June 8, 2021

Shenzhen Peninsula Medical Co. 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: K202126
Trade/Device Name: Disposable Surgical Mask (Model: Flat-type)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 28, 2021
Received: May 11, 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,

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)*
K202126

Device Name
Disposable Surgical Mask (Model: Flat-type)

Indications for Use *(Describe)*
Disposable Surgical Mask is Device that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluids and particulate material.

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 for K202126

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

510(k) Owner's Name: Shenzhen Peninsula Medical Co. Ltd.

Establishment Registration Number: 3016746323

Address: 3F Block A, Building F2, Changfeng Industrial Park, Liuxian 3rd Road, 68# Xin'an Street, Bao'an District, Shenzhen, 518100, P.R.China.

Contact Person: Zhang Sudi

Email: 283068426@qq.com

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

2. Date of the summary prepared: June 8, 2021

3. Subject Device Information

Type of 510(k): Traditional

Classification Name: Mask, Surgical

Common name: Surgical Mask

Trade Name: Disposable Surgical Mask

Model Name: Flat-type

Review Panel: Surgical Apparel

Product Code: FXX

Regulation Number: 21 CFR 878.4040

Regulatory Class: II

4. Predicate Device Information

Sponsor: Acme Filter Mask Inc.

Trade Name: Surgical Face Mask with Ear-Loop

Classification Name: Mask, Surgical

Common name: Surgical Mask

510(K) Number: K123115

Review Panel: Surgical Apparel

Product Code: FXX

Regulation Number: 21 CFR 878.4040

Regulatory Class: II

5. Device Description

The Disposable Surgical Mask is Flat Pleated style mask, utilizing ear loops way for wearing, and they all has nose piece design for fitting the Disposable Surgical Mask around the nose.

The Disposable Surgical Mask are manufactured with three layers, the inner and outer layers are made of spun bond polypropylene, only the outer layers' color is blue (colorant: 29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32 copper, CAS number: 147-14-8) and the middle layer is made of melt blown polypropylene filter.

The model of proposed device, ear loops, is held in place over the users' mouth and nose by two elastic ear loops welded to the Disposable Surgical Mask. The elastic ear loops are not made with natural rubber latex.

The nose piece contained in the Disposable Surgical Mask is in the middle layer of Disposable Surgical Mask to allow the user to fit the Medical surgical mask around their noses, which is made of malleable aluminum wire.

The Medical surgical mask is sold non-sterile and is intended to be single use, disposable device.

The dimensions of each Disposable Surgical Mask is length 17.5cm±1cm and width 9.5cm±1cm. The dimensions of nosepiece is length 85±1 mm and width 3.0±0.5 mm, and the ear loop is length 180±10 mm and width 3.0±0.5 mm.

The Disposable Surgical bag packaging material is Polypropylene and box packaging are carton.

6. Intended Use / Indications for Use

Disposable Surgical Mask is Device that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluids and particulate material.

7. Comparison to predicate device and conclusion

Elements of Comparison	Subject Device	Predicate Device	Verdict
Company	Shenzhen Peninsula Medical Co. Ltd.	Acme Filter Mask Inc.	--
510 (k)	K202126	K123115	--
Trade Name	Disposable Surgical Mask	Surgical Face Mask with Ear-Loop	--
Classification Name	Mask, Surgical	Mask, Surgical	Same
Classification	Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same
Intended use	Disposable Surgical Mask is Device that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluids and particulate material.	Surgical Face Mask is Device that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluids and particulate material.	Same
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 piece	Malleable aluminum wire	Malleable aluminum wire	Same
Ear loops	Polyester	Polyester	Same
Design features	Color: Blue Ear loops	Color: Blue Ear loops	Same
Mask Style	Flat Pleated	Flat Pleated	Same
Specification	Length: 17.5cm±1cm	Length: 17.5cm±1cm	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
and Dimension	Width: 9.5cm±1cm	Width: 9.5cm±1cm	
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	Fluid Resistance	Different Note 1
Particulate Filtration Efficiency	≥ 95%	Average 94.79% for Solid Aerosol Filtration Efficiency Efficiency More than 99.5% for Viral Filtration Efficiency	Different Note 1
Bacterial Filtration Efficiency	≥ 95%	pass at 99.9%	Different Note 1
Differential Pressure	< 5.0 mm H_2O/cm^2	pass at 3.3 mm H_2O/cm^2	Different Note 1
Flammability	Class 1	Class 1	Same
Shelf life	2 years	Not public	Different Note 2
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	Under the conditions of the study, the subject device non-polar and	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
	polar extracts were determined to be non-sensitizing.	polar extracts were determined to be non-sensitizing.	

Comparison in Detail(s):

Note 1:

Although the “Fluid Resistance Performance”, “Particulate Filtration Efficiency”, “Bacterial Filtration Efficiency” and “Differential Pressure” of subject device is little difference with predicate device, it meets the requirement of essential performance standard ASTM F2100-19 level 1. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device when used as labeled.

Note 2:

Although the “Shelf life” of the subject device is different from the predicate device, the aging test showed that the requirements of essential performance standard ASTM F2100-19 level 1. So, the differences between the predicate device and the subject device will not affect the safety and effectiveness of the subject device.

8. Summary of Non-Clinical Performance Testing

- Performance Testing summary

Test item (Performance Level 1)	Test method	Pass criteria	Test results /Verdict
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	≥ 95%	32/32 Passed at ≥95% / Pass

	Staphylococcus aureus according to ASTM F2100:2019		
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 <5 mmH_2O/cm^2 / Pass
Sub-micron particulate filtration efficiency at 0.1 µm of Polystyrene Latex Spheres	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 ≥95% / 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	Fluid resistant claimed at 80 mm Hg	32/32 Passed at 80 mmHg/ Pass

	Known Velocity) according to ASTM F2100:2019		
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

According to ISO 10993-1:2009, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is A-Limited (≤24h). 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	ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation	Under the conditions of the study, the subject device non-polar and polar	Pass

	extracts of the target device are irritating.	and skin sensitization	extracts were determined to be non-irritating.	

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10. Final Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202126, the Disposable Medical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K123115.