June 4, 2021

Everwin Toys (Dongguan)., Ltd.
℅ Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road,
Huangpu District
Guangzhou, Guangdong 510700
China

Re: K203388
Trade/Device Name: Disposable medical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 25, 2021
Received: May 5, 2021

Dear Cassie Lee:

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 Murray III, Ph.D.
Acting 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)*
K203388

Device Name
Disposable medical mask

Indications for Use *(Describe)*
The Disposable medical masks are intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids, and particulate materials. This device is single-use and provided non-sterile.

Model: WSKZ-001
Color : Blue

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 for K203388

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

**1. Date of the summary prepared: June 04, 2021**

**2. Submitter's Information**

510(k) Owner's Name: EVERWIN TOYS (DONGGUAN)., LTD.
Establishment Registration Number: 3012360847
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**Application Correspondent :**
Contact Person : Ms. Cassie Lee
Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel : +86 20 8266 2446
Email : regulatory@glomed-info.com

**3. Subject Device Information**

Type of 510(k): Traditional
Classification Name: Mask, Surgical
Common name: Surgical Mask
Trade Name: Disposable medical mask
Model: WSKZ-001
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Regulatory Class: II

**4. Predicate Device Information**

Sponsor: Protect U Guard, LLC
Device Name: Protect U Guard Earloop and Tie-On Mask (Blue, White or Green)
Model: P10031, P10032, P10033, P10041, P10042, P10043
Classification Name: Mask, Surgical
510(K) Number: K153409
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Regulation Class: II

**5. Indications for Use**

The Disposable medical masks are intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids, and particulate materials. This device is single-use and provided non-sterile.

Model: WSKZ-001
Color: Blue

**6. Device Description**

The Disposable medical mask is flat pleated type mask, utilizing ear loops way for wearing, and they all have nose clip design for fitting the facemask around the nose. The Disposable medical mask is only one model: WSKZ-001 and the color is blue.

The Disposable medical mask is manufactured with three layers, the inner and outer layers are made of spunbond polypropylene, only the outer layers' color is blue (colorant: Pigment Blue, CAS number: 147-14-8), and the middle layer is made of melt blown fabric.

Ear loops, which is held to cover the users' mouth and nose by two Ammonium nylon elastic bands ultrasonic welded to the Disposable Medical Mask. The elastic ear loops are not made with natural rubber latex.

The nose clip contained in the Disposable medical mask is in the middle layer of Disposable medical mask to allow the user to fit the Disposable medical mask around their noses, which is made of Polypropylene and metallic iron.

The Disposable medical mask is sold non-sterile and is intended to be single use, and the intended environment is professional healthcare facility environment. The shelf life of each Disposable medical mask is 2 years.

The dimensions of each Disposable medical mask are length 175mm and width 95mm. The dimension of nose clip is length 100mm, and the ear loop is length 170mm.

**7. Comparison of Technological Characteristics**

The following table identifies technological characteristics shared between the subject device and Predicate:

| **Elements of Comparison** | **Subject Device (K203388)** | **Predicate Device (K153409)** | **Comparison** |
|---|---|---|---|
| Company | EVERWIN TOYS (DONGGUAN)., LTD. | Protect U Guard, LLC | -- |
| 510 (k) | K203388 | K153409 | -- |
| Trade Name | Disposable medical mask | Protect U Guard Earloop and Tie-On Mask (Blue, White or Green) | -- |
| Model | WSKZ-001 | Earloop Models: Blue (P10031), White (P10032), or Green (P10033)<br>Tie-On Models: Blue (P10041), White (P10042), or Green (P10043) | -- |
| Classification Name | Mask, Surgical | Mask, Surgical | Same |
| Classification | Class II Device, FXX<br>(21 CFR878.4040) | Class II Device, FXX (21 CFR878.4040) | Same |

| | | | |
|---|---|---|---|
| Intended use | The Disposable medical masks are intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids, and particulate materials. This device is single-use and provided non-sterile. | 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.<br>Earloop Models: Blue (P10031), White (P10032), or Green (P10033)<br>Tie-On Models: Blue (P10041), White (P10042), or Green (P10043)<br>Over-The-Counter Use | Similar |
| Material | | | |
| **Elements of Comparison** | **Subject Device (K203388)** | **Predicate Device (K153409)** | **Comparison** |
| Outer facing layer | Spunbond Polypropylene | Spunbond Polypropylene | Same |
| Middle layer | Melt blown polypropylene | Melt blown polypropylene | Same |
| Inner facing layer | Spunbond Polypropylene | Spunbond Polypropylene | Same |
| Nose clip | Polypropylene and metallic iron | Aluminum strip | Similar Note 1 |
| Ear loops | Ammonium nylon elastic | Urethane elastic fiber | Similar Note 1 |
| Design features | Color: Blue<br>Ear loops | Color: Blue, White,<br>Green Ear loops | Same |
| Dimension | 17.5cm x 9.5 cm | 17.7cm x 9.5 cm | Similar Note 1 |
| OTC use | Yes | Yes | Same |
| Sterility | Non-Sterile | Non-Sterile | Same |
| Use | Single Use, Disposable | Single Use, Disposable | Same |
| Performance Testing | Level 1 | Level 1 | Same |
| Fluid Resistance Performance | Pass at 80 mmHg | Pass at 80 mmHg | Same |
| Particulate Filtration Efficiency | ≥96.1% | 99.18% at 0.1 micron | Similar Note 2 |
| Bacterial Filtration Efficiency | ≥99.2% | 99.17% | Similar Note 2 |
| Differential Pressure | <4.0 mm $H_2O/cm^2$ | 3.79 mm $H_2O/cm^2$ | Similar Note 2 |
| Flammability | Class 1 | Class 1 | Same |
| Biocompatibility | | | |

| | | | |
|---|---|---|---|
| Cytotoxicity | Under the conditions of the study, the subject device extract was determined to be non-cytotoxic. | Under the conditions of the study, the subject device extract was determined to be non-cytotoxic. | Same |
| Irritation | Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating. | Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating. | Same |
| Sensitization | Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing. | Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing. | Same |

**Comparison in Detail(s):**

**Note 1:**

Although the "Ear loops", "Nose clip" and "Dimension" of subject device is a little different from predicate device, they all meet the requirements of essential performance standard ASTM F2100 and ISO 10993 series. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

**Note 2:**

Although the "Particulate Filtration Efficiency", "Bacterial Filtration Efficiency" and "Differential Pressure" of subject device is a little different from predicate device, they all meet the level 1 requirements of essential performance standard ASTM F2100. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

**8. Non-Clinical Performance Testing Summary:**

| **Test item (Performance Level 1)** | **Test method** | **Pass criteria** | **Test results** |
|---|---|---|---|
| Bacterial filtration efficiency | 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 according to ASTM F2100:2019 | ≥ 98% | 32/32 Passed at ≥99.2% / Pass |
| Differential pressure (Delta-P) | EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019 | <5.0 mm $H_2O/cm^2$ | 32/32 Passed at <4.0 mm $H_2O/cm^2$/ Pass |
| Particulate Filtration Efficiency | ASTM F2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres according to ASTM F2100:2019 | ≥ 95% | 32/32 Passed at ≥96.1% / Pass |

| | | | |
|---|---|---|---|
| Resistance to penetration by synthetic blood, minimum pressure in mmHg for pass result | ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) according to ASTM F2100:2019 | Fluid resistant claimed at 80 mmHg | 32/32 Passed at 80 mmHg/ Pass |
| Flame spread | 16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019 | Class 1 | 32/32 Passed ≥3 Seconds burn Time-Class 1 / Pass |

**Biocompatibility Testing Summary:**

According to ISO 10993-1: 2018, the nature of body contact for the subject device is the Surface Device category, Skin Contact, and duration of the contact is A-Limited (<24 h). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

| Title of the test | Purpose of the test | The source of references (Test method) | Acceptance criteria | Test results |
|---|---|---|---|---|
| In vitro Cytotoxicity Test | Under the research conditions, determine whether the target device extract is cytotoxic. | ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity | Under the conditions of the study, the subject device extract was determined to be non-cytotoxic. | Pass |
| Skin Sensitization Test | Under the research conditions, determine whether the non-polar and polar extracts of the target device are sensitive. | ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization | Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing. | Pass |
| Skin Irritation Test | Under the research conditions, determine whether the non-polar and polar extracts of the target device are irritating. | ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization | Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating. | Pass |

## 9. Summary of Clinical Performance Test

No clinical study is included in this submission.

## 10. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device, Disposable medical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K153409, Protect U Guard Earloop and Tie-On Mask (Blue, White, or Green).