January 23, 2022

Feliks Plastik Laminasyon Ve Ambalaj Malzemeleri Sanayi
℅ W. Rogers
Owner
Rogers Consulting
11110 Arranmore Cove
Roanoke, Indiana 46783

Re: K212111
Trade/Device Name: Myflon Surgical Mask Level 3
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 8, 2021
Received: December 13, 2021

Dear W. Rogers:

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, 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.

51 0(k) Number *(if known)*
K212111

Device Name
Myflon Surgical Mask Level 3

Indications for Use *(Describe)*
Myflon Surgical Mask Level 3 is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. This face mask is 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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K212111 510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Myflon Surgical Mask Level 3, 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:	Feliks Plastik Lam Ve Amb Mal San Ve Tic A.S. Eskishir Organize Sanayi Bolgesi 26. Cad No. 9 26110 Eskisehir Turkey Establishment Registration Number: 3017355692
Contact Person:	Ali Serdar Serteser Manager +90 533 209 72 95
510(k) Number:	K212111
Designated Submission Correspondent:	W. Victoria Rogers Rogers Consulting 11110 Arranmore Cove Roanoke, Indiana 46783 574-265-8356
Date:	January 20, 2022
Subject Device:	Myflon Surgical Mask Level 3
Common Name:	Surgical Mask
Classification Name:	Surgical Mask
Product Code:	FXX
Regulation Number:	(21 CFR 878.4040)
Review Panel:	General & Plastic Surgery
Regulation Class:	Class II
Predicate Device:	Freudenberg Surgical Mask (K210063)

Purpose and Device Description:

The Myflon Surgical Mask Level 3 is blue in color, composed of three-layers, a flat-pleated type mask, utilizing ear loops for wearing. The Myflon Surgical Mask Level 3 materials consist of an outer cover (polypropylene spunbond, blue), middle filtration layer (polypropylene, melt-blown, white), and inner cover comfort/support layer web (polypropylene spunbond, white). Each mask has stretchable elastic laminate (Spunbond/elastic film/spunbond bond) ear loops to secure the mask over the user's mouth and nose and includes a polyethylene/ polypropylene coated wire nosepiece to provide a firm fit over the face and nose. This face mask is a single use, disposable device, provided non-sterile. This device is not made with natural rubber latex.

Intended Use and Indication for Use:

Myflon Surgical Mask Level 3 is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. This face mask is 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 nonsterile.

Technological Characteristics Comparison:

	Subject Device Myflon Surgical Mask Level 3, K2112111	**Primary Predicate Device** Freudenberg Surgical Mask K210063	**Remark**
ASTM 2100 Level 3 Mask	3	3	Same
Intended Use/ Indications for Use	Myflon Surgical Mask Level 3 is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. This face mask is	The Freudenberg Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate	Same

	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 nonsterile.	material. This face mask is 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 nonsterile.	
Outer Materials	Polypropylene spunbond, blue	Spun-bond polypropylene	Similar
Filter Media	Polypropylene, melt-blown, white	Melt blown polypropylene	Same
Inner Material	Polypropylene spunbond, white	Spun-bond polypropylene	Same
Nose Piece	Polyethylene/ polypropylene coated wire	Malleable polyethylene coated wire	Similar
Ear Loops	Spunbond/elastic film/spunbond bond	Polyester spandex blend	Similar
Specifications	Length: 175mm Width: 95mm	Length: 175 mm +/- 1mm Width: 95 mm +/- 1mm	Same
Mask Style	Flat-pleated	Flat-pleated	Same
Color	Blue	White	Different
Sterilization	Non-sterile	Non-sterile	Same

Summary of Non-Clinical Testing:

- The product was tested in alignment with "Guidance for Industry and FDA Staff – Surgical Masks – Premarket Notification [510(k)] Submission" Guidance Document
  - 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
  - ASTM F2100-19, Standard Specification for Performance Of Materials Used In Medical Face Masks
  - ASTM F1862-17, Standard Test Method for Resistance of Medical Face Masks to Penetration By Synthetic Blood (Horizontal Projection Of Fixed Volume At A Known Velocity)
  - EN 14683: European standard for face masks
  - 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;
  - ASTM F2299-03, Stand test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;

- 16 CFR 1610, Standard for the Flammability of clothing textiles.

Bench Testing			
Test	**Standard/ Regulation**	**Acceptance Criteria**	**Results**
Barrier Testing - Fluid resistance	ASTM F1862	Pass at 160mmHg	Passed
Barrier Testing- Particle Filtration Efficiency	ASTM F2299	Pass ≥98%	Passed
Barrier Testing - Bacterial Filtration Efficiency	ASTM F2101	Pass ≥98%	Passed
Safety Testing - Flammability Class	16 CFR 1610	Class 1 (≧ 3.5 seconds)	Passed - Class I Non-Flammable
Physical Testing - Differential Pressure Delta-P	EN14683	Passed <6.0 H2O/cm2	Passed

Biocompatibility			
Test	**Standard**	**Acceptance Criteria**	**Results**
Safety Testing - Cytotoxicity	ISO 10993-5	Comply with ISO 10993-5	Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic
Safety Testing - Irritation	ISO 10993-10	Comply with ISO 10993-10	Under the conditions of the study, the proposed device extract was determined to be non-irritating
Safety Testing - Sensitization	ISO 10993-10	Comply with ISO 10993-10	Under the conditions of the study, the proposed device extract was determined to be non-sensitizing

Clinical Tests:

- No clinical tests were performed.

Substantial Equivalence Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the Myflon Surgical Mask Level 3 is as safe, as effective, and performs as well as or better than the predicate device.sa