November 2, 2021

Guangdong Lide Medical Technology Co., Ltd.
% Ying Hou
Consultant
Microkn Business Consulting (Shanghai) Co., Ltd
Room 1215, Block A, No 3699, Gonghexin Road, Jingan District
Shanghai, 200435
China

Re: K210222
Trade/Device Name: Disposable Medical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 5, 2021
Received: September 22, 2021

Dear Ying Hou:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210222

Device Name
Disposable Medical Mask

Indications for Use *(Describe)*
The surgical face masks (Ear loops) 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 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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"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."

510K Summary

According to the requirements Per 21 CFR §807.92:

Company:	Guangdong Lide Medical Technology Co.,Ltd.
Address:	HFDB-05-2102 Ecological Technology City, West Side of Haizi Road, Chengdong Town, Haifeng County， Shanwei City516400, Guangdong Province, China
Contact Person:	Zhuang Shenglin Telephone: 18664514268 E-mail: 158953590@qq.com
Common Name	Disposable Medical Mask
Classification Name:	21 CFR 878.4040
Legal Manufacturer:	Guangdong Lide Medical Technology Co.,Ltd. HFDB-05-2102 Ecological Technology City, West Side of Haizi Road, Chengdong Town, Haifeng County， Shanwei City516400, Guangdong Province, China
Predicate Device	
Predicate Device:	Surgical Face Masks (Ear loops and Tie-on)
510(k) Number:	K160269
Consultant	
Company	Microkn Business Consulting (Shanghai) Co., Ltd.
Address	Room 1219, Block A, No 3699, Gonghexin Road, Jingan District, Shanghai, China
Contact Person	Yuling Chen
Telephone	+86 15021397762
Email	Yuling.chen@microkn.com

1. Indications for use

The surgical face masks (Ear loops) 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 non-sterile.

2. Description of the Device

The Surgical Face Mask are Non-sterile, single use, 3 layers, flat-pleated style with mask belt and nose clip. The outer layer and inner facing layer of face mask consist of spunbond polypropylene, and the middle layer consists of melt blown polypropylene filter. Each mask contains mask belt to secure the mask over the user's face and mouth with nose clip to firmly fit over the nose. This device is not made from any natural rubber latex.The structure of this device is illustrated by figure .1

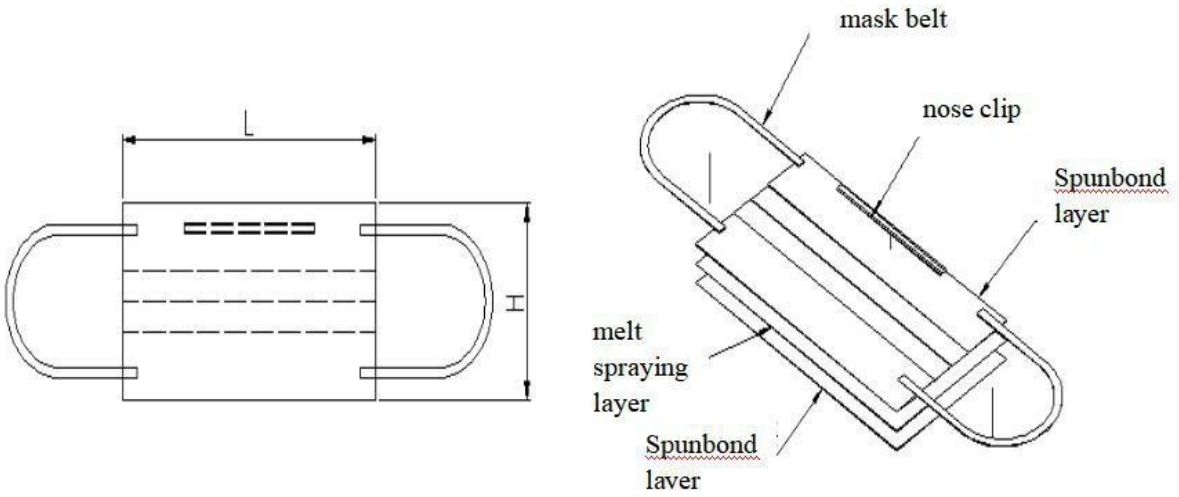

Figure.1 Structure

3. Sizes of the product

The sizes of the product shown in Table 1.

Table 1 The sizes of the product

Model	Size (mm)		layers
	Length(L)	Width(H)	
Earloop style 175×95	175±5%	95±5%	3

4. Components

The main components of proposed device are shown in Table 2.

Table 2 Main Components of Proposed Device

Components	Function Description	Applied Model(s)
Outer Spunbond layer	Block water and prevent droplets from entering the mask	All Models
Components	**Function Description**	**Applied Model(s)**
Meltblown layer	Filter	All Models
Inner Spunbond layer	moisture absorption	All Models
Nose clip	fixed geometry	All Models
Mask belt	secure the mask over the user's face and mouth	All Models

5. Technological Characteristics Comparison to Predicate Device

Feature	Proposed Device	Predicate device
510(K)#	K210222	K160269 (EL 10000)
Level	Level 1	Level 1
Manufacturer	Guangdong Lide Medical Technology Co.,Ltd.	San-M Package Co., Ltd.
Common Name	Surgical Mask	Surgical Mask
Classification	Class II	Class II
Product Code	FXX	FXX

Feature	Proposed Device	Predicate device	
Intended Use	The surgical 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 non-sterile.	The surgical 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 devices are intended for use in infection control practices to reduce the patient exposure to blood and body fluids. This is a single-use, disposable device, provided non-sterile.	
Materials			
Outer Material	Polypropylene	Polypropylene	
Inner Material	Polypropylene spunbond Polypropylene meltblown	Polypropylene spunbond Polypropylene meltblown	
Ear Loops/mask belt	Nylon and Spandex	Polyester, polyurethane, polyester spunbond	
Colorant	White (Inner) and blue (Outer side)	White (Inner) and blue (Outer side)	
Specifications	Length:175mm±5mm Width:95mm±5mm	Length:90±3mm	Length:90±3mm

Feature	Proposed Device	Predicate device	
		Width:175±5mm	Width:180±5mm
Mask Style	Flat-pleated	Flat-pleated	
Sterility	Non-sterile	No- sterilization	
Performance Testing (ASTM F2100-19)	Level 1	Level 1	
BFE	Pass at 99.99%	Pass at 99.6%	
Particulate Filtratin Efficiency	Pass at 98.33	Pass at >98%	
Differential Pressure	Pass at 4.1 mmH2O/cm2	Pass at 2.0 mmH2O/cm2	
Resistance to penetration by blood	Pass at 80mmHg	Pass at 80mmHg	
Flammability	Class 1	Class 1	
Biocompatibility Contact Category	Skin	Skin	
Biocompatibility Contact Duration	Prolong	Prolong	
Shelf life	1 year	Unavailable from public information (Difference 1)	

Difference 1: Real-time aging testing was carried out to decide the shelf life of the proposed surgical mask. Testing results demonstrated that the life of the surgical mask is 1 years. The difference will not generate negative affect for the safety and performance of the device used following the IFU.

6. Summary of Non-Clinical Test Data

The following nonclinical testing was performed to demonstrate the subject device conform to the standard or test methodology found in the summary table below. The results demonstrate the subject device met the acceptance criteria or specifications described below.

6.1 Animal Study

None

6.2 Performance Study

Test Methodology	Purpose	Acceptance Criteria	Results
Level ASTM F2100-19	To define the performances of the medical face mask	Level 1	Level 1
Resistance to penetration by systhetic blood ASTM F1862	To evaluate the resistance of medical face masks to penetration by the impact of a small volume of high-velocity stream of synthetic blood. Medical face mask pass/fail determinations are based on visual detection of synthetic blood penetration.	Minimum 80mmHg	Pass at 80mmHg
Particulate Filtration Efficiency ASTM F2299	To measure the initial particle filtratioon efficiency of materials used in medical face mask using monodispersed polystyrene latex sphere aerosols.	≥95%	Pass at 98.33%
BFE ASTM F2101	To measure the bacterial filtration efficitency (BFE) of medical face mask materials, employing a ratio of the upstream bacterial challenge to downstream residual concentration to	≥95%	Pass at 99.99%

Test Methodology	Purpose	Acceptance Criteria	Results
	determine filtration efficiency of medical face mask materials		
Differential Pressure EN 14683:2019+AC:2019 AnnexC	To determine the breathability of medical face mask by measuring the differential air pressure with the airflow direction from the inside of the mask to the outside of the mask.	＜5.0mmHg	Pass at 4.1 mmH_2O/cm_2
Flammability 16 CFR 1610	To measure the response of materials, products, or assemblies to heat and flame.	Class 1	Class 1
Cytotoxicity	The purpose of this study was to determine the potential of a test article to cause cytotoxicity	Non-cytotoxic	Non-cytotoxic
Irritation test	The purpose of this study was to evaluate the test article for the potential to cause skin irritation in the rabbit.	Non-irritation	Non-irritation
Sensitization test	The purpose of this study was to evaluate the potential of the test articles to cause delayed dermal contact sensitization in the guinea pig maximization test.	Non-sensitization	Non-sensitization

7. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.