DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 7, 2017

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

Re: K160337
Trade/Device Name: SafeCare Open Back Protective Gowns
ValueCare Open Back Protective Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: June 20, 2017
Received: June 27, 2017

Dear Mary 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Mark S. Fellman -S

for

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160337

Device Name
ValueCare® Open Back Protective Gowns

Indications for Use *(Describe)*
These gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. The back of the gown is open and non-protective . They are not intended for use in the operating room.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160337

Device Name
SafeCare® Open Back Protective Gowns

Indications for Use *(Describe)*
These gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. The back of the gown is open and non-protective . They are not intended for use in the operating room.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

K160337

Regulatory Affairs Contact: Ms. Mary Mejaes
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Date Summary Prepared: July 3, 2017

Common Name: Single Use/Non-Sterile Open Back Protective Gowns

Classification Name: Surgical Isolation Gowns,
Class II, 21 CFR 878: 4040, Product Code : FYC

Proprietary Name: SafeCare® Open Back Protective Gowns
ValueCare® Open Back Protective Gowns

Device Description: SafeCare® Open Back Protective Gowns (Models: 46969-097X, 46969097XB, 46969097X-10, 46969-098 & 46969-098D) and ValueCare® Open Back (Model: 4550-25X) Protective Gowns are open back gowns made from extruded plastic film.

The SafeCare® and ValueCare® Open Back Protective gowns provide barrier protection to the wearer from body fluids and particulate materials and have passed barrier testing according to ANSI/AAMI PB70:2012 Level 3 protection or equivalent.

The significant design points of the gowns are:

1. Made from extruded plastic film to provide an effective barrier meeting the requirements for penetration testing as per ANSI/AAMI PB70: 2012 Level 3 according to AATCC 42:2013 and AATCC 127:2014 test methods.
2. Backless to provide comfort
3. Thumb loops at the wrist which help to hold gown sleeves down
4. Back has perforations so the gowns can be removed without taking over the head in case they are contaminated

Predicate Device: Poly-Med Disposable Personal Protective Gown Apron, 510(k) K925077

Indications for Use: These gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. The back of the gown is open and non-protective. They are not intended for use in the operating room.

Comparison of Subject and Predicate Devices:

Aspect	**Subject Device:** ValueCare®Open Back Protective Gowns 510K No: K160337	**Subject Device:** SafeCare®Open Back Protective Gowns 510K No: K160337	**Predicate Device:** PolyMed Disposable Personal Protective Gown Apron 510K No: K925077
Design	Design includes open back, thumb loops, back perforation for easy removal and waist tie	Design includes open back, thumb loops, back perforation for easy removal and waist tie	Design includes open back, thumb loops, back perforation for easy removal and waist tie
Material	Made from extruded plastic film.	Made from extruded plastic film.	Made from extruded plastic film.
Material Color	Blue	Blue or Yellow	Blue, Red, Pink, White, Yellow
Indications for Use	These gowns are intended to protect health care patients and health care personnel from the transfer of micro-organisms, body fluids and particulate material. The back of the gown is open and non- protective. They are not intended for use in the operating room.	These gowns are intended to protect health care patients and health care personnel from the transfer of micro-organisms, body fluids and particulate material. The back of the gown is open and non- protective. They are not intended for use in the operating room.	Designed for use in healthcare to provide liquid and aerosol resistance.
Labeling Claims	These gowns are intended to protect health care patients and health care personnel from the transfer of micro-organisms, body fluids and particulate material. The back of the gown is open and non- protective. They are not intended for use in the operating room. * Non-Sterile	These gowns are intended to protect health care patients and health care personnel from the transfer of micro-organisms, body fluids and particulate material. The back of the gown is open and non- protective. They are not intended for use in the operating room. * Non-Sterile	In compliance with OSHA Bloodborne Pathogen Standard, 29, CFR Part 1910.1030. Provides liquid and aerosol blood resistance.

	* Not Made with Natural Rubber Latex * Meets ANSI/AAMI PB70: 2012 Level 3 * Open Back Non-protective * Single Use, Disposable	* Not Made with Natural Rubber Latex * Meets ANSI/AAMI PB70: 2012 Level 3 * Open Back Non-protective * Single Use, Disposable	
Biocompatibility - Sensitization and Irritation	Under the condition of the studies: ISO 10993-10:2010, the device is non-irritating and non- sensitizing	Under the condition of the studies: ISO 10993-10:2010, the device is non-irritating and non- sensitizing	Not provided
Biocompatibility-Cytotoxicity	Under the condition of the studies: ISO10993-5:2009, The test device extract did not show potential toxicity to L-929 cells	Under the condition of the studies: ISO 10993-5:2009, The test device extract did not show potential toxicity to L-929 cells	Not provided
Barrier Testing	ANSI/AAMI PB70: 2012 Level 3: AATCC 127:2014 Hydrostatic Pressure Test AATCC 42:2013 Impact Penetration Test	ANSI/AAMI PB70: 2012 Level 3: AATCC 127:2014 Hydrostatic Pressure Test AATCC 42:2013 Impact Penetration Test	Not provided
Flammability	Meets Class 1 "normal flammability " in accordance to 16 CFR Part 1610	Meets Class 1 "normal flammability " in accordance to 16 CFR Part 1610	Not provided
Sterility	Provided non-sterile	Provided Non-sterile	Provided Non-sterile

Summary of the technological characteristics of the device compared to the Predicate Device:

- The PolyMed Disposable Personal Protective Gown Apron 510(k) K925077 and the SafeCare® Open Back Protective Gowns and ValueCare® Open Back Protective Gowns 510(k) K160337 are both made from extruded Plastic Film material.
- The construction and design features which include an open back, thumb loops, heat sealed sleeve seams and perforated back for easy removal are found in both gowns.
- Both the subject and predicate device are being promoted as suitable to be worn by health care professionals as barrier protection.
- Neither gown is intended to be used for surgical procedures and both are provided non-sterile.

- The SafeCare® and ValueCare® Open Back Protective Gowns are substantially equivalent to the PolyMed Disposable Personal Protective Gown Apron in that they both provide the following characteristics: fluid barrier and tensile strength.

Summary of Testing:

Test Performed	Test Standard	Results
Dermal Irritation Test	ISO 10993-10:2010 Skin Irritation	Under the conditions of the studies: ISO 10993-10:2010, the subject device is non-irritating.
Dermal Sensitization Test	ISO 10993-10:2010 Skin Sensitization	Under the conditions of the studies: ISO 10993-10:2010, the subject device is non-sensitizing.
Cytotoxicity Test	ISO 10993-5:2009 In Vitro Cytotoxicity	Under the conditions of the studies: ISO 10993-5:2009, the SafeCare® Open Back Protective Gowns and ValueCare® Open Back Protective Gowns extract did not show potential toxicity to L-929 cells.
Flammability Test	16 CFR Part 1610	Subject Device meets Class 1 requirements per NFPA 16 CFR Part 1610
Fluid Penetration Test	ANSI/AAMI PB70:2012 AATCC 127:2014 Hydrostatic Pressure Test and AATCC 42:2013 Impact Penetration test	SafeCare® Open Back Protective Gowns and ValueCare® Open Back Protective Gowns have been successfully tested and meet the Level 3 requirements of the ANSI/AAMI PB70:2012 Liquid Barrier classifications.

Conclusion:

Based on the results of biocompatibility testing, physical performance testing, and intended use the subject devices are as safe and as effective and perform as well as the predicate device. The SafeCare® and ValueCare® Open Back Protective Gowns are substantially equivalent to the predicate device cleared under K925077.