June 7, 2021

Qingdao Likangyuan Medical Device Co., Ltd.
% Helen Nan
General Manager
Wenzhou Cytech Information Service Co., Ltd.
Room302. Building3, Hangqian Mansion, Hangqian Street,
Lucheng District
Wenzhou, Zhejiang 325000
China

Re: K202580
Trade/Device Name: Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 16, 2021
Received: May 6, 2021

Dear Helen Nan:

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 and Part 809); 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,

Bifeng Qian -S

For Clarence W. Murray III, Ph.D.
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)*
k202580

Device Name
Disposable Surgical Mask

Indications for Use *(Describe)*
The Disposable Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. This face mask is 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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510(k) Summary for K202580

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

1.0 Submitter Information

Company:	Qingdao Likangyuan Medical Device Co., Ltd.
Address:	No.257 Leigongshan Road,Huangdao District,Qingdao,Shandong, 266423, China
Phone:	086-532-89052813
Contact Name:	Ying Xu
Title:	Quality Control Manager
E-mail:	likangyuan@hotmail.com

Date of Preparation: June 4, 2021

2.0 Submission Correspondent:

Company:	Wenzhou Cytech Information Service Co., Ltd.
Mailing Address:	Room302, Building3, Hangqian Mansion, Hangqian Street, Lucheng District, Wenzhou, Zhejiang, 325000, CHINA
Contact Name:	Helen Nan
Title:	General Manager
Email:	ctc_registration@hotmail.com

3.0 Subject Device Information

Trade/Device Name:	Disposable Surgical Mask
Model:	Ear-loop Type
Common Name:	Surgical Face Mask
Regulation Description:	Surgical apparel
Device:	Mask, Surgical
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Device Class:	Class II

4.0 Predicate Device Information

Submitter:	DemeTECH Corporation
510k Number:	K201479
Trade/Device Name:	DemeMASK
Common Name:	Surgical Face Mask
Regulation Description:	Surgical apparel
Device:	Mask, Surgical
Review Panel:	General Hospital

Product Code: FXX
Regulation Number: 21 CFR 878.4040
Device Class: Class II

5.0 Device Description

The Disposable Surgical Masks (non-sterile) are 3-ply, ear loop, flat-pleated surgical masks. The devices are manufactured with three layers, the inner and outer layers are made of spunbond polypropylene, and the middle layer is made of melt blown polypropylene filter. There surgical masks to be secured on users via ear loops made of spandex and nylon. Each mask contains a nose piece to firmly fit over the nose. The devices are sold non-sterile and are intended to be single use and disposable. This device is not made from any natural rubber latex.

6.0 Indications for Use

The Disposable Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. This face mask is 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.

7.0 Comparison of Technological Characteristics

Table 1 - General Comparison

Device	Predicate Device	Proposed Device	Comparison
Manufacturer	DemeTECH Corporation	Qingdao Likangyuan Medical Device Co., Ltd.	N/A
510K Number	K201479	K202580	N/A
Trade/Device Name	DemeMASK	Disposable Surgical Mask (non-sterile)	N/A
Product Code	FXX	FXX	Same
Classification	Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)	Same
Intended Use	The Disposable Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. This face mask is intended for use in infection control practices	The Disposable Surgical Masks (non-sterile) 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	Same

	to reduce the potential exposure to blood and body fluids. This is a single use, disposable device provided non-sterile.	infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device provided non-sterile.	
Material			
Outer Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Middle Layer	Melt Blown Polypropylene Filter	Melt Blown Polypropylene Filter	Same
Inner Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Nose Piece	Single Galvanize Wire, Coated By PE	Single Galvanize Wire, Coated By PE	Same
Mask Style	3 Ply, Ear Loops, Flat-Pleated Style	3 Ply, Ear Loops, Flat-Pleated Style	Same
Ear loops	Spandex and Nylon	Spandex and Nylon	Same
Color	White	Blue (Outer layer) White (Inner layer)	Similar
Dimension (Width)	9.5 cm ±1 cm	9.5 cm	Similar
Dimension (Length)	17.5 cm ±1 cm	17.5 cm	Similar
OTC Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Shelf life	No Shelf Life	2 yrs	Different
Use	Single Use	Single Use	Same
ASTM F2100 Level	Level 3	Level 3	Same

Table 2 - Performance Testing

Device	**Predicate Device** DemeMASK	**Proposed Device** Disposable Surgical Mask	**Comparison**

Fluid Resistance Performance **ASTM F1862**	Pass at 160 mmHg (Level 3 Fluid Resistance)	Pass at 160 mmHg (Level 3 Fluid Resistance)	Same
Particulate Filtration Efficiency **ASTM F2299**	Pass at ≥99%	Pass at ≥99%	Same
Bacterial Filtration Efficiency **ASTMF2101**	Pass at ≥99%	Pass at ⩾99%	Same
Differential Pressure (Delta P) **MIL-M-36954C**	Average 3.6 mmH2O/cm^2	Average 3.7 mmH2O/cm^2	Similar
Flammability **16 CFR 1610**	Class 1	Class 1	Same
Biocompatibility **ISO 10993-5** and **ISO 10993-10**	Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	Same

8.0 Summary of Non-clinical Tests Performed on the Proposed Device

The proposed device was tested and conformed to 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.

Table of Conformity to Standards

Standards	Name
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)
ASTM F2100-19	Standard Specification for Performance of Materials Used in Medical Face Masks
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
MIL-M-36954C	Differential Pressure (Delta-P)
ASTM F2299/F2299M-03	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
16 CFR PART 1610	Standard for the flammability of clothing textiles

ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for Irritation and skin sensitization

Table of Performance Testing-Bench

Standards	Disposable Surgical Mask Ear Loop	Acceptance Criteria	Result
Resistance to penetration by synthetic blood **ASTM F1862**	32 out of 32 passed in 160 mm Hg	29 out of 32 passed in 160 mm Hg	Pass
Sub-micron particulate filtration efficiency at 0.1 micron **ASTM F2299**	≥99%	≥98%	Pass
Bacterial filtration efficiency **ASTM F2101-19**	≥99%	≥98%	Pass
Differential pressure **MIL-M-36954**	Average 3.7 mmH2O/cm^2	< 6.0 mmH2O/cm^2	Pass
Flame spread **16 CFR 1610**	Class 1 Non-Flammable	Class 1 Non-Flammable	Pass

9.0 Table of Biocompatibility Testing

Standards	Proposed Device	Result
Cytotoxicity **ISO 10993-5**	Under the conditions of the study, the device is non-cytotoxic.	Pass
Skin Sensitization Test **ISO 10993-10**	Under the conditions of the study, the device is non-sensitizing.	Pass
Skin Irritation Test **ISO 10993-10**	Under the conditions of the study, the device is non-irritating.	Pass

9.0 Summary of Clinical Performance Test

No clinical study is included in this submission.

10.0 Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202580, the Disposable Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K201479.