March 4, 2021

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

Re: K201732
Trade/Device Name: Dukal Corporation Level 3 Surgical Face Masks with Ear loop, Dukal Corporation Level 3 Surgical Face Masks with Tie On
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX

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 February 16, 2021. Specifically, FDA is updating this SE Letter to remove proprietary information from the 510k summary as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ryan Ortega, PhD, OHT4: Office of Surgical and Infection Control Devices, (240-402-2303), Email Ryan.Ortega@fda.hhs.gov.

Sincerely,

Jessica Mavadia-shukla -S

For Ryan Ortega, PhD
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

February 16, 2021

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

Re: K201732
Trade/Device Name: Dukal Corporation Level 3 Surgical Face Masks with Ear Loop, Dukal Corporation Level 3 Surgical Face Masks with Tie On
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 8, 2021
Received: February 11, 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,

Jessica Mavadia-shukla -S

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)*
K201732

Device Name
Dukal Corporation Level 3 Surgical Face Masks with Ear Loop and Dukal Corporation Level 3 Surgical Face Masks with Tie On

Indications for Use *(Describe)*
The Dukal Corporation Level 3 Surgical Face Masks 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K201732 510(k) SUMMARY

510(k) Premarket Notification for Dukal Corporation Level 3 Surgical Face Masks with Ear Loop and Level 3 Surgical Face Masks with Tie On

In accordance with the requirements set forth in Title 21 CFR §807.92, we are providing this 510(k) Summary and also notifying you of our intent to manufacture, package, and put into commercial distribution Level 3 Surgical Face Mask with Ear Loop and Level 3 Surgical Mask with Tie On.

1. **Submitter**: Dukal Corporation
   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 Engineer
   2 Fleetwood Court
   Ronkonkoma NY 11779
   Telephone Number: 631-656-3800 ext. 133
   Fax Number: 631-656-3810
4. **Date Summary Prepared**: February 16, 2021
5. **Name of Device**: Dukal Corporation Level 3 Surgical Face Masks with Ear Loop, Dukal Corporation Level 3 Surgical Face Masks with Tie On
6. **Trade Name**: Dukal Corporation Level 3 Surgical Face Masks with Ear Loop, Dukal Corporation Level 3 Surgical Face Masks with Tie On
7. **Common/Classification Name**: Surgical Mask
8. **Regulation Number**: 21 CFR §878.4040
9. **Device Class**: Class II
10. **Regulation Name**: Surgical Apparel
11. **Product Code**: FXX
12. **Predicate Device**: Cardinal Health Level 3 Surgical Mask with Anti-Fog Foam Strip
    (Catalog # AT73635)
    510k: K192374
13. **Device Description**: Face Masks intended to protect health care patients and personnel from the transfer of microorganisms, body fluids and particulate material.

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

15. **Indications for Use:** The Dukal Corporation surgical masks 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.

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

Identification of legally marketed device to which Dukal Corporation is claiming equivalence:

For the Level 3 Surgical Face Masks with Ear loop and Tie On:

Cardinal Health Level 3 Surgical Mask with Anti-Fog Foam Strip (Catalog # AT73635)

- K192374
- Cleared: 12/2/2019

17. Substantial Equivalence Comparison Table (Ear loop and Tie On):

Element of Comparison	**Predicate Device Cardinal Health (K192374) Level 3 Surgical Mask with Anti-Fog Foam Strip (Catalog # AT73635)**	**Subject Device Dukal Corporation (K201732) Level 3 Surgical Face Masks with Ear Loop and Level 3 Surgical Face Masks with Tie On**	**Comparison**
Intended Use	Cardinal Health Level 3 Surgical Masks with Anti-Fog Foam Strip are intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates.	The Dukal Corporation Level 3 surgical masks 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.	Similar
Material Composition	Four-layer mask constructed of: 1 layer of nonwoven polyester/polyethylene blend (inner facing) 1 layer of nonwoven polyolefin melt blown (filter media) 1 layer of nonwoven polyester/polyethylene blend (middle layer) 1 layer of polyolefin spunbond material (outer facing)	Outer and Inner Material: Polypropylene (Spunbond) Filter Material: Polypropylene (Meltblown) Nose Piece Material: Malleable aluminum wire Ear loop Material: Spandex elastic, polyester Tie On Material: Polypropylene (Spunbond)	Similar
Dimensions	7 inches x 4 inches	17.5 x 9.5 cm	Similar
Mask Style	Pleated	Pleated	Same
Design Features	Anti-fog foam strip, ties and malleable nosepiece	Option for Ear Loop & Option for Tie On (both with malleable aluminum wire)	Similar
Sterility	Non-Sterile	Non-Sterile	Same

Use	Single Use; Disposable	Single Use; Disposable	Same
Biocompatibility	The Cardinal Health Level 3 Surgical Mask with Anti-Fog Foam Strip was tested in accordance with ISO 10993 and passed acceptance criteria.	The device was tested in accordance with ISO 10993 and passed acceptance criteria under the conditions of the studies. • Under the conditions of the study, the device did not show potential toxicity to L929 cells. Per ISO 10993- 5 Cytotoxicity test • Under the conditions of the study, the response of the device was categorized as negligible for skin irritation per 10993- 10 Irritation test • Under the conditions of the study, the device showed no significant evidence of causing skin Sensitization per 10993- 10 Sensitization test	Similar

18. **Technical Characteristics**: The Dukal Corporation Level 3 Surgical Face Masks with Ear Loop and Level 3 Surgical Face Masks with Tie On have similar technological characteristics as and are substantially equivalent to the above respective Cardinal Health Level 3 Surgical Mask with Anti- Fog Foam Strip.

19. **Performance Data:** The following performance data were provided in support of the substantial equivalence determination:

Comparison Summary of ASTM F2100 Performance Testing and Biocompatibility Testing Results

Test	Test Results of Subject Device Dukal Corporation (K201732) Level 3 Surgical Face Masks with Ear Loop and Level 3 Surgical Face Masks with Tie On (conforms to ASTM F2100-19 Level 3 requirements)	Test Results of Predicate Device Cardinal Health (K192374) Level 3 Surgical Mask with Anti- Fog Foam Strip (Catalog # AT73635) (conforms to ASTM F2100-11 Level 3 requirements)	Comparison
ASTM F2101-Bacterial Filtration Efficiency (BFE)	>99.9%	99.7% (average)	Similar
ASTM F2299-Particulate Filtration Efficiency	>99%	99.2% (average)	Similar
EN 14683-Differential Pressure	≤4.6 mmH2O/cm2	(Referencing Mil-M- 36954C) 2.8 mmH2O/cm2 (average)	Similar
ASTM F1862-Fluid Resistance	Pass at 160mmHg (29 out of 32 test articles passed)	Pass at 160 mmHg (31 out of 32 test articles passed)	Similar
16 CFR 1610-Flammability	Class I	Class I	Same

20. Conclusions:

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K)

submission K201732, Dukal Corporation Level 3 Surgical Face Masks with Ear Loop and Level 3 Surgical Face Masks with Tie On are as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K192374.