March 29, 2022

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

Re: K210321
Trade/Device Name: Dukal Level 1 Pediatric Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: OXZ
Dated: February 22, 2022
Received: February 28, 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,

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

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)*
K210321

Device Name
Dukal Level 1 Pediatric Face Mask

Indications for Use *(Describe)*
The Dukal Level 1 Pediatric Face Masks are intended to be worn by the patient/child to cover the nose and mouth to provide a barrier for the respiratory tract from microorganisms, body fluids, and particulate material. Recommended ages are 4-12. The face mask is specifically for use with patients whose age or illness may prevent them from taking necessary precautions in situations where transfer of microorganisms, body fluids, and particulates can occur. The face masks are recommended for use in a healthcare setting with appropriate adult supervision. The Dukal Level 1 Pediatric Face Masks are single use, disposable devices that are 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.

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510(k) SUMMARY K210321
510(k) Premarket Notification for Dukal Level 1 Pediatric Face Mask

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 Level 1 Pediatric Face Mask

6. **Trade Name**: Dukal Level 1 Pediatric Face Mask

7. **Common/Classification Name**: Pediatric/Child Facemask

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

12. **Predicate Device**: Prestige Ameritech Pediatric/Child Face Mask (level 1)
    - 510k #K160100, cleared on 10/7/2016

13. **Device Description**: Pediatric face masks are intended to be worn by the patient/child to cover the nose and mouth to provide a barrier for the respiratory tract from microorganisms, body fluids, and particulate material. The mask is available in the following product sizes:

    Regular Size (14.5x9cm)
    Extra Small Size (12.5x8cm)

The Dukal Level 1 Pediatric Face Mask (both sizes) are composed of three layers of materials and pleated to form the mask. The inner layer is composed of Polypropylene (Spunbond), the middle layer is Polypropylene (Meltblown) filter material, and the outer layer is polypropylene (Spunbond).

The masks (both sizes) are held in place on wearer with knitted polyester/spandex elastic ear loop and contain a malleable aluminum nosepiece strip.

The masks (both sizes) have decorative patterns, printed with colored inks.

14. **Packaging**: 50 masks/box

15. **Indications for Use:** The Dukal Level 1 Pediatric Face Masks are intended to be worn by the patient/child to cover the nose and mouth to provide a barrier for the respiratory tract from microorganisms, body fluids, and particulate material. Recommended ages are 4-12. The face mask is specifically for use with patients whose age or illness may prevent them from taking necessary precautions in situations where transfer of microorganisms, body fluids, and particulates can occur. The face masks are recommended for use in a healthcare setting with appropriate adult supervision. The Dukal Level 1 Pediatric Face Masks are single use, disposable devices that are provided non-sterile.

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

Element of Comparison	**Predicate Device Ameritech Pediatric/ Child Face's Mask (K160100)**	**Subject Device Dukal Level 1 Pediatric Face Masks**	**Comparison**
Indications for Use	The Prestige Ameritech Pediatric/Child Face Mask is intended to be worn by the patient/child. The Pediatric/Child Facemask is a single use, disposable device, provided non-sterile. The Pediatric/Child Facemask is	The Dukal Level 1 Pediatric Face Masks are intended to be worn by the patient/child to cover the nose and mouth to provide a barrier for the respiratory tract from microorganisms, body fluids, and particulate material. Recommended ages are 4-12. The face mask is	Similar

	intended to be worn by the patient (ages 4-12) to cover the nose and mouth to provide a barrier for the respiratory tract for microorganisms and particulate materials. The mask is specifically for use with patients whose age or illness may prevent them from taking necessary precautions in situations where transfer of microorganisms, body fluids, and particulates can occur.	specifically for use with patients whose age or illness may prevent them from taking necessary precautions in situations where transfer of microorganisms, body fluids, and particulates can occur. The face masks are recommended for use in a healthcare setting with appropriate adult supervision. The Dukal Level 1 Pediatric Face Masks are single use, disposable devices that are provided non-sterile.	
Intended Use Sites	Healthcare setting- This Face Mask is recommended for use in a healthcare setting with appropriate adult supervision.	Healthcare setting- The Dukal Level 1 Pediatric Face Mask is recommended for use in a healthcare setting with appropriate adult supervision.	Same
Sterilization and Shelf Life	The Prestige Ameritech Pediatric/Child Face Mask is not provided sterile, has no proposed shelf life/expiration date, and is not a reprocessed single use device. The device is manufactured from non-woven materials that are not impacted by storage conditions or aging and thus does not have a shelf life. Storage conditions will not affect device safety of effectiveness.	The Dukal Level 1 Pediatric Face Mask is not provided sterile, has no proposed shelf life/expiration date, and is not a reprocessed single use device. The device is manufactured from non-woven materials that are not impacted by storage conditions or aging and thus the device does not have a shelf life Storage conditions will not affect device safety of effectiveness.	Same
Anthropometry	Based on an anthropometric study sample that is representative of the current US population in both gender and racial distribution, the Prestige Ameritech Child's/Pediatric face mask will provide adequate coverage to children between the ages of 4-12 years old, of weight between 24-153 pounds, and of height between 3'3" and 5'4".	Based on an anthropometric study sample that is representative of the US population in both gender and racial distribution, the Dukal Level 1 Pediatric Face Mask will provide adequate coverage to children between the ages of 4-12 years old of weight between 25-176 pounds, and of height between 3'00" – 5'08'".	Similar

Material Composition	The Prestige Ameritech Pediatric/Childs Face Mask is manufactured using ultrasonic bonding, composed of three layers of materials and pleated to form the mask. The inner layer is composed of nonwoven, the middle layer is meltblown polypropylene filter material, and the outer layer is cellulose. Decorative patterns are printed with colored inks. Masks are held in place on wearer with knitted polyester/spandex elastic earloop and contain a malleable aluminum nosepiece strip. The Pediatric/Child's Face Mask is appropriately sized to the smaller faces of children across a diverse population. All of the materials used in this device are typical materials commonly used in the construction of Surgical Masks and are being used in current legally marketed devices. This product is not made with natural rubber latex.	The Dukal Level 1 Pediatric Face Mask is manufactured using ultrasonic hot sealing, composed of three layers of materials and pleated to form the mask. The inner layer is composed of Polypropylene (Spunbond), the middle layer is Polypropylene (Meltblown) filter material, and the outer layer is polypropylene (Spunbond). Decorative patterns are printed with colored inks. Masks are held in place on wearer with polyester/spandex elastic earloop and contain a malleable aluminum wire nose piece. The Pediatric/Child's Face Mask is appropriately sized to the smaller faces of children across a diverse population. All of the materials used in this device are typical materials commonly used in the construction of Surgical Masks and are being used in current legally marketed devices. This product is not made with natural rubber latex.	Similar
Regulation, Classification, Product Code	Regulation Number: 21 CFR §878.4040 Device Class: Class II Regulation Name: Surgical Apparel Product Code: OXZ	Regulation Number: 21 CFR §878.4040 Device Class: Class II Regulation Name: Surgical Apparel Product Code: OXZ	Same
Product Color	Decorative patterns are printed with colored inks	Decorative patterns are printed with colored inks	Similar
Mask Style	Pleated	Pleated	Same
Design Features	Ear Loop	Ear Loop	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use; Disposable	Single Use; Disposable	Same
Biocompatibility	Under the conditions of each study, the Prestige Ameritech	Under the conditions of each study, the Dukal Level 1 Pediatric Face Mask	Same

	Pediatric/Child Face Mask is non-cytotoxic (ISO 10993-5), is non-irritating (ISO 10993-10), and is non-sensitizing (ISO 10993-10) and has met the requirements per ISO- 10993-1.	is non-cytotoxic (ISO 10993-5), is non-irritating (ISO 10993-10), is non-sensitizing (ISO 10993-10), and has met the requirements per ISO-10993-1.	

Comparison Summary of Non-Clinical Testing Results

Test Standards	Predicate Device Ameritech Pediatric/ Child Face's Mask (K160100)	Subject Device Dukal Level 1 Pediatric Face Masks	Remark
ASTM F2101- Bacterial Filtration Efficiency (BFE)	96.32%	>99%	Similar
ASTM F2299- Particulate Filtration Efficiency	98%	>99%	Similar
EN14683- Differential Pressure	1.74 mmH2O/cm^2 (using Differential Pressure, Mil M36954C)	≤3.1mmH2O/cm^2	Similar
ASTM F1862- Fluid Resistance	n/a	Passed at 80 mmHg	Similar
16 CFR 1610-Flammability	Class I	Class I	Similar
Biocompatibility-10993-5-Cytotoxicity & 10993-10-Irritation & Sensitization	Tested under ISO 10993 Standard: • 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 categorized as negligible. • Under the conditions of the study, the device showed no significant evidence of causing skin sensitization.	Tested under ISO 10993 Standard: • 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 categorized as negligible. • Under the conditions of the study, the device showed no significant evidence of causing skin sensitization.	Similar
Total Lead Content Analysis	Tested under CPSC-CH-E1002-08	Tested under CPSC-CH-E1002-08.3 & CPSC-CH-	Similar

		E1001-08.3	
Phthalate Analysis	Tested under CPSC-CH-C1001-09.3	Tested under CPSC-CH-C1001-09.4	Similar
Safety of Toys – Migration of certain elements	Tested under EN 71-3	Tested under EN 71-3	Similar
Mechanical Hazards (Small parts, sharp edges, and sharp points)	Tested under ASTM F963-17 (sec. 4.6, 4.7, and 4.9), 16 CFR Part 1500, 16 CFR Part 1501	Tested under ASTM F963-17 (sec. 4.6, 4.7, and 4.9), 16 CFR Part 1500, 16 CFR Part 1501	Similar

Non-Clinical Test Results:

The subject pediatric face masks were tested and found conformance with following standards:

- ASTM F1862/1862M-17, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2101-19, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- ISO 22609:2004, Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
- EN 14683: 2019, Medical Face Masks-Requirements and Test Methods
- AS4381:2015, Single-Use Face Masks for Use in Health Care
- 16 CFR 1610, Standard for the Flammability of Clothing Textiles
- ASTM F2299/F2299M-03, Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F2100-19, Standard Specification for Performance of Materials Used in Medical Face Masks
- 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
- CPSC-CH-E1002-08.3, Standard Operating Procedure for Determining Total Lead (Pb) in Non-metal Children's Products
- CPSC-CH-C1001-09.4, Standard Operating Procedure for the Determination of Phthalates
- CPSC-CH-E1001-08.3, Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry)
- EN 71-3:2019, Safety of Toys-Migration of Certain Elements
- ASTM F963-17, Standard Consumer Safety Specification For Toy Safety
- 16 CFR Part 1500, Hazardous Substances and Articles: Administration and Enforcement Regulations
- 16 CFR Part 1501, Method For Identifying Toys And Other Articles Intended For Use By Children Under 3 Years Of Age Which Present Choking, Aspiration, Or Ingestion Hazards Because Of Small Parts

Summary for Non-Clinical Testing

Test Item	Test Standard Methods	Test Requirements	Subject Device Dukal Level 1 Pediatric Face Masks (meets ASTM F2100-19 Level 1 requirements)	Remark
Bacterial Filtration Efficiency Performance (BFE) (%)	ASTM F2101	≥95%	>99%	Meets requirement
Particulate Filtration Efficiency Performance (PFE) (%)	ASTM F2299	≥95%	>99%	Meets requirement
Differential Pressure (Delta-P) (mm $H2O/cm^2$)	EN 14683	<5.0	≤3.1mm$H2O/cm^2$	Meets requirement
Fluid Resistance Performance (mmHg)	ASTM F1862	80 mmHg	Passed at 80 mmHg	Meets requirement
Flammability	16 CFR part 1610	Class I No Flame Spread	Class I No Flame Spread	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 skin sensitization.	-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 skin sensitization.	Meets requirement
Mechanical	Tested under ASTM	Pass under	Pass	Meets

Hazards (Small parts, sharp edges, and sharp points)	F963-17 (sec. 4.6, 4.7, and 4.9), 16 CFR Part 1500, 16 CFR Part 1501	requirements for CPSIA Section 106 ASTM F963-17 Mechanical Hazards: under As received, Normal Use, Impact, Torque, and Tension conditions		requirement
Total Lead Content Analysis	Tested under CPSC-CH-E1002-08.3 & CPSC-CH-E1001-08.3	Each accessible component shall not contain more than 100 ppm of lead in children's products.	Pass	Meets requirement
Phthalate Analysis	Tested under CPSC-CH-C1001-09.4	Children's toy or child care article does not contain phthalate concentrations of more than 0.1 percent (1000 ppm) in plasticized components.	Pass	Meets requirement
Safety of Toys – Migration of certain elements	Tested under EN 71-3	The migration of elements from toy materials shall not exceed the limits for restricted elements.	Pass	Meets requirement

Summary for Clinical Testing: Not Applicable. See Anthropometry information in section 16 of this 510k summary. Relevant anthropometric data was searched, appraised, analyzed and summarized to demonstrate that the Dukal Level 1 Pediatric Face Mask will provide adequate coverage to children between the ages of 4-12 years old of weight between 25-176 pounds, and of height between 3'00" – 5'08'".

Conclusions: The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission, Dukal Level 1 Pediatric Face Masks, are as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K160100.