September 10, 2021

ReMade USA LLC
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K212451
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 4, 2021
Received: August 5, 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)*
K212451

Device Name
Surgical Mask

Indications for Use *(Describe)*
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 nonsterile.

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.

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"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."

510(k) SUMMARY
K212451

This summary of 510(k) is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

ReMade USA LLC
2915 E Washington Blvd
Los Angeles, CA 90023 USA
Tel: +1.323.578.5448
Fax: N/A

Contact Person: David Durst
Date Prepared: May 21, 2021

II. DEVICE

Name of Device:	Surgical Mask
Classification Name:	Surgical Mask
Regulation:	21 CFR §878.4040
Regulatory Class:	Class II
Product Classification Code:	FXX

III. PREDICATE DEVICE

Predicate Manufacturer:	DemeTECH Corporation
Predicate Trade Name:	Deme MASK Surgical Face Mask
Predicate 510(k):	K201479

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The surgical face masks are non-sterile, single use, 3 layers, flat-pleated style with ear loops and nose piece. The outer layer and inner facing layer of face mask consists of Spunbond Polypropylene, and the middle layer consists of Melt Blown Polypropylene Filter. Each mask contains ear loops to secure the mask over the user's face and mouth with a nose piece to firmly fit over the nose. This device is not made from any natural rubber latex.

V. INDICATIONS FOR USE

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 nonsterile.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device:

Device	Proposed Device	Predicate Device	Result
Manufacturer	ReMade USA LLC	DemeTECH Corporation	-
510K Number	K212451	K201479	-
Product CommonName	SURGICAL MASK	DemeMASK Surgical Mask	Same
Product Code	FXX	FXX	Same
Classification	Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)	Same
Indications for Use	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.	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
Model	3 Ply, Ear Loops, Flat-Pleated Style	3 Ply, Ear Loops/Tie-on, Flat-PleatedStyle	Similar
Materials			
Outer Facing Layer	Spunbond Polypropylene 25gsm	Spunbond Polypropylene	Same
Middle Layer	Melt Blown Polypropylene Filter 25gsm	Melt Blown PolypropyleneFilter	Same
Inner Facing Layer	Spunbond Polypropylene 25gsm	Spunbond Polypropylene	Same

Nose Piece	Single Galvanized Iron Wire, coated with Polypropylene 3.0mm±1.0mm Length/1 ±0.1mm Thick/ 0.5±0.01mm Diameter	Galvanized wire coated with PE (Dimensions Unknown)	Similar
Ear Loops	80% Nylon; 20% Spandex Length: 4.0mm±0.15, Thickness: 1.0mm±0.15mm	Polyester spandex blend	Similar
Color	Blue	White	Different
Dimension (Width)	9.5 cm ± 1cm	9.5cm ± 1cm	Same
Dimension (Length)	17.5 cm ± 1cm	17.5cm ± 1cm	Same
OTC Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use	Single Use	Same
ASTM F2100 Level	Level 3 – ASTM F2100-19	Level 3 – ASTM F2100-19	Same

VII. SUMMARY of NON-CLINICAL PERFORMANCE TESTING

The subject device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004. A summary of the benchtop performance testing results is provided below in Table 2.

Table 2 – Benchtop Performance Testing

Item	Purpose	Acceptance Criteria	Subject Device - ReMade Surgical Mask
Level 3 Resistance to Penetration by Synthetic Blood STM F1862	The purpose of this testing is to demonstrate the Resistance to Penetration by Synthetic Blood ASTM F1862 of the subject device.	29 Out of 32 pass at 160 mmHg	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at 160mmHg Lot 1: 32/32 passed. Lot 2: 32/32 passed. Lot 3: 32/32 passed

Particulate Filtration Efficiency ASTM F2299	The purpose of this testing is to demonstrate the Particulate Filtration Efficiency ASTM F2299 of the subject device.	≥ 98%	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥98% Lot 1: 32/32 passed. Lot 2: 32/32 passed. Lot 3: 32/32 passed
Bacterial Filtration Efficiency ASTM F2101	The purpose of this testing is to demonstrate the Bacterial Filtration Efficiency ASTM F2101 of the subject device.	≥ 98%	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥98% - ASTM F2101 Lot 1: 32/32 passed. Lot 2: 32/32 passed. Lot 3:32/32 passed
Differential Pressure EN 14683:2019	The purpose of this testing is to demonstrate the Differential Pressure EN 14683:2019 of the subject device.	< 6.0 mmH_20/cm^2	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at <6.0 H2O/cm2 Lot 1: 32/32 passed. Lot 2: 32/32 passed. Lot 3: 32/32 passed.
Class 1 Flammability 16 CFR 1610	The purpose of this testing is to demonstrate the Flammability 16 CFR 1610 of the subject device.	Class 1: < 3.5 second burn time	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed Class 1 16 CFR 1610 Lot 1: 32/32 passed (DNI) Lot 2: 32/32 passed (DNI) Lot 3: 32/32 passed (DNI)

Sterilization & Shelf-life Testing

Not Applicable (This is a non-sterile device and shelf-life is not applicable to this device because of low likelihood of time-dependent product degradation.)

Biocompatibility Testing

Biocompatibility testing was performed in accordance with ISO 10993-1:2018. Specifically, the following testing endpoints were evaluated.

Table 3 - Biocompatibility Testing

Biocompatibility Testing Endpoints	Acceptance Criteria	Result
Cytotoxicity – ISO 10993-5	Non-Cytotoxic	Pass
Skin Sensitization – ISO 10993-10	Non- Sensitizing	Pass
Skin Irritation – ISO 10993-10	Non-Irritating	Pass

Table 4 – Summary of Non-Clinical Performance Testing
The following standards have been used to evaluate the ReMade USA 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 14683:2019	Standard Test Method for Differential Pressure
16 CFR Part 1610	Standard for Flammability
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

Software Verification and Validation Testing
Not Applicable (Passive Device)

Electrical safety and electromagnetic compatibility (EMC)
Not Applicable (Passive Device)

Animal Study
Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Human Clinical Performance Testing
Clinical testing was not required to demonstrate the safety and effectiveness of the device.

VIII. CONCLUSIONS
The conclusions drawn from the performance data demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device K201479, DemeMASK Surgical Face Mask manufactured by DemeTECH Corporation.