DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 15, 2016

Protect U Guard, LLC
Mr. Brent Laartz
President
1840 Mease Drive
Suite 319
Safety Harbor, Florida 34695

Re: K153409
Trade/Device Name: Protect U Guard Earloop and Tie-On Mask (Blue, White or Green)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 10, 2016
Received: October 11, 2016

Dear Mr. Laartz:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153409

Device Name
Protect U Guard Earloop and Tie-On Mask (Blue, White, or Green)

Indications for Use *(Describe)*

Earloop Mask and Tie-On Mask is intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids, and airborne particles. This device is single-use and provided non-sterile.

Earloop Models: Blue (P10031), White (P10032), or Green (P10033)

Tie-On Models: Blue (P10041), White (P10042), or Green (P10043)

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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."

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October 10 , 2016

510K SUMMARY

This 510K Summary information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510K number is: K153409

1. Submitter's Identification:

   Protect U Guard, LLC
   1840 Mease Drive Suite 319
   Safety Harbor, FL 34695
   Telephone: (813) 815-0530
   Fax: 1 (844)-821-4418

   Contact Person: Brent W. Laartz, MD,
   President blaartz@protectuguard.com

2. Device Name:

   Protect U Guard Earloop and Tie-On Mask (Blue, White or Green)

3. Device Common Name:
   a. Surgical Facemask

4. Regulation Name, Device Product Code and Classification:
   a. Surgical Apparel
   b. FXX Class II
   c. 21 CFR 878.4040

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5. Device Description:

Earloop Mask and Tie-On Mask is a single use non-sterile three layer mask with outer layer (Layer #1) and inner layer (Layer #3) made of spunbound polypropylene and a middle layer (Layer #2) made with meltblown polypropylene filter. Layer #1 has either no pigment (White) or a pigment (Either Blue or Green). There are 2 options for the mask to be secured on the user, either earloops or 2 sets of ties. Earloops are made of urethane elastic fiber and the ties are made of spunbound polypropylene. The nosepiece is a pliable aluminum strip covered by a polypropylene spunbound material and is encased between Layers # 1 and 2 and is affixed in place by ultrasonic heat seal. The three layers of material are pleated 3 times and Layer #3 is folded over the two other layers in front of the Layer #1. An edge material with 30 gsm spunbound polypropylene material is wrapped around the 3 layers at the 2 lateral edges. All 4 edges are ultrasonically heat sealed and ties or earloops are attached inside the edge material and ultrasonically heat sealed. All of the materials in the Standard Earloop Mask and the Standard Tie-On Mask are latex free. All materials are being used in currently marketed devices.

Dimensions: 9.5 cm x 17.7 cm

Specifications:

Layer #1 (Outer Layer): Spunbound Polypropylene. 20 gsm. (Either White, Blue, Or Green)

White: No Pigment

Blue Pigment: Indanthrene or CI Pigment Blue 60. CAS 81-77-6

Green Pigment: Phthalocyanine Green G. CAS 1328-53-6

9.5 cm x 17.7 cm

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Layer #2 (Middle Layer): Meltblown Polypropylene. 25 gsm. White.

9.5 cm x 17.7 cm

Layer #3 (Inner Layer) Spumbound Polypropylene. 25gsm. White.

12.6 cm x 17.7 cm

Nosepiece: 10 cm x 0.2 cm Aluminum Wrapped in Polypropylene

Edge: Spunbound Polypropylene. 30gsm.

Length 9.5 cm. 3.0 cm width folded to 1.5cm. White.

Attached Using Ultrasonic Heat Seal.

Earloop: Urethane Elastic Fiber. #2. 17cm Long. White.

Attached Using Ultrasonic Heat Seal.

Ties: Spunbound Polypropylene. #4. 40gsm.

Total Length 95 cm. 2.4 cm width folded to 1.2 cm. White.

Attached Using Ultrasonic Heat Seal.

6. Intended Use:

Earloop Mask and Tie-On Mask is intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids, and airborne particles. This device is single-use and provided non-sterile.

Earloop Models: Blue (P10031), White (P10032), or Green (P10033)

Tie-On Models: Blue (P10041), White (P10042), or Green (P10043)

Over-The-Counter Use

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7. Comparison to Predicate Device:

Predicate Device: Tiger Medical Products Earloop and Tie On Mask (K122717)

Description	Our Device (K153409)	Predicate Device (K122717)
Materials	Spunbound Polypropylene Meltblown Polypropylene	Spunbound Polypropylene Meltblown Polypropylene
Dimensions	9.5cm x 17.7 cm	Approx 9cm x 17 cm
Inner Layer	Spunbound Polypropylene	Spunbound Polypropylene
Middle Layer	Meltblown Polypropylene	Meltblown Polypropylene
Outer Layer	Spunbound Polypropylene	Spunbound Polypropylene
Nosepiece	Aluminum strip	Aluminum strip
Attachment	Urethane elastic fiber earloop or spunbound polypropylene tie	Urethane elastic fiber earloop or spunbound polypropylene tie
Mask Style	Earloop or Tie-On Flat Pleated	Earloop or Tie-On Flat Pleated
Fluid Resistance	Pass at 80 mm Hg	Fluid Resistant
Particle Filtration Efficiency	99.18% at 0.1 micron	99.54% at 0.1 micron
Bacterial Filtration Efficiency	99.17%	>99.9%
Flammability Class	1	1
Delta – P	3.79 mmH_2O/cm^2	3.38 mmH_2O/cm^2
Biocompatibility	Under the conditions of the study, the device is non-cytotoxic, non-irritating, and non- sensitizing.	No Cytotoxicity No Sensitization No Irritation
Latex	Not Made With Natural Rubber Latex	Latex Free
Indications For Use	Earloop Mask and Tie-On Mask is intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids, and airborne particles. This device is single-use and provided non-sterile.	Surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood, and body fluids, and airborne particulates.

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8. Conformity to Standards outlined in the Guidance Document: "Guidance for Industry and FDA Staff Surgical Masks - Premarket Notification [510(k)] Submissions." The below standards are outlined in the guidance document under the heading Risk To Health:
    a. Fluid Resistance
        i. ASTM F1862/F1862M – 13. Standard test method for resistance of medical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity)
        ii. Fluid Resistance tested at 80 mm Hg, passed 29 of 32. Conforms to this standard for fluid resistance at 80mm Hg.
        iii. Adaptations, Deviation, or Differences from the Methods of the Conformance Standard: None.
    b. Adequate Barrier for Bacteria
        i. ASTM F2101 – 14. Standard test method for evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of staphylococcus aureus.
        ii. Bacterial Filtration Efficiency tested at 99.17%. Conforms to this standard.
        iii. Adaptations, Deviation, or Differences from the Methods of the Conformance Standard: None.
    c. Adequate Air Exchange
        i. MIL-M-36954C. Differential Pressure (Delta-P)
        ii. Tested at a Delta P of 3.79 which corresponds to a comfort level of warm. Conforms to this standard.
        iii. Adaptations, Deviation, or Differences from the Methods of the Conformance Standard: None.
    d. Adequate Particlulate Barrier
        i. ASTM F2299/F2299M – 03 (2010). Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres. With the exception of the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks.
        ii. Particulate Filtration Efficiency result was 99.18% for particles of 0.1 micron. Conforms to this standard.
        iii. Adaptations, Deviation, or Differences from the Methods of the Conformance Standard: None, except the procedure incorporated a non-neutralized

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challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks.

e. Flammability
    i. Code of Federal Regulations (CFR): 16 CFR Part 1610. Standard for the Flammability of Clothing Textiles.
    ii. Flammability testing Passed as a Class 1. Conforms to this standard. See Nelson Labs report following.
    iii. Adaptations, Deviation, or Differences from the Methods of the Conformance Standard: None except, anhydrous calcium chloride was used as a desiccant rather than anhydrous silica gel. This is not expected to alter testing results.

f. Biocompatibility
    i. ISO 10993 Part 5 and 10. Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity. Part 10: Tests for irritation and skin sensitization.
    ii. Under the conditions of the study, the device is non-cytotoxic, non-irritating, and non-sensitizing.
    iii. Adaptations, Deviation, or Differences from the Methods of the Conformance Standard: For Skin Sensitization, the Guinea Pig Buehler Sensitization Test is chosen as the most appropriate option. For Cytotoxicity, the Minimal Essential Media (MEM) option was chosen which conforms to the standard. Otherwise No deviations.

g. Latex
    i. ASTM D6499-12. Standard test method for the immunological measurement of antigenic protein in natural rubber and its products.
    ii. Not made with natural rubber latex.
    iii. Adaptations, Deviation, or Differences from the Methods of the Conformance Standard: None.

9. Conclusions:

Materials, intended use, mask style, design features, and performance test results of Earloop Mask and Tie-On Mask are similar to the predicate device. The Protect U Guard Earloop and Tie-On Mask (Blue, White or Green) is substantially equivalent to the Predicate Device.