February 5, 2021

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

Re: K201421
Trade/Device Name: Dukal Corporation Level 2 Surgical Mask with Ear Loops; Dukal Corporation Level 2 Surgical Mask with Ear Loops and Face Shield; Dukal Corporation Level 2 Surgical Mask with Adjustable Tie Ons
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 28, 2021
Received: February 4, 2021

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 CAPT Elizabeth Claverie, M.S.
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)*
K201421

Device Name
Dukal Corporation Level 2 Surgical Mask with Ear Loops
Dukal Corporation Level 2 Surgical Mask with Ear Loops and Face Shield
Dukal Corporation Level 2 Surgical Mask with Adjustable Tie Ons

Indications for Use *(Describe)*
The Dukal Corporation Level 2 Surgical Mask with Ear Loops, Dukal Corporation Level 2 Surgical Mask with Ear Loops and Face Shield, and Dukal Corporation Level 2 Surgical Mask with Adjustable Tie Ons are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device, 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

K201421

In accordance with the requirements set forth in Title 21 CFR §807.92
Prepared on Feb 5, 2021

1. Submitter:

Dukal Corporation
2 Fleetwood Court
Ronkonkoma NY 11779
Phone: 631-656-3800
Fax: 631-656-3810
FDA Registration Number: 2435946

2. **Regulatory Affairs Contact:**

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

3. **Name of Device**:

Dukal Corporation Level 2 Surgical Mask with Ear Loops
Dukal Corporation Level 2 Surgical Mask with Ear Loops and Face Shield
Dukal Corporation Level 2 Surgical Mask with Adjustable Tie Ons

Trade Name:

Dukal Corporation Level 2 Surgical Mask with Ear Loops
Dukal Corporation Level 2 Surgical Mask with Ear Loops and Face Shield
Dukal Corporation Level 2 Surgical Mask with Adjustable Tie Ons

Common/Classification Name: Surgical Mask
Regulation Number: 21 CFR §878.4040
Device Class: Class II
Regulation Name: Surgical Apparel
Product Code: FXX

4. **Predicate Device:**

San-M Package Co., LTD Level 2 Face Mask Models: EL20000, EL 20010, TO 20000, and TO 20010
510(K) number: K160269
Cleared: 9/6/2016

5. **Device Description**:

Face Masks intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms,

body fluids, and particulate material.

6. **Indications for Use:** The Dukal Corporation Level 2 Surgical Mask with Ear Loops, Dukal Corporation Level 2 Surgical Mask with Ear Loops and Face Shield, and Dukal Corporation Level 2 Surgical Mask with Adjustable Tie Ons are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device, provided non-sterile.

7. Comparison of technological characteristics between the predicate and subject devices

Element of Comparison	**Predicate Device** **San-M Package Co., LTD Level 2 Face Mask Models: EL 20000, EL 20010, TO 20000, and TO 20010 (K160269)**	**Subject Device** **Dukal Corporation Level 2 Surgical Mask with Ear Loops, Dukal Corporation Level 2 Surgical Mask with Ear Loops and Face Shield, and Dukal Corporation Level 2 Surgical Mask with Adjustable Tie Ons (K201421)**	**Remark**
Indications For Use	The surgical face masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device, provided non-sterile.	The Dukal Corporation Level 2 Surgical Mask with Ear Loops, Dukal Corporation Level 2 Surgical Mask with Ear Loops and Face Shield, and Dukal Corporation Level 2 Surgical Mask with Adjustable Tie Ons are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device, provided non-sterile.	Same
Material Composition	• Outer material: Polypropylene • Inner material: Polypropylene • Filter Media: Polypropylene Spunbond Polypropylene Meltblown • Nose Clamp: Polyethylene coated steel wire • Ear loops:	• Outer and Inner Material: Pure Polypropylene (Spunbond) • Filter Material: Polypropylene (Meltblown) • Nose Piece Material: Malleable aluminum wire • Ear loop Material: Spandex elastic, polyester	Similar

		Polyester, polyurethane • Side tapes: Polyester spunbond (ear loops mask only) • Tie tapes: Polypropylene spunbond or polyester spunbond		• Tie on Material: Pure Polypropylene (Spunbond)	
Dimensions		Length: 90 ± 3 mm; Width: 175 ± 5 mm	Length: 90 ± 3 mm; Width: 180 ± 5 mm	9.5 x 17.5cm	Similar
Mask Style		Flat-pleated		Flat-pleated	Similar
Design Features		Visor option: polyester		Fluid Shield option: Polyethylene (PE)	Similar
Sterility		Non-Sterile		Non-Sterile	Similar
Use		Single Use; Disposable		Single Use; Disposable	Similar
Biocompatibility	10993-5-Cytotoxicity	Under the conditions of the studies, the device did not show toxicity to L929 cells.		Under the conditions of the study, the device was non-cytotoxic.	Similar
	10993-10-Irritation	Under the conditions of the study, the device was non-irritating.		Under the conditions of the study, the device was non-irritating.	Similar
	10993-10-Sensitization	Under the conditions of the study, the device was non-sensitizing.		Under the conditions of the study, the device was non-sensitizing.	Similar

Test Standards	**Subject Device (K201421) (conforms to ASTM F2100-19 Level 2 requirements)**	**Predicate Device (K160269) (conforms to ASTM F2100-11 Level 2 requirements)**	**Comparison**
ASTM F2101- Bacterial Filtration Efficiency (BFE)	>99%	>98%	Similar
ASTM F2299- Particulate Filtration Efficiency	>99%	99.6%	Similar
Mil-M-36954C or EN14683- Differential Pressure	≤4.9 mmH2O/cm2	Pass at 1.6 mmH2O/cm2	Similar
ASTM F1862- Fluid Resistance	Pass at 120mmHg (30 out of 32 test articles passed)	Pass at 120 mmHg	Similar
16 CFR 1610-Flammability	Class I	Class I	Similar

8. Non-clinical test results

The subject surgical 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 F2101-14, 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)
- MIL-M-36954C Section 4.4.1.2, Military Specification, Mask, Surgical, Disposable
- EN 14683: 2014 Annex B and C, 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
- 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

Performance Summary for Non-Clinical Testing:

Test Standards	**ASTM Level 2 Requirements**	**Subject Device (K201421)**	**Remark**
ASTM F2101- Bacterial Filtration Efficiency (BFE)	≥98%	>99%	Meets requirement
ASTM F2299- Particulate Filtration Efficiency	≥98%	>99%	Meets requirement
Mil-M-36954C, EN14683 -Differential Pressure	<6.0 mm H2O/cm2	≤4.9 mmH2O/cm2	Meets requirement
ASTM F1862- Fluid Resistance	120 mmHg	Passed at 120mmHg (30 out of 32 test articles passed)	Meets requirement
16 CFR 1610- Flammability	Class I No Flame Spread	Class I	Meets requirement

9. Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K201421, the Dukal Corporation Level 2 Surgical Mask with Ear Loops, Dukal Corporation Level 2 Surgical Mask with Ear Loops and Face Shield, and Dukal Corporation Level 2 Surgical Mask with Adjustable Tie Ons are as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K160269.