February 5, 2021

Freudenberg Performance Materials LP
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K210063
Trade/Device Name: Freudenberg Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 8, 2021
Received: January 11, 2021

Dear Prithul Bom:

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 Elizabeth F. Claverie-Williams, MS, CAPT, USPHS-CC
Assistant Director
DHT4B: Division of Infection Controland 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)*
K210063

Device Name
Freudenberg Surgical Mask

Indications for Use *(Describe)*
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 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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510(k) Summary

510(k) Number:	K210063
Sponsor Information:	Freudenberg Performance Materials LP 3500 Industrial Drive Durham, NC 27704 United States Sponsor Contact: Eberhard Link Technical Market Manager - Medical 919-349-8389 eberhard.link@freudenberg-pm.com
Contact Person:	Eberhard Link Technical Market Manager - Medical 919-349-8389 eberhard.link@freudenberg-pm.com
Date of Summary Preparation:	February 2, 2021
Trade Name:	Freudenberg
Common Name:	Surgical Mask
Classification Name:	Surgical Apparel
Proprietary Name:	Freudenberg
Regulation Medical Specialty:	General and Plastic Surgery
Review Panel:	General Hospital
Product Code:	FXX
Device Classification:	Class II per 21 CFR §878.4040
Predicate Device:	SURGICAL FACE MASK (K182514) – Model Ear Loop
Intended Use:	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 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.
Device Description:	The Freudenberg Surgical Mask is composed of three-layers and is flat-pleated. The Freudenberg Surgical Mask materials consist of an outer cover web (polypropylene spunbond, white), insertion layer (polypropylene, melt-blown, white), and inner cover web (polypropylene spunbond, white). Each mask

contains polyester spandex blend ear loops to secure the mask over the user's mouth and nose and includes a polyethylene coated wire nosepiece to provide a firm fit over the nose. This face mask is a single use, disposable device, provided non-sterile. This device is not made with natural rubber latex.

Available Model Number:

FPMD2020	Surgical Mask

Comparison of Proposed and Predicate Devices:

Item(s)	**Proposed Device (K210063)** Freudenberg Surgical Mask	**Predicate Device (K182514)** SURGICAL FACE MASK	**Comparison**
Intended Use / Indications for Use	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 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.	The Disposable 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.	**Same, minor differences to correct grammar**
Type of Use	Over-The-Counter Use (21 CFR 801 Subpart C)	Over-The-Counter Use (21 CFR 801 Subpart C)	**Same**
Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	**Same**
Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	**Same**
Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	**Same**
Nose piece	Malleable polyethylene-coated wire	Malleable aluminum wire	**Similar, both nose pieces are composed of malleable metal.**
Nose piece length	10.0cm ±1cm	Not provided	**-**

Item(s)	**Proposed Device (K210063)** Freudenberg Surgical Mask	**Predicate Device (K182514)** SURGICAL FACE MASK	Comparison
Ear loops	Polyester spandex blend	Polyester	**Similar, both mask ear loops use polyester**
Ear loop length	14.5cm -1/+2.5cm	Not provided	**-**
Color	White	White	**Same**
Mask Style	Flat Pleated	Flat Pleated	**Same**
Length	17.5cm ±1cm	17.5cm ±1cm	**Same**
Width	9.5cm ±1cm	9.5cm ±1cm	**Same**
Sterile	Non-Sterile	Non-Sterile	**Same**
Use	Single Use	Single Use	**Same**
Performance Testing	Level 3 - ASTM F2100-19	Level 2 - ASTM F2100-11	**Different, subject devices exceeded predicate device in one performance test. ASTM F2100-19 uses different test method for measuring Delta-P (H_2O/cm^2)**
Fluid Resistance Performance	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at 160mmHg - ASTM F1862 Lot 698002: 31/32 passed Lot 697715: 32/32 passed Lot 697944: 31/32 passed	32/32 passed at 120 mmHg - ASTM F1862	**Similar, subject device exceeded fluid resistance of predicate device**
Bacterial Filtration Efficiency	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥98% - ASTM F2101 Lot 698002: 32/32 passed at 99.9% Lot 697715: 32/32 passed at 99.9% Lot 697944: 32/32 passed at 99.9%	pass at 99.6%- ASTM F2101	**Similar, both devices meet ASTM F2101**

Item(s)	**Proposed Device (K210063)** Freudenberg Surgical Mask	**Predicate Device (K182514)** SURGICAL FACE MASK	**Comparison**
Particulate Filtration Efficiency	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥98% - ASTM F2299 Lot 698002: 32/32 passed at 99.6±0.1% Lot 697715: 32/32 passed at 99.5±0.1% Lot 697944: 32/32 passed at 99.7±0.1%	pass at 99.88% - ASTM F2299	**Similar, both devices meet ASTM F2299**
Differential Pressure (Delta P)	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at <6.0 H_2O/cm^2 – ASTM F2100 / EN 14683:2019, Annex C Lot 698002: 29/32 passed at 5.3mm H_2O / cm^2 Lot 697715: 30/32 passed at 5.3mm H_2O / cm^2 Lot 697944: 31/32 passed at 5.7mm H_2O / cm^2	pass at 3.0mmH_2O/cm^2 - MIL-M036954C	**Similar, subject device utilized ASTM F2100-19 test methods (FR Recognition Number 6-425)**
Flammability	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed Class 1 16 CFR 1610 Lot 698002: 32/32 passed Lot 697715: 32/32 passed Lot 697944: 32/32 passed	Class 1 16 CFR 1610	**Same**
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	**Same**
Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	**Same**
Sensitization	Under the conditions of the study, the subject device non-polar and polar	Under the conditions of the study, the subject device non-polar and polar	**Same**

Item(s)	Proposed Device (K210063) Freudenberg Surgical Mask	Predicate Device (K182514) SURGICAL FACE MASK	Comparison
	extracts were determined to be non-sensitizing.	extracts were determined to be non-sensitizing.	

Summary of Non-Clinical Performance Testing:

The following standards have been used to evaluate the Freudenberg Surgical Mask:

ASTM F2100	Standard Specification for Performance of Materials Used in Medical Face Masks
ASTM F1862	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
ASTM F2299	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
ASTM F2101	Standard Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
EN 14683	Standard Test Method for Differential Pressure
16 CFR Part 1610	Standard for the Flammability of Clothing
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity of medical devices
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Non-clinical tests were conducted on three non-consecutive lots to verify that the proposed device met all design specifications as the predicate device, or better. The test results demonstrate that the proposed device conforms to the recognized standards ASTM F2100, ASTM F1862, ASTM F2299, ASTM F2101, EN 14683, 16 CFR Part 1610, and ISO 10993 in addition to the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004.

Summary of Clinical Performance Test:

No clinical study is included in this submission.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device K210063 is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K182514.