March 10, 2021

Allmed Medical Products Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
13th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K202411
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 8, 2021
Received: February 11, 2021

Dear Ivy Wang:

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)*
K202411

Device Name
Surgical Mask
Ear loops

Indications for Use *(Describe)*
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 of the wearer to blood and body fluids. This is a single use, disposable device(s), 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

K202411

Date of Summary prepared: 2021-03-10

A. Applicant:

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B. Device:

Trade Name: SURGICAL MASK
Common Name: SURGICAL FACE MASK
Model: Ear loops (LP121014)

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

C. Predicate device:

K110455
Kimberly-Clark KC100 Mask
Kimberly-Clark

D. Indications for use of the device:

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 of the wearer to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

E. Device Description:

The Surgical Masks are blue color, single use, three-layer, flat –folded masks with nose clip and ear loops.

The Surgical Masks are manufactured with three layers, the inner and outer layers are made of polypropylene spunbonded nonwoven, and the middle layer is made of polypropylene melt-blown nonwoven filter.

The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex.

The nose clip in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of iron strip wrapped by plastic.

The surgical masks are sold non-sterile and are intended to be single use, disposable devices.

F. Comparison with predicate device

Table 1 General Comparison

Device		**Proposed Device**	**Predicate Device**	**Result**
Manufacturer		Allmed Medical Products Co., Ltd.	Kimberly-Clark	
510K number		K202411	K110455	
Model Name		SURGICAL MASK	Kimberly-Clark KC100 Mask	Similar
Classification		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intend 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 of the wearer to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	The Kimberly-Clark KC100 Face 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 of the wearer to blood and body fluids. The Kimberly-Clark KC100 face mask(s) is a single use, disposable device(s), provided non-sterile.	Same
Design Features		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	Similar
Material	**Outer facing layer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle	Melt blown polypropylene	Melt blown polypropylene filter	Same

	layer	filter		
	Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clip	iron strip coated with polypropylene	NA	Different
	Ear loops	Spandex elastic	Polyester/ lycra knitted	Different
Color		Blue	Variety (include blue)	Similar
Dimension (Length)		175±8mm	165±19mm	Similar
Dimension (Width)		95±9mm	102 ± 19mm	Similar
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level		Level 1	Level 1	Same
Biocompatibility		ISO10993	ISO10993	Same

Table 2 - Comparison of Performance Testing

Item	**Proposed device**	**Predicate device**	**Acceptance Criteria (level 1)**	**Result**
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 80 mmHg, 3 lots	pass at 80 mmHg	29 out of 32 pass at 80 mmHg	Similar
Particulate Filtration Efficiency ASTM F2299	Pass at 99.85%, 99.90%, 99.75%	Pass at 98.4%	≥ 95%	Similar
Bacterial Filtration Efficiency ASTM F2101	Pass at 99.9%, 99.9%, 99.9%	Pass at 99.7%	≥ 95%	Similar
Differential Pressure (Delta P) EN 14683 Annex C	Pass at 4.6mmH_2O/cm^2 4.5mmH_2O/cm^2 4.6mmH_2O/cm^2	Pass at 3.0mmH_2O/cm^2	< 5.0mmH_2O/cm^2	Similar
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	Same

Table 3 Biocompatibility Comparison

Item	**Proposed device**	**Predicate device**	**Result**
Cytotoxicity	Under the conditions of the study, the device is	Under the conditions of the study, the device is	Same

	non-cytotoxic.	non-cytotoxic.	
Irritation	Under the conditions of the study, the device is non-irritating.	Under the conditions of the study, the device is non-irritating.	Same
Sensitization	Under the conditions of the study, the device is non-sensitizing	Under the conditions of the study, the device is non-sensitizing	Same

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as same or similar to the predicate device. The test results demonstrated that the proposed 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:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ASTM F2100, Standard Specification for Performance of Materials Used In 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);
- EN 14683, Medical Face Masks—Requirements and Test Methods;
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
- ASTM F2299, Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;
- 16 CFR 1610, Standard for the Flammability of clothing textiles;

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202411, the surgical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K110455.