January 21, 2021

Premier Guard USA LLC
℅ Valerie Followell
President-Owner
Followell Compliance Consultants LLC
8049 Tripp Ave
Skokie, Illinois 60076

Re: K202595
Trade/Device Name: Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 19, 2020
Received: December 21, 2020

Dear Valerie Followell:

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 CAPT Elizabeth Claverie, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202595

Device Name
Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask

Indications for Use *(Describe)*
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 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.

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."

K202595
510(k) SUMMARY

Submission Correspondent

Contact Person: Valerie Followell
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Date Prepared

January 7, 2021

Device Information

Trade Name: Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask
Common Name: Surgical Mask
Classification Name: Surgical Mask
Product Code: FXX
Classification Panel: General Hospital
Regulatory Class: Class II
Regulation Number: 21 CFR 878.4040

Predicate Device Information

Wuhan Dymex Healthcare Co. Ltd. Surgical Face Mask
K182515

Device Description

The device description for the Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask is in accordance with the FDA Guidance Document*, Surgical Masks – Premarket Notification [510K)] Submissions* issued on March 5, 2004. The Premier Guard Face Mask is a flat-pleated style mask with elastic ear loops to secure it over the users' mouth and face. The mask consists of three-layers. The inner facing layer is white and is manufactured from spunbond polypropylene (three layers of nonwoven

polypropylene). The inner filter material is made of meltblown fiber. The outer facing layer is blue and is manufactured from spunbond polypropylene (three layers of nonwoven polypropylene). The mask is a single use, disposable device, provided non-sterile.

The proposed device is not made from natural rubber latex.

Indications for Use

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 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 fluid. This is a single use, disposable device, provided non-sterile

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask	Wuhan Dymex Healthcare Co. Ltd. Surgical Face Mask	Different
510(k) Reference	K202595	K182515	Different
Product Owner	Premier Guard USA LLC	Wuhan Dymex Healthcare Co., Ltd.	Different
Product Code	FXX	FXX	Same
Indications for Use	The Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Masks are intended to be worn to protect both 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(s) provided non-sterile.	The Disposable Surgical Face Masks are intended to be worn to protect both 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(s) provided non-sterile.	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Mask Style	Flat Pleated, Ear Loops, 3 Layers	Flat Pleated, Ear Loops, 3 Layers	Same
Mask Color	Blue	Yellow	Different

Materials			
Nose Piece (material)	Polyethylene laminated soft annealed carbon steel wire	Malleable aluminum wire	Different
Ear Loops (material)	Nylon and Spandex	Spandex	Similar
Outer Facing Layer	Spunbond polypropylene	Spunbond polypropylene	Same
Middle Layer	Melt blown fiber	Melt blown polypropylene filter	Similar
Inner Facing Layer	Spunbond polypropylene	Spunbond polypropylene	Same
Dimensions - Width	175mm	17.5cm±1cm	Same
Dimensions - Length	95mm	9.5cm±1cm	Same
ASTM F2100 Level	Level 3	Level 2	Different
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic	Under the conditions of the study, the device is non-cytotoxic	Same
Sensitization	Under the conditions of the study, the device is non-sensitizing	Under the conditions of the study, the device is non-sensitizing	Same
Irritation	Under the conditions of the study, the device is non-irritating	Under the conditions of the study, the device is non-irritating	Same
Prescription vs. OTC	OTC	OTC	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single Use	Single Use	Same

Discussion of Similarities and Differences

The differences in material composition and the colorant do not raise new questions of safety or effectiveness as biocompatibility testing was performed on the final finished device and the results demonstrate that the subject device is non-cytotoxic, non-sensitizing and non-irritating.

When tested for fluid resistance per ASTM F1862 at 160 mmHg the Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask met the requirements for a level 3 face mask. The predicate device was tested at 120 mmHg, therefore, meeting the requirements for a level 2 face mask. The Premier Guard USA 3 Layer Ear Loop ASTM

Level 3 Surgical Face Mask provided a higher level of fluid resistance as compared to the predicate device and when tested per ASTM F1862.

Summary of Testing and Supporting Information

Testing was conducted to demonstrate substantial equivalence of the Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask to the predicate, Wuhan Dymex Healthcare Co. Ltd. Surgical Face Mask K182515.

Premier Guard USA followed the "Guidance for Industry and FDA Staff Surgical Masks - Premarket Notification [510(k)] Submissions Document [Issued on: March 5, 2004 and a correction posted on July 14, 2004]".

A summary of testing is presented below with more information provided in the applicable sections.

Non-Clinical Performance Testing

The Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask was tested in accordance with the tests recommended in the FDA guidance document, *Guidance for Industry and FDA Staff Surgical Masks – Premarket Notification [510(k)] Submission* issued March of 2004. Based upon the guidance document the following testing has been performed.

- Fluid Resistance per ASTM F1862
- Particulate Filtration Efficiency per ASTM F2299
- Bacterial Filtration Efficiency per ASTM F2101
- Differential Pressure (Delta P) per EN 14683
- Flammability per 16 CFR 1610

TABLE 2: PERFORMANCE TESTING

Test	Subject Device	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862	Pass at 160 mmHg	29 out of 32 pass at 160 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	≥98%	≥98%	Pass
Bacterial Filtration Efficiency ASTM F2101	≥98%	≥98%	Pass
Differential Pressure (Delta P) EN 14683	<6mmH_2O/cm^2	<6mmH_2O/cm^2	Pass
Flammability 16 CFR 1610	Class 1	Class 1	Pass

Performance Testing (Animal)

The biocompatibility evaluation for the Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask was conducted in accordance with ANSI/AAMI/ISO 10993-1:2018 *Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process*, as recognized by FDA. The Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask is classified as a surface contacting device. Specific biocompatibility tests were selected under the guidance of ISO 10993-1:2018 Annex A.

TABLE 3: BIOCOMPATIBILITY TESTING

Test	Subject Device	Result
Cytotoxicity ISO 10993-5	Grade 0	Pass
Sensitization ISO 10993-10	No sensitization reactions were observed in test animals	Pass
Irritation ISO 10993-10	Primary Irritation score=0 (Negligible)	Pass

Clinical Testing

This section does not apply. No clinical testing was performed.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the devices are as safe, as effective, and perform as well as or better than the legally marketed predicate device, K182515 Wuhan Dymex Healthcare Co., Ltd. Surgical Face Masks.