July 25, 2021

Mid-America Safety Corp.
% Prithul Bom
Accredited Person, Reviewer
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K211984
Trade/Device Name: MASC Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 23, 2021
Received: June 25, 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 Clarence W. Murray, III, PhD
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.

510(k) Number *(if known)*
K211984

Device Name
MASC Surgical Mask

Indications for Use *(Describe)*

The MASC 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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Mid-America Safety Corp.
800 GREENLEAF AVE, ELK GROVE VILLAGE IL 60007
www.midamericasafety.com, info@midamericasafety.com

K211984

510(k) Summary

Sponsor Information: Mid-America Safety Corp.
800 Greenleaf Ave.
Elk Grove Village, 60007

Contact Person: Phil Fan, CEO
847-979-8606
Phil@midamericasafety.com

Summary Preparation Date: 5/7/2021
Type of 510(k) Submission: Traditional 510 (k)

Device Name/Classification:

Classification Name:	Surgical Apparel
Common Name:	Surgical Mask
Proprietary Name:	MASC Surgical Mask
Model	NFR03U-01A, NFR03U-01B
Classification Panel:	General and Plastic Surgery
Review Panel:	General Hospital
Product Code:	FXX
Device Classification:	Class II, 21 CFR 878.4040

Legally Marketed Predicate Device:

Classification Name:	Surgical Apparel
Common Name:	Surgical Face Mask
Model:	YX011, YX121
Classification Panel:	General and Plastic Surgery
Review Panel:	General Hospital
Product Code:	FXX
Device Classification:	Class II, 21 CFR 878.4040
510 (k) number:	K202161
Manufacturer:	Hunan EEXI Technology & Service Co.,Ltd.

Indications for Use:

The MASC Surgical Mask is intended to be worn to protect bot the patient and the 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 MASC Surgical Mask is a three-ply, nonwoven, flat pleated mask. The MASC surgical mask consists of an outer layer (polypropylene spun-bond, blue), a middle filter layer (Polypropylene melt-blown, white), and an inner layer (Polypropylene spun-bond, white). The three layers of the mask body are collated with ultrasonically welded edges and comes in two models, an ear- loop model (NFR03U-01A) and a tie-on model (NFR03U-01B). The polyester spandex blend ear loops or polypropylene tie-on band are ultrasonically bonded to the sides of the non-filtration area of the mask to secure the mask over the user's mouth, nose and chin. A malleable polyethylene coated wire nosepiece is placed within the top binding for comfort and individualized fit over the nose. The MASC Surgical Mask is a single use, disposable, non-sterile device which conforms to ASTM F2100-19 Level 3. This device does not contain any natural rubber latex or fiber glass materials.

Technological Characteristic Comparison:

Table 1 Comparison of Subject and Predicate Devices

Item(s)	Subject Device MASC Surgical Mask	Predicate Device Hunan EEXI Technology & Service Co.,Ltd. Surgical Face Mask	Comparison
510(k) #	K211984	K202161	
Commercial Name	MASC Surgical Mask	Surgical Face Mask	
Common Name	Surgical mask	Surgical Face mask	Same
Regulation Name	Surgical apparel	Surgical apparel	Same
Regulation Class	Class II	Class II	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Product Code	FXX	FXX	Same

Product Description	The MASC surgical mask is a three-ply, nonwoven, flat pleated mask. The MASC surgical mask consists of an outer layer (polypropylene spun-bond, blue), a middle filter layer (Polypropylene melt-blown, white), and an inner layer (Polypropylene spun-bond, white). The three layers of the mask body are collated with ultrasonically welded edges and comes in two models, including ear- loop (NFR03U-01A) and tie-on (NFR03U-01B). The polyester spandex blend ear loops or polypropylene tie-on band are ultrasonically bonded to the sides of the non-filtration area of the mask to secure the mask over the user's mouth, nose and chin. A malleable polyethylene coated wire nosepiece is placed within the top binding for comfort and individualized fit over the nose. The MASC Surgical Mask is a single use, disposable, non-sterile device which conforms to ASTM F2100-19 Level 3. This device does not contain any natural rubber latex or fiber glass materials.	The proposed devices are single use, three-layer, flat masks with straps and nose piece. The Surgical Face Masks are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The model of proposed device, YX011, is held in place over the user's mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are not made with natural rubber latex. The model of proposed device, YX121, is held in place over the user's mouth and nose by four ties welded to the face mask. The tie is made of spun-bond polypropylene. The nose piece contained in the proposed device is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of polyethylene and iron. The proposed devices are sold non-sterile and are intended to be single use, disposable devices.	Similar

Intended Use / Indications for Use	The MASC 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 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 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
Design feature	Ear-loop, Tie-on	Ear-loop, Tie-on	Same
Type of use	Over-The-Counter Use (21 CFR 801 Subpart C)	Over-The-Counter Use (21 CFR 801 Subpart C)	Same
Material Composition			
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	Polyethylene and wire	Polyethylene and wire	Same
Ear loop	Elastic Polyester/spandex blend	Elastic fiber	Similar
Tie-on	Spun-bond polypropylene	Spun-bond polypropylene	Same
Specifications			
Mask Style	Flat Pleated	Flat Pleated	Same
Length	17.5cm ±1.0 cm	17.5cm ±1.0cm	Same
Width	9.5cm ±1.0cm	9.5cm ±1.0 cm	Same
Sterile	Non-Sterile	Non-Sterile	Same
Use	Single Use	Single Use	Same
Color	Blue	Blue	Same
Ear-loop	16.5cm ± 2.5cm		
Tie-On	10.0mm± 3mm x 87.0 cm±5.0cm		
Performance			
Performance Testing	Level 3-ASTM F2100-19	Level 3-ASTM F2100-19	Same

Fluid Resistance	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at 160mmHg -- ASTM F1862 Lot 09142020-03U: 32/32 passed Lot 10052020-03U: 32/32 passed Lot 10072020-03U: 32/32 passed	Meet the ASTM F2100 Requirements for Level 3 Classification,) passed at 160mmHg -- ASTM F1862	Same
Bacterial Filtration Efficiency	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥ 98% - ASTM F2101 Lot 09142020-03U: 32/32 passed at 99.9% Lot 10052020-03U: 32/32 passed at 99.9% Lot 10072020-03U: 32/32 passed at 99.9%	Meet the ASTM F2100 Requirements for Level 3 Classification, passed at ≥98% - ASTM F2101	Same
Particulate Filtration Efficiency	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥ 98% - ASTM F2299 Lot 09142020-03U: 32/32 passed at 99.6 % Lot 10052020-03U: 32/32 passed at 99.9% Lot 10072020-03U: 32/32 passed at 99.9 %	Meet the ASTM F2100 Requirements for Level 3 Classification, passed at ≥98% - ASTM F2299	Same
Differential Pressure (Delta P)	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at <6.0 H2O/cm2 – ASTM F2100 / EN 14683:2019, Annex C Lot 09142020-03U: 32/32 passed at 4.6mm H2O/ cm2 Lot10052020-03U: 32/32 passed at 4.6mm H2O / cm2 Lot 10072020-03U: 32/32 passed at 4.7mm H2O / cm2	Meet the ASTM F2100 Requirements for Level 3 Classification, passed at <6.0 H2O/cm2 – ASTM F2100 / EN 14683:2019, Annex C	Same

Flammability	Three non-sequential lots of 32 (total of 96 ear- loop NFR03U-01A) passed Class 1 16 CFR 1610 Lot 09142020-03U: 32/32 passed Lot10052020-03U: 32/32 passed Lot 10072020-03U: 32/32 passed	Passed Class 1 16 CFR 1610	Same
Flammability	Three non-sequential lots of 32 (total of 96 tie-on NFR03U-01B) passed Class 1 16 CFR 1610 Lot 09142020-03B: 32/32 passed Lot10052020-03B: 32/32 passed Lot 10072020-03B: 32/32 passed	Passed Class 1 16 CFR 1610	Same
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

Based on the comparison of the proposed and predicate device, the ear-loops pose a possible technological difference as the predicate does not specify the type of elastic fiber which might comprise their ear-loop.

Summary of Non-Clinical Performance Testing

Performance tests were performed to verify that the device meets the acceptance criteria.

Table 2 provides a listing of the standards used in the performance testing.

Table 2: Standard Test Methodologies

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 **ISO 22609**	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

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM F1862	Fluid Resistance	160mmHg	Passed
ASTM F2101	Bacterial Filtration Efficiency	≥ 98%	Passed
ASTM F2299	Particulate Filtration Efficiency	≥ 98%	Passed
EN 14683	Differential Pressure (Delta P)	< 6.0 mm H_2O/cm^2	Passed
16 CFR Part 1610	Flammability	Class 1 (≥ 3.5 seconds)	Passed
ISO 10993-5	Cytotoxicity	Reactivity grade should not be greater than grade 2	Passed
ISO 10993-10	Irritation	The difference between the test article and the control mean score is 1.0 or less	Passed
ISO 10993-10	Sensitization	Grading score is 0	Passed

Summary of Clinical Testing

Not applicable; no clinical testing was performed.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the Hunan EEXI Technology & Service Co, Ltd. Surgical Face Mask of cleared under K202161.