March 4, 2022

Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd
% Eva Li
Consultant
Shanghai Sungo Management Consulting Company Limited
Room 1309, Dongfang Building, 1500# Century Ave
Shanghai, Shanghai 200122
China

Re: K213358
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 23, 2022
Received: February 23, 2022

Dear Eva Li:

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,

Clarence W. Murray, III, PhD
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)*
K213358

Device Name
Surgical Mask

Indications for Use *(Describe)*
The Surgical Mask intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These devices 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 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

A. 510(k) Number: K213358

B. Sponsor

Shenzhen SafeSecure Medical Infection Control Tech Co.,Ltd.
Address: 6A01, Block 1, Ahoke Plaza, Daling Community, Minzhi Street, Longhua District, 518109 Shenzhen City, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Contact Person: Patty Chen
Position: Marketing Manager
Tel: +86-755-27040468
Email: patty.chen@anbaopack.com

C. Date Prepared: Jan 23th, 2022

D. Submission Correspondent

Submission Correspondent
Primary contact: Ms. Eva Li
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1309, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-58817802
Email: eatereva@hotmail.com
Secondary contact: Mr. Raymond Luo
Room 1309, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: fda.sungo@gmail.com

E. Subject Device

Trade Name: Surgical Mask
Model(s):

Model#	Description
EH-1	Folded form with ear loops,3 layers, white color
EH-2	Folded form with head straps, 3 layers, green color

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 878.4040
Review Panel: Surgical Apparel

F. Predicate device:

K110455
Kimberly-Clark KC100 Mask
Kimberly-Clark

G. Indications for use:

The Surgical Mask intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These devices 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 sterile.

H. Device Description:

The model EH-1 is made of mask body, nose clip, ear loops and nose pad, whit color.
The model EH-2 is made of mask body, nose clip, straps and nose pad, green color.

The mask body is manufactured with three layers, the inner and outer layers are made of non-woven Spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter.

The straps and ear loops are held in place over the users' mouth and nose by two elastic straps welded to the mask body. It is made of nylon & spandex.

The nose clip in the layers of mask body is to allow the user to fit the mask body around their nose. It is made of polypropylene plastic wrapped metallic wire.

The nose pad which is made by 100% polyurethane is placed between the nose bridge and the mask body to let the user feel comfortable.

The buckle is use to clamp the ear loops and adjust the length and tightness of the mask. It is made of Polypropylene.
The colorant of white (EH-1)is Titanium dioxide, CAS Number is 13463-67-7; and the colorant of green(EH-2) is Pigment Green 7, CAS Number is 1328-53-6.
The EH-1 will be provided in white and the EH-2 will be provided in green. The Surgical Masks are sold sterilized with ethylene oxide gas and are intended to be single use, disposable devices.

I. Technological Characteristic Comparison

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Comparison
Manufacturer	Shenzhen SafeSecure Medical Infection Control Tech Co.,Ltd.	Kimberly-Clark	
510(K) number	K213358	K110455	
Model Name	EH-1, EH-2	Kimberly-Clark KC100 Mask	---
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same

Indications for use		The Surgical 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(s), provided non-sterile.	The Kimberly-Clark KC100 Procedure Mask(s) is 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. The Kimberly-Clark KC100 Procedure Mask(s) is a single use, disposable devices, provided non-sterile.	Same
Description		EH-1: Folded form with ear loops,3 layers, white color EH-2: Folded form with head straps, 3 layers, green color	Ear Loops, Tie-On, Flat Pleated, 3 layers	Different.
Material	Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clip	polypropylene plastic wrapped metallic wire	N/A	Different.
	Nose pad	100% polyurethane	N/A	Different.
	Ear loops	Nylon& Spandex	Polyester/lycra knitted	Different.
	Head straps	Nylon& Spandex	N/A	Different.
	Buckle	polypropylene	N/A	Different.
Color		Green/white	Variety (include blue)	Similar
Dimension（length）		1/2 length:108±5mm(EH-1) 1/2 length:106±5mm(EH-2)	165±19mm	Different.
Dimension（width）		155±5mm(EH-1) 165±5mm(EH-2)	102±19mm	Different.
OTC use		Yes	Yes	Same

Sterility	Sterile	Non-Sterile	Different.

Use		Single use, Disposable	Single use, Disposable	Same
ASTM F2100 Level		Level 3	Level 1	Similar.
Biocompatibility	Cytotoxicity ISO 10993-5	Non-cytotoxic under the conditions of the study	Non-cytotoxic under the conditions of the study	Same
	Skin Sensitivity ISO 10993-10	Non-sensitizer under the conditions of the study	Non-sensitizer under the conditions of the study	Same
	Skin Irritation ISO 10993-10	Non-irritating under the conditions of the study	Non-irritating under the conditions of the study	Same

The proposed device has different design to the predicate device, and because the different design so the proposed device has nose pad and buckle which the predicate device does not include. The dimensions differ, and the material of nose clip and ear loops/head straps and the color is different to the predicate device, the sterility of the proposed device is different to the predicate device. The subject device conducted testing to demonstrate compliance with ASTM F2100 with the different models meeting the Level 3 criteria, while the predicate device met the ASTM F2100 Level 1 criteria.

Summary of Non-Clinical Performance Testing.

Non-clinical tests were conducted to verify that the subject device met all design specifications. The test results demonstrated that the subject device complies with the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004:

Table 2a-Performance Testing Plan

Test Method	Purpose
ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks	This specification defines the minimum performance requirements for materials used in the construction of medical face masks.
ASTM F1862, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at A Known Velocity)	Determine the ability of a mask to resist penetration of simulated blood
ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus	Determine the ability of a mask to resist penetration of microbiological organisms
ASTM F2299, Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres	Determine the ability of a mask to resist penetration by microscopic particulates
Differential Pressure (Delta P) (EN 14683)	Determine the resistance of a mask to air flow
16 CFR 1610, Standard for the Flammability of clothing textiles	Determine the ability of a mask to resist ignition from an externally supplied source

- Table 2b-Performance Testing Result

Lot No.	Test	Acceptance Criteria		Test Result
Model EH-1 Lot 01EH01F20210-1	Synthetic Blood Penetration Resistance Performance ASTM F1862	≥ 29 samples out of 32 pass (AQL 4%)	Level 3 pass at 160mmHg	pass at 160mmHg
Model EH-1 Lot 01EH01F20210-4	Differential Pressure (Delta P) (EN 14683)	29 out of 32 pass 29 out of 32 pass	Level 3 pass at ≥98%	≥98%
	Bacterial Filtration Efficiency (ASTM F2101)	29 out of 32 pass	Level 3 pass ≤ 6.0 mmH20/cm2	≤ 6.0 mmH20/cm2
	Particulate Filtration Efficiency ASTM F2299	29 out of 32 pass	Level 3 pass at ≥98%	≥98%
Model EH-1 Lot 01EH01F20210-6	Flammability 16 CFR 1610	Class I		Class I
Model EH-2 Lot 01EH02F20210-2	Synthetic Blood Penetration Resistance Performance ASTM F1862	≥ 29 samples out of 32 pass (AQL 4%)	Level 3 pass at 160mmHg	pass at 160mmHg
Model EH-2 Lot 01EH02F20210-4	Differential Pressure (Delta P) (EN 14683)	29 out of 32 pass 29 out of 32 pass	Level 3 pass at ≥98%	≥98%
	Bacterial Filtration Efficiency (ASTM F2101)	29 out of 32 pass	Level 3 pass ≤ 6.0 mmH20/cm2	≤ 6.0 mmH20/cm2
	Particulate Filtration Efficiency ASTM F2299	29 out of 32 pass	Level 3 pass at ≥98%	≥98 %
Model EH-2 Lot 01EH02F20210-7	Flammability 16 CFR 1610	Class I		Class I

Item	Purpose	Acceptance Criteria	Results
Cytotoxicity ISO 10993-5	Demonstrate cytotoxic biocompatibility	Under the conditions of the study, the device is non-cytotoxic.	No cytotoxic
Skin Irritation ISO 10993-10	Demonstrate non-irritability	Under the conditions of the study, the device is non-irritating.	non-irritability
Skin Sensitization ISO 10993-10	Demonstrate non-sensitization	Under the conditions of the study, the device is non-sensitizing	non-sensitization

B. Summary of Clinical Performance Tests

No clinical study is included in this submission.

L. Conclusion

Based on the nonclinical tests performed, the subject Surgical Masks are as safe, as effective, and perform as well as or better than the legally marketed predicate device, Kimberly-Clark KC100 Mask cleared under K110455.