGICAL GOWNS meet Level 3 of AAMI Liquid Barrier Classifications and the BAM ULTRA REINFORCED GOWNS meet Level 4 of the AAMI Liquid Barrier Classifications in their critical zones. The base material of the gowns is the same for the three categories. The sizing is the same except the BAM ULTRA REINFORCED GOWNS are longer. The only other difference is the chest and sleeve reinforcement panels added. BAM Reinforced blue SMS Surgical Gowns have a one layer SMS fabric added to the chest and sleeves. BAM Ultra Reinforced Blue SMS Surgical Gowns have a PET + PE film reinforcement added to the chest and sleeves. These gowns have been EtO sterilized.

BAM STANDARD, REINFORCED AND ULTRA REINFORCED SURGICAL GOWNS are also sold as bulk non-sterile, single use items, to repackager/ relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.

See Page 2 for a Product List

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart 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
Office of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k)_____

Elizabeth D. Mansin-Well
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093835

| No. | Model No. | Name | Size | Category |
|---|---|---|---|---|
| 1 | L: 1990<br>XL:1991<br>XXL: 1992 | OR SMS Gown, Standard with Fabric Reinforcement Sleeves<br>(BAM Sterile Standard blue SMS Surgical Gowns) | Large (L), X-Large (XL), XX-Large (XXL) | Standard |
| 2. | L: 1990U<br>XL:1991U<br>XXL: 1992U | OR SMS Gown, Standard with Fabric Reinforcement Sleeves<br>(BAM Non-sterile Standard blue SMS Surgical Gowns) | Large (L), X-Large (XL), XX-Large (XXL) | Standard |
| 3. | L:2000<br>XL:2001<br>XXL:2002 | OR SMS Gown, with Fabric Reinforcement Chest and Sleeves<br>(BAM Sterile Reinforced blue SMS Surgical Gowns) | Large (L), X-Large (XL), XX-Large (XXL) | SMS Fabric Reinforced |
| 4. | L:2000U<br>XL:2001U<br>XXL:2002U | OR SMS Gown, with Fabric Reinforcement Chest and Sleeves<br>(BAM Non-sterile Reinforced blue SMS Surgical Gowns) | Large (L), X-Large (XL), XX-Large (XXL) | SMS Fabric Reinforced |
| 5. | L: 2010<br>XL:2011<br>XXL: 2012 | OR SMS Gown, with Film Reinforcement Chest and Sleeves<br>(BAM Sterile Ultra Reinforced blue SMS Surgical Gowns) | Large (L), X-Large (XL), XX-Large (XXL) | PET+ PE Film Reinforced |
| 6. | L: 2010U<br>XL:2011U<br>XXL: 2012U | OR SMS Gown, with Film Reinforcement Chest and Sleeves<br>(BAM Non-sterile Ultra Reinforced blue SMS Surgical Gowns) | Large (L), X-Large (XL), XX-Large (XXL) | PET+PE Film Reinforced |