March 30, 2022

Dukal, LLC
Megan Quevedo
Quality and Regulatory Affairs Supervisor
2 Fleetwood Court
Ronkonkoma, New York 11779

Re: K212464
Trade/Device Name: Dukal AAMI Level 4 Open-Back Protective Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: QPC
Dated: March 2, 2022
Received: March 2, 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,

For 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)*
K212464

Device Name
Dukal AAMI Level 4 Open-Back Protective Gown

Indications for Use *(Describe)*
The Dukal AAMI Level 4 Open-Back Protective Gowns are intended to protect health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material. These gowns are not intended for use in the operating room.

The Dukal AAMI Level 4 Open-Back Protective Gown meets the barrier protection requirements of AAMI Level 4 per ANSI/AAMI PB70, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities, but has an open back which is non-protective.

These gowns are single use, disposable medical devices 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.

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

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## 510(k) K212464 SUMMARY
## 510(k) Premarket Notification for Dukal AAMI Level 4 Open-Back Protective 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**: March 29, 2022

5. **Name of Device**: Dukal AAMI Level 4 Open-Back Protective Gown

6. **Trade Name**: Dukal AAMI Level 4 Open-Back Protective Gown

7. **Common/Classification Name**: Gown, Non-Sterile, Non-Isolation, Intended to Provide Moderate or High Barrier Protection

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

12. **Predicate Device**: Cardinal Health Poly-Coated Open-Back Protective Gowns (level 4)
    - 510k #K182830, cleared on 4/26/2019

13. **Device Description**: Dukal AAMI Level 4 Open-Back Protective Gowns are intended to protect health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material. These gowns are not intended for

use in the operating room. The gowns are available on Regular and X-Large sizes.

Dukal AAMI Level 4 Open-Back Protective Gowns are made with laminate material (SMS nonwoven material with polyethylene film).

All gowns are blue, with neck removal feature, belt ties, and thumb hook cuff sleeves.

These gowns are single use, disposable devices, that are provided non-sterile.

14. **Packaging**: 10 gowns/bag, 5 bags/case

15. **Indications for Use:** The Dukal AAMI Level 4 Open-Back Protective Gown are intended to protect health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material. These gowns are not intended for use in the operating room.

The Dukal AAMI Level 4 Open-Back Protective Gown meets the barrier protection requirements of AAMI Level 4 per ANSI/AAMI PB70, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities, but has an open back which is non-protective.

These gowns are single, use, disposable medical devices provided non-sterile.

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

| **Element of Comparison** | **Predicate Device Cardinal Health (K182830) Poly-Coated Open-Back Gown** | **Subject Device Dukal Open-Back Protective Gown (K212464)** | **Comparison** |
|---|---|---|---|
| Indications for Use | The Cardinal Health Poly-Coated Open-Back 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 | The Dukal AAMI Level 4 Open-Back Protective Gowns are intended to protect health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material. These gowns are | Same |

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|---|---|---|---|
| | Cardinal Health Poly-Coated Open-Back Protective Gown meets the barrier protection requirements of AAMI Level 4 per *ANSI/AAMI PB70:2012, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities*, but has an open back which is non-protective. The Cardinal Health™ Poly-Coated Open-Back Protective Gown is a single use, disposable medical device provided non-sterile | not intended for use in the operating room.<br><br>The Dukal AAMI Level 4 Open-Back Protective Gown meets the barrier protection requirements of AAMI Level 4 per ANSI/AAMI PB70, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities, but has an open back which is non-protective.<br><br>These gowns are single, use, disposable medical devices provided non-sterile. | |
| Barrier Protection Level | AAMI Level 4 per *ANSI/AAMI PB70:2012, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities*, but has an open back which is nonprotective. | AAMI Level 4 per *ANSI/AAMI PB70:2012, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities*, but has an open back which is nonprotective. | Same |
| Regulation, Classification, Product Code | Regulation Number: 21 CFR §878.4040<br>Device Class: Class II<br>Regulation Name: Surgical Apparel<br>Product Code: QPC | Regulation Number: 21 CFR §878.4040<br>Device Class: Class II<br>Regulation Name: Surgical Apparel<br>Product Code: QPC | Same |
| Material Composition | Laminate (spunbond polypropylene coated with polyethylene) | Laminate (Spunbond + Meltblown + Spunbond (SMS) with polyethylene film) | Similar |
| Product Color and Sizes | Blue<br>Universal and XX-Large | Blue<br>Regular and X-Large | Similar |
| Design Features | Thumbhook cuff formed into sleeve or knit cuff sewn onto sleeve for keeping the sleeves in place on the wearer | Thumbhook cuff formed into sleeve for keeping the sleeves in place on the wearer | Similar |

| | | | |
|---|---|---|---|
| | Belt Ties integrated into body<br>Neck removal feature | Belt Ties integrated into body<br>Neck removal feature | |
| Sterility | Non-Sterile | Non-Sterile | Same |
| Use | Single Use; Disposable | Single Use; Disposable | Same |
| Biocompatibility | Under the conditions of each study, the Cardinal Health™ Poly-Coated Open- Back Protective Gown is non-cytotoxic (ISO 10993-5), is non-irritating (ISO 10993-10), and is non-sensitizing (ISO 10993-10). | Under the conditions of each study, the Dukal AAMI Level 4 Open-Back Protective Gown is non-cytotoxic (ISO 10993-5), is non-irritating (ISO 10993-10), is non-sensitizing (ISO 10993-10). | Same |

**Comparison Summary of Non-Clinical Testing Results**

| **Test** | **Test Results of Subject Device Dukal AAMI Level 4 Open-Back Protective Gown (meets ANSI/AAMI PB70:2012 Level 4 requirements)**<br><br>***Note: Below results are for Sleeve and Body material*** | **Test Results of Predicate Device Cardinal Health (K182830) Poly-Coated Open-Back Gown (meets ANSI/AAMI PB70:2012 Level 4 requirements)**<br>***Finished Good Test Results: Mean (min/max)***<br><br>***Note: Below results are for Sleeve and Body material*** | **Comparison** |
|---|---|---|---|
| **Basis Weight ASTM D3776/D3776M-20** | 50±6 gsm | 43.3 (39.9 / 46.1) gsm<br>(according to previous revision ASTM D3776/D3776M-17) | Similar |
| **Tensile Strength ASTM D5034-21** | Machine Direction (MD)<br>≥ 30 N<br><br>Cross Direction (CD)<br>≥ 30 N | 14.2 (12.6 / 16.1) lb (CD)<br>(according to previous revision ASTM D5034-17) | Similar |
| **Tear Strength ASTM D5587-15 (2019)** | Machine Direction (MD)<br>≥ 10 N<br><br>Cross Direction (CD)<br>≥ 10 N | 6.0 (4.4 / 7.5) lb (MD) | Similar |
| **Seam Strength (ASTM D 1683)** | ≥30N | ≥30N | Same |
| **Flammability CPSC, Part 1610** | Class 1 | Class 1 | Same |

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|---|---|---|---|
| **Lint Generation (ISO 9073-10)** | Size of particles counted: 3mcg-25mcg | Size of particles counted: 3mcg-25mcg | Same |
| **Hydrostatic Head AATCC 127:2018** | >130 cmH20 | >130 (130 / >130) cmH20<br>*>51 (51 / >51) inH20*<br>(According to previous revision AATCC 127:2017) | Same |
| **Viral barrier (resistance to bacteriophage Phi-X174)**<br><br>**ASTM F1671-13** | Pass (For AAMI Level 4 Requirements): None Seen for Penetration of Phi-X174 Bacteriophage | Pass (For AAMI Level 4 Requirements): None Seen for Penetration of Phi-X174 Bacteriophage | Same |
| **Liquid Barrier Performance Classification Properties** | **All areas tested meet Level 4 performance requirements (ASTM F1671), which is the highest standardized level of barrier performance**<br><br>The Dukal AAMI Level 4 Open-Back Protective Gown meets the barrier protection requirements of AAMI Level 4 per *ANSI/AAMI PB70:2012, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities*, but has an open back which is non-protective. Testing was performed in accordance with ASTM F1671 using 3 lots and 32 samples per lot in each critical zone area. The critical zone areas tested were the body or sleeve (same material) and the heat sealed seam(s). | **All areas tested meet Level 4 performance requirements (ASTM F1671), which is the highest standardized level of barrier performance**<br>The Cardinal Health™ Poly-Coated Open-Back Protective Gown meets the barrier protection requirements of AAMI Level 4 per *ANSI/AAMI PB70:2012, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities*, but has an open back which is non-protective. Testing was performed in accordance with ASTM F1671 using 3 lots and 32 samples per lot in each critical zone area. The critical zone areas tested were the body or sleeve (same material) and the heat sealed seam(s). | Same |
| **Sterilization Modality** | None, non-sterile | None, non-sterile | Same |
| **Biocompatibility-Cytotoxicity (ISO 10993-5), Irritation & Sensitization (ISO 10993-10)** | • Under the conditions of the study, the device did not show cytotoxicity potential.<br><br>• Under the conditions of the study, the irritation response | • Under the conditions of the study, the device did not show cytotoxicity potential.<br><br>• Under the conditions of the study, the irritation response | Same |

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| | category of the device was classified as Negligible.<br><br>• Under the conditions of the study, the device showed no significant evidence of causing skin sensitization. | category of the device was classified as Negligible.<br><br>• Under the conditions of the study, the device showed no significant evidence of causing skin sensitization. | |

**Non-Clinical Test Results:**
The subject protective gowns were tested and found conformance with the following standards:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles
- AATCC 127: 2018 Water Resistance: Hydrostatic Pressure 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
- ASTM D5587-15 (2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
- 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 D3776/D3776M-20 Test Methods for Mass Per Unit Area (Weight) of Woven Fabric
- ASTM D5034-21 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- 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
- ISO 10993-1:2018 Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process

**Summary for Non-Clinical Testing:**

| Test Item | Test Standard Methods | Test Requirements | Test Results of Subject Device Dukal AAMI Level 4 Surgical Gown<br>***Note: Below results are for Sleeve and Body material*** | Remark |
|---|---|---|---|---|
| Blood-Borne Pathogens penetration | ASTM F1671 | Pass (For AAMI Level 4 Requirements): None Seen for Penetration of Phi-X174 Bacteriophage | Pass | Meets requirement |
| Hydrostatic pressure | AATCC 127 | ≥100cm H2O (Individual)<br>≥140cm H2O (Average) | >130 cm H2O | Meets requirement |
| Basis weight | ASTM D3776 | 50±6 gsm | 50±6 gsm | Meets requirement |
| Tensile strength | ASTM D 5034 | Machine Direction (MD)<br>≥ 30 N | Machine Direction (MD)<br>≥ 30 N | Meets requirement |
| | | Cross Direction (CD)<br>≥ 30 N | Cross Direction (CD)<br>≥ 30 N | |
| Tear strength | ASTM D5587 | Machine Direction (MD)<br>≥ 10 N | Machine Direction (MD)<br>≥ 10 N | Meets requirement |
| | | Cross Direction (CD)<br>≥ 10 N | Cross Direction (CD)<br>≥ 10 N | Meets requirement |
| Seam Strength | ASTM D 1683 | ≥30N | ≥30N | Meets requirement |
| Lint generation | ISO 9073-10 | Size of particles counted: 3mcg-25mcg | Size of particles counted: 3mcg 25mcg | Meets requirement |
| Flammability | 16 CFR Part 1610 | Class I | Class I | Meets requirement |

| | | | | |
|---|---|---|---|---|
| Biocompatibility | ISO 10993-5<br><br>ISO 10993-10 | -Under the conditions of the study, the device does not show cytotoxicity potential.<br><br>-Under the conditions of the study, the irritation response category of the device is classified as Negligible.<br><br>-Under the conditions of the study, the device shows no significant evidence of causing skin sensitization. | -Under the conditions of the study, the device did not show cytotoxicity potential.<br><br>-Under the conditions of the study, the irritation response category of the device was classified as Negligible.<br><br>-Under the conditions of the study, the device showed no significant evidence of causing skin sensitization. | Meets requirement |

**Summary for Clinical Testing:** Not Applicable

**Conclusions:** The conclusion drawn from the nonclinical tests demonstrates that the subject devices in this 510(k) submission, Dukal AAMI Level 4 Open-Back Protective Gowns, are as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K182830**.**