April 7, 2022
Dukal Corporation
Megan Quevedo
Quality and Regulatory Affairs Engineer
2 Fleetwood Court
Ronkonkoma, New York 11779

Re: K203237
Trade/Device Name: Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, and Sterile AAMI Level 4 Splicing Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA

Dear Megan Quevedo:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 18, 2022. Specifically, FDA is updating this SE Letter for a correction to the 510(k) Summary as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Bifeng Qian, M.D., Ph.D., Office of Surgical and Infection Control Devices, at via phone: (301) 796-2261 or email: bifeng.qian@fda.hhs.gov.

Sincerely,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Acting 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

March 18, 2022

Dukal Corporation
Megan Quevedo
Quality and Regulatory Affairs Engineer
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Ronkonkoma, New York 11779

Re: K203237
Trade/Device Name: Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, and Sterile AAMI Level 4 Splicing Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA
Dated: March 10, 2022
Received: March 16, 2022

Dear Megan Quevedo:

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,

Clarence W. Murray III -S

Clarence W. Murray III, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203237

Device Name
Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, and Sterile AAMI Level 4 Splicing Surgical Gown

Indications for Use *(Describe)*
The Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, and Sterile AAMI Level 4 Splicing Surgical Gown 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. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, Dukal AAMI Level 3 Reinforced Surgical Gown and Sterile AAMI Level 3 Surgical Gown met the requirements for Level 3 classification; Dukal Sterile AAMI Level 4 Surgical Gown and Sterile AAMI Level 4 Splicing Surgical Gown met the requirements for Level 4 classification.

The Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, and Sterile AAMI Level 4 Splicing Surgical Gown are single use, disposable medical devices, and are provided 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.

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510(k) SUMMARY K203237

510(k) Premarket Notification for Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, and Sterile AAMI Level 4 Splicing Surgical Gown

1. **Submitter**:

Dukal, LLC
2 Fleetwood Court
Ronkonkoma NY 11779
Phone: 631-656-3800
Fax: 631-656-3810

2. **FDA Registration Number**: 2435946

3. **Regulatory Affairs Contact**:

Megan Quevedo
Quality and Regulatory Affairs Supervisor
2 Fleetwood Court
Ronkonkoma NY 11779
Telephone Number: 631-656-3800 ext. 133
Fax Number: 631-656-3810

4. **Date Summary Prepared**: April 7, 2022

5. **Name of Device**: Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, Sterile AAMI Level 4 Splicing Surgical Gown

6. **Trade Name**: Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, Sterile AAMI Level 4 Splicing Surgical Gown

7. **Common/Classification Name**: Surgical Gowns

8. **Regulation Number**: 21 CFR §878.4040
9. **Device Class**: Class II
10. **Regulation Name**: Surgical Apparel
11. **Product Code**: FYA

12. **Predicate Device**: Xuchang Zhengde Environstar Medical Products Co., Ltd

SMS Standard Surgical Gown (level 3), SMS Surgical Gown with Reinforcement (level 3), BVB Surgical Gown (level 4), BVB Splicing Surgical Gown (level 4).

- 510k #K192290, cleared on 4/30/2020.

13. **Device Description**:

Surgical Gowns 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. The Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, and Sterile AAMI Level 4 Splicing Surgical Gown are single use, disposable medical devices, and are provided sterile. Each type of Surgical Gown is available in six product sizes: M, L, XL, XXL, XXXL and XXXL-XL.

Dukal Sterile AAMI Level 3 Reinforced Surgical Gown and Sterile AAMI Level 3 Surgical Gown are made with SMS nonwoven material. The Dukal Sterile AAMI Level 4 Surgical Gown and Sterile AAMI Level 4 Splicing Surgical Gown are made with BVB material.

Only the Dukal Sterile AAMI Level 3 Reinforced Surgical Gown is reinforced with laminated material. Dukal Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, Sterile AAMI Level 4 Splicing Surgical Gown are non-reinforced.

Only the Sterile AAMI Level 4 Splicing Surgical gown has a different material for the back of the gown (SMS nonwoven fabric). The back of the gown for the Sterile AAMI Level 4 Surgical gown is made with BVB material.

All gowns are blue, with hook and loop closures, belt ties, and knitted cuff sleeves.

14. **Packaging**:

Packaging for Level 3 Gowns:
Sizes M and L: 1 gown/pouch, 28 pouches/case
Sizes XL: 1 gown/pouch, 26 pouches/case
Sizes XXL, XXXL and XXXL-XL: 1 gown/pouch, 24pouches/case

Packaging for Level 4 Gowns:
Sizes M: 1 gown/pouch, 28 pouches/case
Sizes L and XL: 1 gown/pouch, 26 pouches/case

Sizes XXL, XXXL and XXXL-XL: 1 gown/pouch, 24pouches/case

15. **Indications for Use:**

The Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, and Sterile AAMI Level 4 Splicing Surgical Gown 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. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, Dukal AAMI Level 3 Reinforced Surgical Gown and Sterile AAMI Level 3 Surgical Gown met the requirements for Level 3 classification; Dukal Sterile AAMI Level 4 Surgical Gown and Sterile AAMI Level 4 Splicing Surgical Gown met the requirements for Level 4 classification. The Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, and Sterile AAMI Level 4 Splicing Surgical Gown are single use, disposable medical devices, and are provided sterile.

16. **Comparison of Technological Characteristics with the Predicate Device**:

AAMI Level 3 Surgical Gowns:

Element of Comparison	**Predicate Device Xuchang Zhengde Environstar Medical Products Co., Ltd SMS Standard Surgical Gown (Level 3) & SMS Surgical Gown with Reinforcement (Level 3) (K192290)**	**Subject Device Dukal Sterile AAMI Level 3 Reinforced Surgical Gown & Sterile AAMI Level 3 Surgical Gown**	**Comparison**
Indications for Use	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	Surgical gown is 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.	Same

Style	Non-reinforced/Reinforced	Non-reinforced/ Reinforced	Same
Weight per square (g/m^2)	50 g/m^2 for SMS Standard Surgical Gown (Level 3), 45 g/m^2 for SMS Surgical Gown with Reinforcement (Level 3)	50 g/m^2 for Sterile AAMI Level 3 Surgical Gown, 45 g/m^2 for Sterile AAMI Level 3 Reinforced Surgical Gown	Same
Material Composition	SMS nonwoven, Laminated material (only for SMS Surgical Gown with Reinforcement (Level 3)), white knitted cuff, white spunbond	SMS nonwoven, Laminated material (only for Sterile AAMI Level 3 Reinforced Surgical Gown), white knitted cuff, white spunbond	Same
Regulation, Classification, Product Code	Regulation Number: 21 CFR §878.4040 Device Class: Class II Regulation Name: Surgical Apparel Product Code: FYA	Regulation Number: 21 CFR §878.4040 Device Class: Class II Regulation Name: Surgical Apparel Product Code: FYA	Same
Product Color	Blue	Blue	Same
Product Sizes	M, L, XL, XXL, XXXL and XXXL-XL	M, L, XL, XXL, XXXL and XXXL-XL	Same
Sterility	Sterile (EO)	Sterile (EO)	Similar
Level	Level 3 per AAMI PB70	Level 3 per AAMI PB70	Same
Use	Single Use; Disposable	Single Use; Disposable	Same
Biocompatibility	Under the conditions of each study, the Xuchang Zhengde Environstar Medical Products Co., Ltd SMS Standard Surgical Gown (Level 3) & SMS Surgical Gown with Reinforcement (Level 3) are non-cytotoxic (ISO 10993-5), are non-irritating (ISO 10993-10), and are non-sensitizing (ISO 10993-10).	Under the conditions of each study, the Dukal Sterile AAMI Level 3 Reinforced Surgical Gown & Sterile AAMI Level 3 Surgical Gown are non-cytotoxic (ISO 10993-5), are non-irritating (ISO 10993-10), and are non-sensitizing (ISO 10993-10).	Same

AAMI Level 4 Surgical Gown:

Element of Comparison	**Predicate Device Xuchang Zhengde Environstar Medical Products Co., Ltd BVB Surgical Gown (Level 4) & BVB Splicing Surgical Gown (Level 4) (K192290)**	**Subject Device Dukal Sterile AAMI Level 4 Surgical Gown & Sterile AAMI Level 4 Splicing Surgical Gown**	**Comparison**

Indications for Use	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	The Dukal surgical gowns 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.	Same
Material Composition	SMS nonwoven, white knitted cuff, white spunbond, and BVB Note: BVB Splicing Surgical Gown (Level 4) has a different material for the back of the gown (SMS nonwoven fabric). The back of the gown for the BVB Surgical Gown (Level 4) is made with BVB material.	SMS nonwoven, white knitted cuff, white spunbond, and BVB Note: Sterile AAMI Level 4 Splicing Surgical gown has a different material for the back of the gown (SMS nonwoven fabric). The back of the gown for the Sterile AAMI Level 4 Surgical gown is made with BVB material.	Same
Regulation, Classification, Product Code	Regulation Number: 21 CFR §878.4040 Device Class: Class II Regulation Name: Surgical Apparel Product Code: FYA	Regulation Number: 21 CFR §878.4040 Device Class: Class II Regulation Name: Surgical Apparel Product Code: FYA	Same
Product Color	Blue	Blue	Same
Style	Non-Reinforced	Non-Reinforced	Same
Weight per square (g/m^2)	For level 4 Surgical gown: 68 g/m^2 for gown body material For level 4 Splicing Surgical Gown: 68 g/m^2 for gown front and sleeve material, with 40 g/m^2 for gown back material	For level 4 Surgical gown: 68 g/m^2 for gown body material For level 4 Splicing Surgical Gown: 68 g/m^2 for gown front and sleeve material, with 40 g/m^2 for gown back material	Same
Product Sizes	M, L, XL, XXL, XXXL and XXXL-XL	M, L, XL, XXL, XXXL and XXXL-XL	Same
Sterility	Sterile (EO)	Sterile (EO)	Similar
Level	Level 4 per AAMI PB70	Level 4 per AAMI PB70	Same
Use	Single Use; Disposable	Single Use; Disposable	Same

Biocompatibility	Under the conditions of each study, the Xuchang Zhengde Environstar Medical Products Co., Ltd BVB Surgical Gown (Level 4) & BVB Splicing Surgical Gown (Level 4) are non-cytotoxic (ISO 10993-5), are non-irritating (ISO 10993-10), and are non-sensitizing (ISO 10993-10).	Under the conditions of each study, the Dukal Sterile AAMI Level 4 Surgical Gown & Sterile AAMI Level 4 Splicing Surgical Gown are non-cytotoxic (ISO 10993-5), are non-irritating (ISO 10993-10), and are non-sensitizing (ISO 10993-10).	Same

Comparison Summary of Non-Clinical Testing Results

AAMI Level 3 Surgical Gowns:

Test	**Test Results of Predicate Device Xuchang Zhengde Environstar Medical Products Co., Ltd SMS Standard Surgical Gown (Level 3) & SMS Surgical Gown with Reinforcement (Level 3) (K192290) (Conforms to ANSI/AAMI PB70:2012 Level 3 requirements)**	**Test Results of Subject Device Dukal Sterile AAMI Level 3 Reinforced Surgical Gown & Sterile AAMI Level 3 Surgical Gown (Conforms to ANSI/AAMI PB70:2012 Level 3 requirements)**	**Comparison**
Flammability (16 CFR 1610)	Class I	Class I	Same
Water Resistance-Hydrostatic Pressure (AATCC 127)	≥50 cm H_2O	≥50 cm H_2O	Same
Water Resistance-Impact Penetration (AATCC 42)	≤1.0 g	≤1.0 g	Same
Tensile strength (ASTM D 5034)	Latitude/Transverse: ≥30N Longitude: ≥30N	Latitude/Transverse: ≥30N Longitude: ≥30N	Same
Tear strength (ASTM D 5733)	Latitude/Transverse: ≥10N Longitude: ≥10N	Latitude/Transverse: ≥10N Longitude: ≥10N	Same

Seam Strength (ASTM D 1683)	≥70 N	≥70 N	Same
Lint Generation (ISO 9073-10)	Size of particles counted: 3mcg-25mcg	Size of particles counted: 3mcg-25mcg	Same
Air Permeability (ASTM D737-18)	Test Pressure: 125Pa; Test area 38 cm^2	Test Pressure: 125Pa; Test area 38 cm^2	Same
Biocompatibility-Cytotoxicity (ISO 10993-5), Irritation & Sensitization (ISO 10993-10); EO Sterilization Residual (ISO 10993-7)	• Under the conditions of the study, the device did not show cytotoxicity potential. • Under the conditions of the study, the irritation response category of the device was classified as Negligible. • Under the conditions of the study, the device showed no significant evidence of causing delayed dermal contact sensitization. • For the sterile surgical gown: the device passed the Ethylene Oxide Sterilization Residuals testing. The residual of EO did not exceed 4mg/device and ECH did not exceed 9mg/device. The TCL of EO did not exceed 10 µg/cm^2 and ECH did not exceed 5000µg/cm^2.	• Under the conditions of the study, the device did not show cytotoxicity potential. • Under the conditions of the study, the irritation response category of the device was classified as Negligible. • Under the conditions of the study, the device showed no significant evidence of causing delayed dermal contact sensitization. For the sterile surgical gown: the device passed the Ethylene Oxide Sterilization Residuals testing. The residual of EO did not exceed 4mg/device and ECH did not exceed 9mg/device. The TCL of EO did not exceed 10 µg/cm^2 and ECH did not exceed 5000µg/cm^2.	Same

AAMI Level 4 Surgical Gowns:

Test	**Test Results of Predicate Device Xuchang Zhengde Environstar Medical Products Co., Ltd BVB Surgical Gown (Level 4) & BVB Splicing Surgical Gown (Level 4) (K192290)(Conforms to ANSI/AAMI PB70:2012 Level 4 requirements)**	**Test Results of Subject Device Dukal Sterile AAMI Level 4 Surgical Gown & Sterile AAMI Level 4 Splicing Surgical Gown (Conforms to ANSI/AAMI PB70:2012 Level 4 requirements)**	**Comparison**
Flammability (16 CFR 1610)	Class I	Class I	Same
Resistance Bacteriophage Phi-X174 (ASTM F1671/F1671M-13)	Passed	Passed	Same
Water Resistance-Hydrostatic Pressure (AATCC 127)	≥120 cm H_2O	≥120 cm H_2O	Same
Water Resistance-Impact Penetration(AATCC 42)	≤1.0 g	≤1.0 g	Same
Tensile strength (ASTM D 5034)	Latitude/Transverse: ≥30N Longitude: ≥30N	Latitude/Transverse: ≥30N Longitude: ≥30N	Same
Tear strength ASTM D 5733	Latitude/Transverse: ≥10N Longitude: ≥10N	Latitude/Transverse: ≥10N Longitude: ≥10N	Same
Seam Strength (ASTM D 1683)	≥70 N	≥70 N	Same
Lint Generation (ISO 9073-10)	Size of particles counted: 3mcg-25mcg	Size of particles counted: 3mcg-25mcg	Same
Air Permeability (ASTM D737-18)	Test Pressure: 125Pa; Test area 38 cm^2	Test Pressure: 125Pa; Test area 38 cm^2	Same

Biocompatibility-Cytotoxicity (ISO 10993-5), Irritation & Sensitization (ISO 10993-10); EO Sterilization Residual (ISO 10993-7)	• Under the conditions of the study, the device did not show cytotoxicity potential. • Under the conditions of the study, the irritation response category of the device was classified as Negligible. • Under the conditions of the study, the device showed no significant evidence of causing delayed dermal contact sensitization. • For the sterile surgical gown: the device passed the Ethylene Oxide Sterilization Residuals testing. The residual of EO did not exceed 4mg/device and ECH did not exceed 9mg/device. The TCL of EO did not exceed 10 µg/cm^2 and ECH did not exceed 5000µg/cm^2.	• Under the conditions of the study, the device did not show cytotoxicity potential. • Under the conditions of the study, the irritation response category of the device was classified as Negligible. • Under the conditions of the study, the device showed no significant evidence of causing delayed dermal contact sensitization. • For the sterile surgical gown: the device passed the Ethylene Oxide Sterilization Residuals testing. The residual of EO did not exceed 4mg/device and ECH did not exceed 9mg/device. The TCL of EO did not exceed 10 µg/cm^2 and ECH did not exceed 5000µg/cm^2.	Same

Non-Clinical Test Results:

The subject surgical gowns were tested and found conformance with the following standards:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles
- AATCC 127: 2017 Water Resistance: Hydrostatic Pressure Test
- AATCC 42:2017 Water Resistance: Impact Penetration Test
- ASTM F1671/F1671M-13 Standard Test Method for Resistance to Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage as a Test System

- ANSI AAMI PB70: 2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended For Use in Health Care Facilities
- ISO 9073-10:2003 Textiles-Test Methods for Nonwovens-Part 10: Lint and Other Particles Generation in the Dry State
- ASTM D1683/D1683M-17:2017/(R)2018 Standard Test Method for Failure in Sewn Seams of Woven Fabrics
- ASTM D5733-99 Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure
- ASTM D5034-09:2017 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- ASTM D737-18:2018 Standard Test Method for Air Permeability of Textile Fabrics
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7:Ethylene Oxide Sterilization Residuals
- ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization

Summary for Non-Clinical Testing:

AAMI Level 3 Surgical Gowns:

Test Item	**Test Standard Methods**	**Test Requirements**	**Test Results of Subject Device Dukal Sterile AAMI Level 3 Reinforced Surgical Gown & Sterile AAMI Level 3 Surgical Gown**	**Remark**
Impact penetration	AATCC 42	≤1.0g (for AAMI Level 3)	≤1.0g	Meets requirement
Hydrostatic pressure	AATCC 127	≥50cm H2O (for AAMI Level 3)	≥50cm H2O	Meets requirement
Tensile strength	ASTM D 5034	Latitude/Transverse: ≥30N Longitude: ≥30N	Latitude/Transverse: ≥30N Longitude: ≥30N	Meets requirement
Tear resistance	ASTM D 5733	Latitude/Transverse: ≥10N Longitude: ≥10N	Latitude/Transverse: ≥10N Longitude: ≥10N	Meets requirement

Seam strength	ASTM D 1683	≥30N	≥70N	Meets requirement
Dye penetration	ASTM F 1929	No leakage	No leakage	Meets requirement
Sealing strength	ASTM F 88	≥3N (180°)	≥3N (180°)	Meets requirement
Flammability	16 CFR Part 1610	Class I	Class I	Meets requirement
Lint generation	ISO 9073-10	Size of particles counted: 3mcg-25mcg	Size of particles counted: 3mcg-25mcg	Meets requirement
Air permeability	ASTM D737	Test Pressure: 125Pa; Test area 38 cm^2	Test Pressure: 125Pa; Test area 38 cm^2	Meets requirement
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-7	-Under the conditions of the study, the device does not show cytotoxicity potential. -Under the conditions of the study, the irritation response category of the device is classified as Negligible. -Under the conditions of the study, the device shows no significant evidence of causing delayed dermal contact sensitization. - The residual of EO does not exceed 4mg/device and ECH does not exceed 9mg/device. The TCL of EO does not exceed 10 µg/cm^2 and ECH does not exceed 5000µg/cm^2.	-Under the conditions of the study, the device did not show cytotoxicity potential. -Under the conditions of the study, the irritation response category of the device was classified as Negligible. -Under the conditions of the study, the device showed no significant evidence of causing delayed dermal contact sensitization. - The residual of EO did not exceed 4mg/device and ECH did not exceed 9mg/device. The TCL of EO did not exceed 10 µg/cm^2 and ECH did not exceed 5000µg/cm^2.	Meets requirement

AAMI Level 4 Surgical Gowns:

Test Item	Test Standard Methods	Test Requirements	Test Results of Subject Device Dukal Sterile AAMI Level 4 Surgical Gown & Sterile AAMI Level 4 Splicing Surgical Gown	Remark
Blood-Borne Pathogens penetration	ASTM F1671	Pass (For AAMI Level 4 Requirements): None Seen for Penetration of Phi-X174 Bacteriophage	Pass	Meets requirement
Impact penetration	AATCC 42	≤1.0g	≤1.0g	Meets requirement
Hydrostatic pressure	AATCC 127	≥120cm H2O	≥120cm H2O	Meets requirement
Tensile strength	ASTM D 5034	Latitude/Transverse: ≥30N Longitude: ≥30N	Latitude/Transverse: ≥30N Longitude: ≥30N	Meets requirement
Tear resistance	ASTM D 5733	Latitude/Transverse: ≥10N Longitude: ≥10N	Latitude/Transverse: ≥10N Longitude: ≥10N	Meets requirement
Seam strength	ASTM D 1683	≥30N	≥70N	Meets requirement
Dye penetration	ASTM F 1929	No leakage	No leakage	Meets requirement
Sealing strength	ASTM F 88	≥3N (180°)	≥3N (180°)	Meets requirement
Flammability	16 CFR Part 1610	Class I	Class I	Meets requirement
Lint generation	ISO 9073-10	Size of particles counted: 3mcg-25mcg	Size of particles counted: 3mcg-25mcg	Meets requirement
Air permeability	ASTM D737	Test Pressure: 125Pa; Test area 38 cm^2	Test Pressure: 125Pa; Test area 38 cm^2	Meets requirement

Biocompatibility	ISO 10993-5 ISO 10993-10	-Under the conditions of the study, the device does not show cytotoxicity potential. -Under the conditions of the study, the irritation response category of the device is classified as Negligible. -Under the conditions of the study, the device shows no significant evidence of causing delayed dermal contact sensitization. - The residual of EO does not exceed 4mg/device and ECH does not exceed 9mg/device. The TCL of EO does not exceed 10 µg/cm^2 and ECH does not exceed 5000µg/cm^2.	-Under the conditions of the study, the device did not show cytotoxicity potential. -Under the conditions of the study, the irritation response category of the device was classified as Negligible. -Under the conditions of the study, the device showed no significant evidence of causing delayed dermal contact sensitization. - The residual of EO did not exceed 4mg/device and ECH did not exceed 9mg/device. The TCL of EO did not exceed 10 µg/cm^2 and ECH did not exceed 5000µg/cm^2.	Meets requirement

Summary for Clinical Testing: Not Applicable

Conclusions: The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission, Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, Sterile AAMI Level 4 Splicing Surgical Gown, are as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K192290**.**