July 28, 2023

Original Mattress Factory Inc.
Nathan Elseser
Director of Personal Protective Equipment
4930 State Road
Cleveland, Ohio 44134

Re: K231618
Trade/Device Name: 3 Layer Surgical Mask (134252531)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 31, 2023
Received: June 2, 2023

Dear Nathan Elseser:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K231618

Device Name
3 Layer Surgical Mask

Indications for Use *(Describe)*
When properly worn, the 3 Layer Surgical Masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate materials. This device is non sterile and for single use only.

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

1. Submitter Information:

Company Name: The Original Mattress Factory, Inc.
d.b.a. Original Medical Supply

Address: 4930 State Road, Cleveland, Ohio, USA 44134

Phone Number: 216-661-8388

Contact Person: Nathan Elseser

Email: Nelseser@OriginalMattress.com

Subject Device Information

Type of 510(k):	Traditional
Common Name:	Surgical Face Mask
Trade Name:	3 Layer Surgical Mask
Classification:	Mask, Surgical
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	Class II

Predicate Device Information:

Sponsor:	Premier Guard USA LLC
Address:	460 Briarwood Drive, Suite 400
Common Name:	Surgical Face Mask
Trade Name:	Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask
510(k) Number:	K202595
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	Class II

2. Device Description

Subject Device (3 Layer Surgical Mask) is single use, 3 layers, flat-pleated style face mask with ear loops and moldable nose piece. The outer layer and inner facing layer of face mask consist of spun-bond polypropylene, and the middle layer consists of melt blown polypropylene filter. Each mask contains polyester / spandex blend ear loops to secure the mask over the user's face and mouth with moldable nose piece to firmly fit over the nose.

3. Intended Use

When properly worn, the 3 Layer Surgical Mask are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate materials. This device is non sterile and for single use only.

4. Test Summary

Subject device has been evaluated for safety and performance by lab bench testing according to the following standards:

- ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Surgical face masks to Penetration by Particulates Using Latex Spheres.
- ASTM F1862 Standard test method for resistance of Surgical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity)
- ASTM F 2101-19 Standard Test Method For Evaluating The Bacterial Filtration Efficiency (BFE) Of Surgical face mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus.
- 16 CFR Part 1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES
- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- During use, the Non Woven Face Mask will directly contact with user's skin, so we have it tested to demonstrate conformance to the following standards.
    - ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For InVitro Cytotoxicity
    - ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

5. Summary of Comparison and Technological Characteristics:

Table 1 - Elements of Comparison

Elements of Comparison	Subject Device	Predicate Device (K202595)	Comments
PRODUCT CODE	FXX	FXX	SAME
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	SAME
Class	II	II	SAME
Product Name	3 Layer Surgical Mask	Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask	–
GENERAL COMPARISON			
Intended Use	When properly worn, the 3 Layer Surgical Masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate materials. This device is non sterile and for single use only.	The Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from the 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
Composite	Flat Pleated, 3 Layers, ear loops	Flat Pleated, 3 Layers, ear loops	SAME

Materials	Outer Facing	Spun-Bond Polypropylene	Spun-Bond Polypropylene	SAME
	Middle	Melt Blown Polypropylene fiber	Melt Blown fiber	SAME
	Inner Facing	Spun-Bond Polypropylene	Spun-Bond Polypropylene	SAME
	Nose Piece	Polyethylene coated annealed carbon steel wire	Polyethylene coated annealed carbon steel wire	SAME
	Ear Loops	Polyester, Spandex	Nylon, Spandex	Different[1]
Color		Blue, White	Blue	SIMILAR
Dimensions (width)		95.0mm (+/- 5.0mm)	95.0mm	SAME
Dimensions (length)		175mm (+/- 5.0mm)	175mm	SAME
Use		Single Use	Single Use	SAME
Sterility		Non-Sterile	Non-Sterile	SAME
ASTM F2100 Level		Level 3	Level 3	SAME
Fluid Resistance Performance ASTM F 1862		Lot 1: 32 out of 32 pass at 160 mmHg Lot 2: 32 out of 32 pass at 160 mmHg Lot 3: 31 out of 32 pass at 160 mmHg	Pass at 160mmHg	Both Predicate and Subject Device PASS
Particulate Filtration Efficiency ASTM F 2299		Lot 1: 99.80% Lot 2: 99.83% Lot 3: 99.87%	$\geq$ 98%	Both Predicate and Subject Device PASS

Bacterial Filtration Efficiency ASTM F 2101	Lot 1: 99.8% Lot 2: 99.8% Lot 3: 99.8%	$\geq$ 98%	Both Predicate and Subject Device PASS
Differential Pressure (Delta P) EN 14683:2019+AC：2019	Lot 1: 4.8 mmHg Lot 2: 4.7 mmHg Lot 3: 4.6 mmHg	< 6mmH_20/cm^2	Both Predicate and Subject Device PASS
Flammability 16CFR 1610	Class 1, Non-Flammable	Class 1, Non-Flammable	Both Predicate and Subject Device PASS
Cytotoxicity	Comply with ISO 10993-5 non-cytotoxic	Comply with ISO 10993-5 non-cytotoxic	SAME
Irritation	Comply with ISO 10993-10 non-irritating	Comply with ISO 10993-10 non-irritating	SAME
Sensitization	Comply with ISO 10993-10 non-sensitizing	Comply with ISO 10993-10 non-sensitizing	SAME

*Notes [1] - Different material used in the ear loops of the masks. Subject Device was tested for & passed biocompatibility and performance testing. This material difference shows no effect on performance or safety of Subject Device as compared to Predicate Device.

6. Non-clinical Tests Performed on the Subject Device

The proposed subject device was tested and conformed to the following standards and recommendations in the Guidance for Industry and FDA Staff: *Surgical Masks – Premarket Notification [510(k)] Submission.*

Table 2 - Performance Testing

Test Methodology	Purpose	Subject Device	Acceptance Criteria	Result
Fluid Resistance Performance (ASTM F 1862)	This test method is used to evaluate the resistance of medical face masks by the impact of a small volume (approx 2ml) of high velocity stream of synthetic blood. Pass/Fail determinations are based on visual detection of synthetic blood penetration.	Lot 1: 32 out of 32 pass at 160 mmHg Lot 2: 32 out of 32 pass at 160 mmHg Lot 3: 31 out of 32 pass at 160 mmHg	29 out of 32 pass at 120 mmHg	PASS
Particulate Filtration Effeciency (ASTM F 2299)	The purpose of this test is to measure the initial particle filtration effeciency of materials using monodispersed aerosols containing suspended latex sphere particulates of 0.1 um diameter.	Lot 1: 99.80% Lot 2: 99.83% Lot 3: 99.87%	$\geq$ 98% PFE	PASS

Bacterial Filtration Effeciency (ASTM F 2101)	The purpose of this test is to measure the Bacterial Filtration Effeciency of the mask as specified in ASTM F 2101.	Lot 1: 99.8% Lot 2: 99.8% Lot 3: 99.8%	$\geq$ 98% BFE	PASS
Flammability 16 CFR 1610	The purpose of this test method is to determine the flammability characteristics of the mask as specified in 16 CFR 1610. Materials in the construction of face masks shall meet the requirements of Class 1, Normal Flammability specified by 16 CFR part 1610.	Lot 1: DNI Lot 2: DNI Lot 3: DNI All 3 Lots met Class 1 Flammability standards	Class 1	PASS
Differential Pressure EN 14683:2019	The purpose of this test method is to determine the overall breathability through the mask barrier in terms of mmH_2O/cm^3. The mask surface is subjected to constant air flow of 8.0 L/min and the pressure differential is measured.	Lot 1: 4.8mmHg Lot 2: 4.7mmHg Lot 3: 4.6mmHg	< 6.0 mmH_20/cm^2	PASS

Table 3 - Biocompatibility Testing

Test Methodology	Purpose	Subject Device	Acceptance Criteria	Result
Cytotoxicity (ISO 10993-5)	The purpose of the test is to determine the biological reactivity of a mammalian cell culture in response to the test article.	Proposed Device scored zero (0) for all reactivity. Non-cytotoxic.	Subject Article must score reactivity results not greater than 2, or a mild reactivity.	PASS
Irritation (ISO 10993-10)	To evaluate the potential skin irritation caused by the extraction of the test article extract contacting with the skin surface of rabbits.	All Scores were Zero(0). Proposed Device was determined to be Non-irritant.	Test article subjected skin areas are graded based on reactivity after 24, 48, & 72 hours.	PASS
Sensitization (ISO 10993-10)	To evaluate the potential test article extracts to cause skin sensitization in the guinea pig according to GPMT Method.	All Scores were Zero(0). Proposed Device was determined to be Non-sensitizer.	Test article subjected skin areas are graded based on reactivity after 24 & 48 hours.	PASS

7. Summary of Clinical Testing

There were no clinical studies performed or included in this submission.

8. Conclusion

The conclusion drawn from the nonclinical tests and substantial equivalence comparison with predicate device demonstrates that the subject device in this 510(k) submission, 3 Layer Surgical Mask, is as safe, effective, and performs as well, or better than the legally marketed predicate device.