November 17, 2021

AZAC Group
Robert Seiple
President
QPM Consulting, LLC
3817 Seville Rd
Denton, Texas 76205

Re: K211538
Trade/Device Name: AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: QPC
Dated: October 8, 2021
Received: October 13, 2021

Dear Robert Seiple:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Clarence W. Murray III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211538

Device Name
AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown

Indications for Use *(Describe)*

The AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown is intended to protect health care personnel and patients from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room.

The AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown gown meets the barrier protection requirements of AAMI Level 3 per ANSI/AAMI PB70:2012 – Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.

The AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown is a single use, disposable medical device and is provided non-sterile.

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.

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510(k) Summary
K211538

AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown

1. Submission Sponsor

AZAC Group
17870 Castleton St., Suite 121 City of Industry, CA, 91748 USA
Contact: Yen Ping Shan
Title: COO

2. Submission Correspondent

Robert Seiple, RAC
President, QPM Consulting, LLC
Email: Robert@QPMconsult.com
Direct number: (940) 390-0961

3. Date Prepared

16 November 2021

4. Device Identification

Type of 510(k) Submission: Traditional

Device:	Gown, Non-Sterile, Non-Isolation, intended to Provide Moderate or High Barrier Protection
Regulation Description	Surgical Apparel
Regulation Number:	21 CFR 878.4040
Product Code:	QPC: Gown, Non-sterile, Non-Isolation, Intended to provide Moderate or High Barrier Protection
Class:	Class 2
Panel:	General Hospital

Trade or Proprietary Name: AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown

5. Legally Marketed Predicate Device(s)

Device name:	BAM Corporation – Safe Care open Care Protective Gowns and ValueCare Open Back Protective Gowns
510(k) number:	K160337
Manufacturer:	BAM Corporation

6. Indication for Use Statement

The AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown is intended to protect health care personnel and patients from the transfer of microorganisms, body fluids and

particulate material. Not intended for use in the operating room

The AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown meets the barrier protection requirements of AAMI Level 3 per ANSI/AAMI PB70:2012 – Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.

The AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown is a single use, disposable medical device and is provided non-sterile.

7. Device Description

The AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown is used in moderate risk situations such as venous blood draws, inserting IVs, and emergency room use. The gown is not sterile; is not an isolation gown and is not indicated for use in the Operating Room.
The AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown is made of one-piece chlorinated polyethylene elastomer non-woven tri-laminate. The Level 3 gown meets the ANSI/ AAMI PB70 Level 3 standards. The gown is a single use, disposable device.

8. Comparison of Technological Characteristics with the Predicate Device

The following table compares the AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown to the BAM Corporation SafeCare Open Back Protective Gowns (K160337).

Table 1 – Comparison AZAC Level 3 Gown vs BAM Corp Gown

Attribute	AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown	BAM Corporation SafeCare Open Back Protective Gowns	Comparison
510(k) Number	K211538	K160337	-
Product Code	QPC	QPC	Same
Regulation Number	878.4040	878.4040	Same
Indications For Use	The AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown is intended to protect health care personnel and patients from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room The AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown meets the barrier protection requirements of AAMI Level 3 per ANSI/AAMI PB70:2012 – Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities. The AZAC Protect X Level 3,	These gowns are intended to protect both 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.	Similar

	Single Use, Non-Sterile, Protective Gown is a single use, disposable medical device and is provided non-sterile.		
Material Composition	Chlorinated polyethylene elastomer (CPE)	Extruded from plastic film	Similar.
AAMI PB70 Barrier Protection Level	Level 3	Level 3	Same
Design Features	Over-the-head slip on Integrated Belt Ties Thumbhook cuffs	Open back, thumb loops, perforated back.	Similar
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Color	Blue and Yellow	Blue and Yellow	Same
Biocompatibility	Under the conditions of the study, non-cytotoxic Under the conditions of the study, not a sensitizer Under the conditions of the study, non-irritating	Under the conditions of the study, non-cytotoxic Under the conditions of the study, not a sensitizer Under the conditions of the study, non-irritating	Same

9. Non-Clinical Performance Data

To demonstrate the safety and effectiveness of AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown and to show substantial equivalence to the predicate device, AZAC Group completed the following non-clinical tests listed in the following table. Results confirm that the design inputs and performance specifications are met. The AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown passed the following tests in accordance with internal requirements and applicable standards as shown below:

Table 2 – Non-clinical performance testing

Test Method	Purpose	Criteria	Result
AAMI PB70:2012	Overall barrier performance	Meet requirements for classification as AAMI PB70 Level 3 gown	Pass
Hydrostatic Pressure Test (AATCC 127:2018)	Resistance to static liquid	NLT 50.0 cm H_2O	Pass
Impact Penetration (AATCC 42-2017)	Resistance to liquid stream	No penetration	Pass
ASTM D 3776 – Mass/unit area	Basis weight of material	26 g/m^2	Pass
ASTM D5034 Breaking Strength – Grab Test	Durability: Grab test	Length – 27 N Width – 31.5 N	Pass
ASTM D5587 Tear Strength – Trapezoid Test	Durability: Trapezoid	Length – 10.5 N Width 14.0 N	Pass
16 CFR 1610 - Flammability	Flammability	Class 1	Pass

ISO 10993-5 Cytotoxicity	Biocompatibility: Cytotoxicity potential	Under the conditions of the study, non-cytotoxic	Pass
10993-10 Sensitization/ Irritation	Biocompatibility: Sensitization and irritation	Under the conditions of the study, not a sensitizer Under the conditions of the study, non-irritating	Pass

10. Clinical Performance Data

Clinical performance data was not used in support of this evaluation.

11. Statement of Substantial Equivalence

The conclusions drawn from the non-clinical testing demonstrate that the AZAC Protect X Level 3, Single Use, Non-Sterile, Protective Gown is as safe, as effective, and performs as well as or better than the legally marketed predicate SafeCare Open Back Protective Gowns (K160337)