March 3, 2021

Han Zhaoqing Sporting Goods Company Limited
℅ Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant LTD
Contact Address

Re: K202316
Trade/Device Name: Medical mask (Model: KKF-1A)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 15, 2021
Received: January 15, 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 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)*
K202316

Device Name
Medical mask (Model: KKF-1A)

Indications for Use *(Describe)*
Medical 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.

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

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510(k) Summary

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

Subject Device: Medical mask (Model: KKF-1A)
510(k) Number: K202316

1. Submitter's Information
510(k) Owner's Name: Han Zhaoqing Sporting Goods Company Limited
Establishment Registration Number: 3016690756
Address: NO.2-1, Kang tai Street, High-tech zone, Zhaoqing City, Guangdong Province, P.R.China
Trade Mark: KOUMASK*TM*
Post Code: 526238
Contact name: Zhang Ming
Tel: +86- 138 2551 8595
E-mail: info@koumask.co

Application Correspondent:
Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

2. Date of the summary prepared date: August 11, 2020

3. Revision date: February 23, 2021

4. Subject Device Information
Type of 510(k): Traditional
Trade Name: Medical mask
Model Name: KKF-1A
Common Name/Regulation Description: Surgical apparel
Classification Name: Mask, Surgical
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 878.4040
Regulation Class: II

5. Predicate Device Information
Predicate Device:
Sponsor: Protect U Guard, LLC.
Trade Name: Protect U Guard Earloop and Tie-On Mask (Blue, White or Green)
Common Name/Regulation Description: Surgical apparel
Classification Name: Mask, Surgical

510(K) Number: K153409
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 878.4040
Regulation Class: II

6. Device Description
The Medical mask are four-layer, flat-folded masks constructed of nonwoven polypropylene materials. The mask is provided with ear loops (polyester and polyurethane), and a malleable nosepiece which is placed within the binding for comfort and individualized fit. The mask not made with latex materials, and all materials are being used in currently marketed devices. The mask will be provided in white. The masks are single-use, disposable devices, provided non-sterile.

7. Intended Use / Indications for Use
Medical 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.

8. Comparison to predicate device and conclusion
The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device**	**Comparison**
Company	Han Zhaoqing Sporting Goods Company Limited	Protect U Guard, LLC.	--
510 (k)	K202316	K153409	--
Trade Name	Medical mask	Protect U Guard Earloop and Tie-On Mask (Blue, White, or Green)	--
Classification Name	Mask, Surgical	Mask, Surgical	Same
Classification	Class II	Class II	Same
Product Code	FXX	FXX	Same
Indication for Use	Medical 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
Intended populations	Adult only	Adult only	Same
Materials			
Outer facing layer	Spunbound Polypropylene	Spunbound Polypropylene	Same
Middle filter layer	- Melt blown polypropylene	Melt blown Polypropylene	Similar

Elements of Comparison	Subject Device	Predicate Device	Comparison
	- Polypropylene		Note 1
Inner facing layer	Spunbound Polypropylene	Spunbound Polypropylene	Same
Nose clip	Polyethylene coated steel wire	Aluminum strip	Same
Ear loops	Polyester	Urethane Elastic Fiber	Same Note 1
Design features	Color: White, Ear loops, Flat Pleated	Earloop or Tie-On Flat Pleated	Similar Note 1
Mask Style	Flat-pleated	Earloop or Tie-On Flat Pleated	Same
Dimensions	16cm x 10.5cm (±0.5cm)	9.5cm x 17.7 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 (ASTM F2100-19)	Level 1 (ASTM F2100)	Same Note 2
Fluid Resistance Performance	Pass at 80 mm Hg (F1862/F1862M − 17)	Pass at 80 mm Hg (F1862/F1862M)	Same
Particulate Filtration Efficiency	99.3% at 0.1 micron (F2299/F2299M − 03 (2017))	99.18% at 0.1 micron (ASTM F2299/F2299M – 03 (2010))	Similar Note 2
Bacterial Filtration Efficiency	Pass at 98.1% (ASTM F2101-19)	99.17% (ASTM F2101-14)	Similar Note 2
Differential Pressure	4.8 mm H_2O/cm^2 (EN 14683: 2019, Annex C)	3.79 mm H_2O/cm^2 (MIL-M-36954C)	Similar Note 2
Flammability	Class 1 (16 CFR 1610)	Class 1 (16 CFR 1610)	Same
Biocompatibility			
Cytotoxicity (ISO 10993-5)	Under the conditions of the study, the subject device was non-cytotoxic.	Under the conditions of the study, the device is non-cytotoxic.	Same
Irritation (ISO 10993-10)	Under the conditions of the study, the subject device was non-irritating.	Under the conditions of the study, the device is non-irritating.	Same
Sensitization (ISO 10993-10)	Under the conditions of the study, the subject device was non-sensitizing.	Under the conditions of the study, the device is non-sensitizing.	Same

Comparison in Detail(s):

Note 1:

Although the “Ear loops”, “Design features”, “Dimensions” and “Middle filter layer” of subject device is a little difference with predicate devices, but the subject device met the performance test and ISO 10993 standards required. So, the differences between the subject devices and predicate devices will not affect the safety and effectiveness.

Note 2:
Although the “Particulate Filtration Efficiency”, “Bacterial Filtration Efficiency” and “Performance Testing” of subject device is little difference from predicate devices, but they all met the requirements of the same standard, and subject device is based on the up to date version of standards, which is better. So, the differences between the subject device and predicate devices will not affect the safety and effectiveness.

Note 3:
Although the “Differential Pressure” of subject device is little difference from predicate devices, but they all met the requirements of the same standard, and subject device is based on the up to date version of standards (in the standard ASTM F2100, the test method for “Differential Pressure” refer to EN 14683 instead of MIL-M-36954C). So, the differences between the subject device and predicate devices will not affect the safety and effectiveness.

9. Summary of Non-Clinical Performance Testing
Non-clinical tests were conducted to verify that the proposed device met all design specifications as the predicate device. The subject device has been evaluated the safety and performance by lab bench testing as follows according to the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004.

Performance Testing summary:

Item	Proposed device	Acceptance Criteria for Level 1	Test Results
Fluid Resistance Performance (mmHg) ASTM F1862	Passed at 80mm Hg	29 out of 32 pass at 80 mmHg	Passed at 80mm Hg
Particulate Filtration Efficiency Performance (%) ASTM F2299	Passed at 99.3%	≥ 95%	Passed at 99.3%
Bacterial Filtration Efficiency Performance (%) ASTM F2101	Passed at 98.1%	≥ 95%	Passed at 98.1%
Differential Pressure (Delta-P) (mm H2O/cm^2) MIL-M-36954C	Passed at 4.8 mmH_2O/cm^2	<5.0 mm H_2O/cm^2	Passed at 4.8 mmH_2O/cm^2
Flammability class Class 1 16 CFR 1610	Class 1	Class 1	Class 1

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 B- prolonged (＞24 h to 30 d). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

Test Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	PASS

Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	PASS
Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	PASS

10. Summary of Clinical Performance Test
No clinical study is included in this submission.

11. Comparison to predicate device and conclusion
The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202316, the Medical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K153409.