March 7, 2021

Guangdong Horigen Mother & Baby Products Co., Ltd
℅ Olivia Meng
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co.,Ltd.
8-9th Floor, R&D Building, No.26 Qinglan Street
Panyu District
Guangzhou, Guangdong 510006
China

Re: K201974
Trade/Device Name: Single-use medical face mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 29, 2021
Received: February 1, 2021

Dear Olivia Meng:

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,

Ryan Ortega, PhD
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)*
K201974

Device Name
Single-use medical face mask

Indications for Use *(Describe)*
Single-use medical face mask is 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.

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.

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510(k) Summary

1. SUBMITTER

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Date prepared	March 6, 2021

2. DEVICE

510K number	K201974
Device Name:	Single-Use Medical Face Mask
Common name:	Surgical Face Mask
Model:	KZ-170A
Regulation number	21 CFR 878.4040
Regulation Class:	II
Product Code:	FXX

3. PREDICATE DEVICE

K153409, Protect U Guard Earloop and Tie-On Mask (Blue, White or Green)

4. DEVICE DESCRIPTION

The proposed device is single-use medical face mask. It is non-sterile and for single use.

The single-use medical face mask is manufactured with three-layers, the inner and

outer layers are made of spun-bond polyethylene, and the middle layer is made of melt blown Polyethylene. The elastic ear loop of proposed device is made of spandex and polyester, not natural rubber latex. The nose piece contained in the proposed device allows the user to fit the face mask around their nose, which is made from zinc strip.

It is a self-inhalation filter mask, which works by filtering the air through the filter material of the mask before being inhaled or exhaled.

5. INDICATIONS FOR USE

The single-use medical face mask is 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Subject Device	Predicate Device	Comparison Result
Manufacturer	Guangdong Horigen Mother & Baby Products Co., Ltd.	Protect U Guard, LLC	NA
510K Number	K201974	K153409	NA
Product Common Name	Single-Use Medical Face Mask	Protect U Guard Earloop and Tie-On Mask (Blue, White or Green)	NA
Intended Use	Single-Use Medical Face Mask is 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.	Same
Mask style	Flat pleated	Flat pleated	Same
Design feature	Ear loop	Earloop or tie-on	Similar
Material of outer facing layer	Spun-bond polyethylene	Spunbound polypropylene	Similar
Material of middle layer	Melt blown Polyethylene	Melt blown polypropylene	Similar

Material of inner facing layer	Spun-bond polyethylene	Spunbound polypropylene	Similar
Nose piece	Malleable polyethylene wire with zinc inside	Aluminum strip	Similar
Attachment	Ear loops: Spandex and polyester	Urethane elastic fiber earloop or spunbound polypropylene tie	Similar
Dimension (Length × Width)	17.5 cm × 9.5 cm	17.7 cm × 9.5 cm	Similar
OTC use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Single use	Yes	Yes	Same
ASTM F 2100 level	Level 1	Level 1	Same
Resistance to Penetration by synthetic blood	80 mmHg	80 mmHg	Same
Sub-Micron Particle Filtration Efficiency	Average 99.8% at 0.1 micron	99.18% at 0.1 micron	Similar
Bacterial Filtration Efficiency	Average 99.9%	Average 99.17%	Similar
Flammability class	1	1	Same
Differential Pressure	Average 2.44 mm H_2O/cm^2	Average 3.79 mmH2O/cm^2	Similar
Biocompatibility			
Cytotoxicity ISO 10993-5	Under the conditions of the study, the device was found non-cytotoxic.	Under the conditions of the study, the device was found non-cytotoxic.	Same
Sensitization ISO 10993-10	Under the conditions of the study, the device was found non-sensitizing.	Under the conditions of the study, the device was found non-sensitizing.	Same
Irritation ISO 10993-10	Under the conditions of the study, the device was found non-irritating.	Under the conditions of the study, the device was found non-irritating.	Same

The subject device is the same as the predicate device in the intended use, mask style, ASTM F2100 level and biocompatibility, and similar in materials and dimension. So the subject device is identical to the predicate device.

7. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

7.1. Non-clinical test performed on the proposed device

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the single-use medical face mask was conducted in accordance with the International Standard ISO 10993-1:2018, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity - (ISO 10993-5: 2009)
- Sensitization - (ISO 10993-10:2010)
- Skin Irritation - (ISO 10993-10:2010)

Performance testing

Performance testing was conducted on the single-use medical face mask. All of the tested parameters met the predefined acceptance criteria.

Item	Test Methods	Result value	Acceptance criteria
Resistance to Penetration by synthetic blood (mmHg)	ASTM F2100-19 ASTM F1862/ASTM F1862-2017	80	Level 1: 80
Sub-Micron Particulate Filtration Efficiency (PFE) at 0.1 micron Test (%)	ASTM F2100-19 ASTM F2299 /ASTM F2299-2003(2017)	Average 99.8%	Level 1: ≥95%
Bacterial Filtration Efficiency Test (BFE), %	ASTM F2100-19 ASTM F2101-19	Average 99.9%	Level 1: ≥95%
Flammability	ASTM F2100-19 16 CFR Part 1610-2019	NA	Class 1
Differential Pressure Test mm H_2O/cm^2	ASTM F2100-19 EN 14683:2019+AC:2019(E) Annex C	Average 2.44	Level 1: <5.0

7.2. Clinical test

No clinical testing was performed.

8. CONCLUSION

8.1. Clinical test conclusion

No clinical study is included in this submission.

8.2. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K201974, the single-use medical face mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K153409.