November 23, 2022

Guangdong Golden Leaves Technology Development Co., LTD
% Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road
Huangpu District
Guangzhou, Guangdong 523000
China

Re: K223068
Trade/Device Name: Medical Protective Mask (model: 8862, 8862A, 8862B, 8862C, 8862D, 8862E)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 28, 2022
Received: September 30, 2022

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,

Anne D. Talley -S for

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K223068

Device Name
Medical Protective Mask (model: 8862, 8862A, 8862B, 8862C, 8862D, 8862E)

Indications for Use *(Describe)*
The Medical Protective Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These 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, provide 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 of K223068

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

1. Submitter's Information

Sponsor Name: Guangdong Golden Leaves Technology Development Co., Ltd.
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Application Correspondent:
Contact Person: Ms. Cassie Lee
Company: 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@share-info.com

2. Date of the summary prepared: Jun 26, 2022

3. Subject Device Information

Type of 510(k): Traditional
Classification Name: Mask, Surgical
Trade Name: Medical Protective Mask
Model Name: 8862, 8862A, 8862B, 8862C, 8862D, 8862E
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Regulatory Class: II

4. Predicate Device Information

Predicate Device:
Sponsor: Jiangxi Hongda Medical Equipment Group Co., Ltd.
Trade Name: Single-Use Medical Face Mask
Classification Name: Mask, Surgical

510(K) Number: K210622
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Regulation Class: II

5. Device Description

The subject device is a four-layer, single-use, flat-folded shape mask. The inner and outer layers of the mask are made of polypropylene spunbonded nonwoven, and the filter (2 layers) is made of polypropylene melt-blown nonwoven. The proposed devices are available in two types, ear loop and headband. The ear loops and headband are made of polyester. The nose clip is made of polypropylene and wire, user can adjust the nose clip according to the shape of the bridge of the nose, and fix the mask on the bridge of the nose to prevent the mask from falling off.

Both the ear loop and headband masks are available in level 1, level 2 and level 3:

Type / Level	Ear Loop	Headband
Level 1	8862B	8862E
Level 2	8862A	8862D
Level 3	8862	8862C

All models are made of the same material and have identical performance, meeting the performance requirements of three levels at the same time.

The device is provided non-sterile.

6. Intended Use / Indications for Use

The Medical Protective Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These 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, provide non-sterile.

7. 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 1	Verdict
Company	Guangdong Golden Leaves Technology Development Co.,	Jiangxi Hongda Medical Equipment Group Co., Ltd.	--

Elements of Comparison	Subject Device	Predicate Device 1	Verdict
	Ltd.		
510 (k)	K223068	K210622	--
Trade Name	Medical Protective Mask	Single-Use Medical Face Mask	--
Classification Name	Mask, Surgical	Mask, Surgical	Same
Classification	Class II	Class II	Same
Product Code	FXX	FXX	Same
Intended use	The Medical Protective Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These 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, provide non-sterile.	The single-use medical face 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, provided sterile and non-sterile.	Same
Mask style	Flat-folded	Flat-pleated	Same
Design feature	Ear loop, headband	Ear loop or tie-on	Similar Note 1
Color	Green	White	Different Note 1
Dimension	Mask body: 205x80mm Nose clip: 100mm Ear loop: 150mm Headband: 350mm	Mask body: 175×95mm Nose Clip: 80~105mm Ear loop: 140~150mm Ties: 330~400mm	Similar Note 1
Use	Single Use, Disposable	Single Use, Disposable	Same
Materials			
Outer facing layer	Polypropylene Spunbonded Nonwoven	Polypropylene Spunbonded Nonwoven	Same

Elements of Comparison	Subject Device	Predicate Device 1	Verdict
Filter layer	Polypropylene Melt-blown Nonwoven	Polypropylene Melt-blown Nonwoven	Same
Inner facing layer	Polypropylene Spunbonded Nonwoven	Polypropylene Spunbonded Nonwoven	Same
Nose Clip	Polypropylene and wire	Polypropylene and iron	Similar Note 1
Ear loops/headband	Polyester	Polyester and spandex	Similar Note 1
Performance Characteristics			
ASTM F2100 Level	Level 1, Level 2, Level 3	Level 1, Level 2, Level 3	Same
Fluid resistance	Level 1: Pass at 80 mmHg Level 2: Pass at 120 mmHg Level 3: Pass at 160 mmHg	Level 1: Pass at 80 mmHg Level 2: Pass at 120 mmHg Level 3: Pass at 160 mmHg	Same
Particulate filtration efficiency	Level 1: ≥95% Level 2: ≥98% Level 3: ≥98%	Level 1: Ear loop (Non-sterile): ≥95% Level 2: Ear loop (Non-sterile): ≥98% Level 3: Ear loop (Non-sterile): ≥98%	Same
Bacterial filtration efficiency	Level 1: ≥95% Level 2: ≥98% Level 3: ≥98%	Level 1: Ear loop (Non-sterile): ≥95% Level 2: Ear loop (Non-sterile): ≥98% Level 3: Ear loop (Non-sterile): ≥98%	Same
Differential pressure	Level 1: ＜5 mmH_2O/cm^2 Level 2: ＜6 mmH_2O/cm^2 Level 3: ＜6 mmH_2O/cm^2	Level 1: Ear loop (Non-sterile): ＜5 mmH_2O/cm^2 Level 2: Ear loop (Non-sterile): ＜6 mmH_2O/cm^2 Level 3: Ear loop (Non-sterile): ＜6	Same

Elements of Comparison	Subject Device	Predicate Device 1	Verdict
		mmH_2O/cm^2	
Fluid resistance	Level 1: Pass at 80 mmHg Level 2: Pass at 120 mmHg Level 3: Pass at 160 mmHg	Level 1: Pass at 80 mmHg Level 2: Pass at 120 mmHg Level 3: Pass at 160 mmHg	Same
Flammability	Class I	Class I	Same
Sterility	Non-sterile	Non sterile/Sterile	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Shelf Life	2 years	3 years	Different Note 2
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the proposed device was non-cytotoxic.	Under the conditions of the study, the proposed device was non-cytotoxic.	Same
Sensitization	Under the conditions of the study, the proposed device was non-sensitizing.	Under the conditions of the study, the proposed device was non-sensitizing.	Same
Irritation	Under the conditions of the study, the proposed device was non-irritating.	Under the conditions of the study, the proposed device was non-irritating.	Same

Comparison in Detail(s):

Note 1:

Although there are a few differences in “Design feature”, “Color”, “Dimension”, materials of “Ear loops/headband” and “Nose Clip” of the subject device and predicate device, they all met the ASTM F2100 and ISO 10993 standards required. So, the differences between the subject device and the predicate devices will not affect the safety and effectiveness.

Note 2:

Although the “Shelf life” of the subject device is a little different from the predicate device, the performance testing of the subject device after accelerated aging has been conducted and the test results show that the subject device after the aging meets the all-performance requirements of ASTM F2100.
So, the differences between the subject device and predicate device will not affect the safety and effectiveness.

8. Summary of Non-Clinical Performance Testing

Performance Testing summary

Test item	Test method	Pass criteria			Test results /Verdict
		For Level 1	For Level 2	For Level 3	
Bacterial filtration efficiency	ASTM F2101-19 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	≥ 95%	≥ 98%	≥ 98%	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	<6.0 mm H_2O/cm^2	<6.0 mm H_2O/cm^2	Pass
Sub-micron particulate filtration efficiency at 0.1 µm of Polystyrene Latex Spheres	ASTM F2299 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%	≥ 98%	≥ 98%	Pass
Resistance to penetration by synthetic blood, minimum pressure in mm Hg 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	Pass at 80 mm Hg	Pass at 120 mm Hg	Pass at 160 mm Hg	Pass

Flame spread	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Class 1	Class 1	Class 1	Pass

Biocompatibility Testing

According to ISO 10993-1: 2018, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of 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:

Title of the test	**Purpose of the test**	**Reference for 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 23: 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. Final Conclusion

The subject device is as safe, as effective, and performs as well as the legally marketed predicate device K210622.