June 3, 2021

Allmed Medical Products Co., LTD
Vince Tian
General Manager of Quality
No. 180 Gongyuan Road Majiadian Town
Zhijiang, Hubei 443200
China

Re: K202128
Trade/Device Name: Allmed Surgical Face Masks (Ear loops)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 28, 2021
Received: May 3, 2021

Dear Vince Tian:

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
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)*
K202128

Device Name
Allmed Surgical Face Masks (Ear Loops)

Indications for Use *(Describe)*
Allmed Surgical Face Masks(Ear Loops) are intended to be worn to protect both patients and healthcare workers from transfer of microorganisms, body fluids, and particulate material. The surgical face mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The surgical face mask is a single use, disposable device 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.

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510(k) SUMMARY

510(k) Number: K202128

510(k) Premarket Notification for Allmed Surgical Face Masks (Ear Loops)

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

1. Submitter: ALLMED MEDICAL PRODUCTS CO., LTD
No.180, GongYuan Road, Majiadian Town, Zhijiang City,
Hubei Province, China 443200
Phone: +86-717-4211111
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2. Regulatory Affairs Contact: Ruby Qiu
Regulatory Affairs Manager 19F, Block A, Taurus Plaza
No.8 Taoyuan Rd, Nanshan District Shenzhen City
Guangdong, China 518055
Telephone Number: 631-656-3800 ext. 133
Fax Number: 631-656-3810

3. Date Prepared: April 20, 2021

4. Device Identification: Name: Allmed Surgical Face Masks (Ear Loops)
Trade Name: Allmed Surgical Face Masks (Ear Loops)
Common/Classification Name: Surgical Mask
Regulation Number: 21 CFR §878.4040
Device Class: Class II
Regulation Name: Surgical Apparel
Product Code: FXX

5. Predicate Device: 510(k) Number: K160269
Name: Surgical Face Masks (Ear loops and Tie-on)
Trade Name: Surgical Face Masks (Ear loops and Tie-on)
Common/Classification Name: Masks, Surgical
Regulation Number: 21 CFR §878.4040
Device Class: Class II
Regulation Name: Surgical Apparel
Product Code: FXX
Manufacturer: SAN-M PACKAGE CO., LTD.

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6. Device Description: Allmed surgical face masks (ear loops) are composed of 3-layers and is flat-pleated. The mask materials consist of an outer layer (polypropylene spunbond, blue), filter layer (polypropylene meltblown, white), and inner layer (polypropylene spunbond, white). The three layers of the mask body are collated and sonically welded around the edges. The surgical face mask contains ear loops attached by welding to secure the mask over the user's mouth and face and includes a malleable nosepiece to provide a firm fit over the nose. The surgical face mask is a single use, disposable device, provided non-sterile.

7. Indications for Use: Allmed Surgical Face Masks(Ear Loops)are intended to be worn to protect both patients and healthcare workers from transfer of microorganisms, body fluids, and particulate material. The surgical face mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The surgical face mask is a single use, disposable device provided non-sterile.

8. Technological Characteristics Comparison Table

Element of Comparison	**Subject Device**	**Predicate Device**	**Comparison**
510(k) Number	**K202128**	**K160269**	
Trade Name	**Allmed Surgical Face Masks (Ear Loops)**	**Surgical Face Masks (Ear loops and Tie-on)**	
Manufacturer	**ALLMED MEDICAL PRODUCTS CO., LTD**	**SAN-M PACKAGE CO., LTD.**	
General			
Indications for Use	Allmed Surgical Face Masks(Ear Loops) are intended to be worn to protect both patients and healthcare workers from transfer of microorganisms, body fluids, and particulate material. The surgical face mask is intended for use in infection control practices to reduce the potential exposure	The surgical mask is intended to be worn to protect both patients and healthcare workers from transfer of microorganisms, body fluids, and particulate material. The surgical mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The surgical mask is a	Same

	to blood and body fluids. The surgical face mask is a single use, disposable device provided non-sterile.	single use, disposable device provided non-sterile.	
Material Composition	Three-layer mask constructed of: Outer layer: Polypropylene Spunbond Filter layer: Polypropylene Meltblown Inner layer: Polypropylene Spunbond Ear loops: Spandex elastic, polyester Nose Piece: Malleable Iron wire with plastic cover/Polypropylene	Three-layer mask constructed of: Outer layer: spunbond polypropylene Filter layer: meltblown polypropylene Inner layer: spunbond polypropylene Ear loops: spandex Nose clip: malleable aluminum wire/PVC	Similar
Dimensions	17.5 x 9.5 cm	17.5 x 9.5 cm	Same
Mask Style	Flat-pleated	Flat-pleated	Same
Design Features	Ear Loop	Ear loops: Polyester, polyurethane Side tapes: Polyester spunbond (ear loops mask only) Tie tapes: Polypropylene spunbond or polyester spunbond Visor option: polyester	Different
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use; Disposable	Single Use; Disposable	Same
Color	Blue	White or Blue	Different
Performance Classification Standard	ASTM F2100 Level 3	ASTM F2100 Level 1, Level 2, and Level 3	Different
Biocompatibility			
Biocompatibility-Cytotoxicity ISO 10993-5: 2009	Under the conditions of the study, the device was non-cytotoxic	Under the conditions of the study, the device was non-cytotoxic	Same
Biocompatibility-Skin Irritation ISO 10993-10: 2010	Under the conditions of the study, the device was non-irritating.	Under the conditions of the study, the device was non-irritating.	Same

Biocompatibility-Skin Sensitization ISO 10993-10: 2010	Under the conditions of the study, the device was non-sensitizing.	Under the conditions of the study, the device was non-sensitizing.	Same
Performance Testing			
ASTM F2101-Bacterial Filtration Efficiency (BFE)	Passed at≥99.9% ASTM F2101	Passed at≥99.9% ASTM F2101	Same
ASTM F2299-Particulate Filtration Efficiency	>99%	99.7%	Same
Differential Pressure	Passed at <6.0 mmH2O/cm2 EN14683:2019 Annex C	Passed at 2.5 mmH2O/cm2 MILM-36954C	Similar
ASTM F1862-Fluid Resistance	Pass at 160mmHg	Pass at 160mmHg	Same
16 CFR 1610-Flammability	Class I	Class I	Same

The subject device is only available in one color (blue), at ASTM F2100 Level 3, only with ear loops, and with no visor option. The predicate is available in a similar configuration.

9. Biocompatibility Testing

The device was determined to be a surface-contacting device with limited duration (<24h). At the study conditions, the device was determined to be non-cytotoxic, non-irritating, and non-sensitizing. The device is biocompatible.

10. Performance Testing

Test Method Test Identification	Purpose	ASTM F2100 Level 3 - Acceptance Criterion	Test Result
ASTM F2101-Bacterial Filtration Efficiency	To determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream.	≥98%, AQL=4%	Passed

ASTM F2299 Particulate Filtration Efficiency	To evaluate the non-viable particle filtration efficiency (PFE) of the test article.	≥98%, AQL=4%	Passed
EN14683:2019 Annex C Differential Pressure	To determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate.	<6.0 mmH_2O/cm^2, AQL=4%	Passed
ASTM F1862 Fluid Resistance	To simulate surgical mask spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids.	Resistant at 160mmHg, 4% AQL	Passed
16 CFR 1610 Flammability	To evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread.	Class 1	Passed

The device was compared to ASTM F2100 Level 3 requirements. The device meets ASTM F2100 Level 3 performance and design criteria at the specified quality level.

11. Clinical Testing

Clinical testing was not performed.

12. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202128, Allmed Surgical Face Masks (Ear Loops) are as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K160269.