April 11, 2021

Diasia Biomedical Technology Co., Ltd.
% Grace Liu
Consultant
Shenzhen Joyantech Consulting Co., Ltd
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K210018
Trade/Device Name: Disposable Medical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 16, 2021
Received: March 23, 2021

Dear Grace Liu:

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 -S

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)*
K210018

Device Name
Disposal Medical Mask

Indications for Use *(Describe)*
The disposable medical masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These 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(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.

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510(k) Summary

K210018

1. Contact Details

1.1 Applicant information

Applicant Name	Diasia Biomedical Technology Co., Ltd.
Address	2F/3F301/4F (Building A) & 2F (Building B), Fuxinlin Industrial Park, Hangcheng Industrial Zone, Taoyuan, Xixiang, Bao'an District, Shenzhen, Guangdong, China
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Date Prepared	2021-04-05

1.2 Submission Correspondent

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Contact person's e-mail	grace@cefda.com; field@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	Disposable Medical Mask
Common name	Surgical Face Mask
Model	TP175x94
Classification	II
Classification name	Mask, Surgical
Product code	FXX
Regulation No.	21 CFR 878.4040

3. Legally Marketed Predicate Device

Trade Name	DemeMASK Surgical Mask
510(k) Number	K201479
Product Code	FXX
Manufacturer	DemeTECH Corporation

4. Device Description

The proposed device is a three-layer, flat pleated mask. Each mask is composed of a mask body, a nose piece and two ear loops. The mask body is manufactured with three layers, the inner layer and the outer layer are made of spunbond polypropylene nonwoven fabric, and the middle layer is made of meltblown polypropylene nonwoven fabric.

The model of proposed device, ear-loop, is held in place over the user's mouth and nose by two elastic ear loops welded to the mask body. The elastic ear loops are made of spandex and nylon, not made from natural rubber latex.

The nose piece is in the layers of face mask to allow the user to fit the face mask around his nose, which is a iron wire with polypropylene covering.

The proposed device is provided non-sterile and is intended to be a single use, disposable device.

5. Intended Use/Indication for Use

The disposable medical masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These 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(s), provided non-sterile.

6. Substantial Equivalence Comparison

Table 1 Substantial Equivalence Comparison

Item	Proposed Device (K210018)	Predicate Device (K201479)	Comment
Product name	Disposable Medical Mask	DemeMASK Surgical Mask	None
Manufacturer	Diasia Biomedical Technology Co., Ltd.	DemeTECH Corporation	None
Product Code	FXX	FXX	Same
Regulation Number	21 CFR § 878.4040	21 CFR § 878.4040	Same
Classification	Class II	Class II	Same
OTC use	Yes	Yes	Same
ASTM Level (ASTM F2100-19)	Level 3	Level 3	Same
Indications for use	The disposable medical masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These masks are intended for use in infection control practices to reduce the potential exposure to	The Disposal 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	Same

	blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	blood and body fluids. This is a single use, disposable device provided non-sterile.	
Design feature	Ear-loop	Ear-loop	Same
Mask style	Flat Pleated	Flat Pleated	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Specifications and Dimensions	Length: 17.5cm±0.5cm Width: 9.4cm±0.5cm	Length: 17.5cm±1cm Width: 9.5cm±1cm	Similar
Sterility	Non-Sterile	Non-Sterile	Same
Materials			
Outer layer	Spunbond polypropylene	Spunbond polypropylene	Same
Middle layer	Meltblown polypropylene filter	Meltblown polypropylene filter	Same
Inner layer	Spunbond polypropylene	Spunbond polypropylene	Same
Nose piece	Iron wire with polypropylene covering	Galvanized wire coated with polyethylene	Different (Issue 1)
Ear loop	Spandex and Nylon – Not made from natural rubber latex	Spandex and Nylon – Not made from natural rubber latex	Same
Performance			
Fluid Resistance ASTM F1862	Pass at 160 mmHg	Pass at 160 mmHg	Same
Bacterial Filtration Efficiency ASTM F2101	Pass at ≥99%	Pass at ≥99%	Same
Particulate Filtration Efficiency ASTM F2299	Pass at ≥99%	Pass at ≥99%	Same
Differential Pressure (Delta-P)	Pass at <6.0 mmH_2O/cm^2	Pass at <6.0 mmH_2O/cm^2	Same
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

Issue 1: The differences in the materials do not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials.

7. Non-clinical Testing

7.1 Biocompatibility testing

The Medical Surgical Mask has been subjected to biocompatibility studies to demonstrate the safety of device. The biocompatibility studies are in accordance with ISO10993:

- In Vitro Cytotoxicity (ISO 10993-5): the device was non-cytotoxic;
- Skin Irritation (ISO 10993-10): the device was non-irritating;
- Skin Sensitization (ISO 10993-10): the device was non-sensitizing.

There is no additional safety risk for the proposed device when compared with the predicate device.

7.2 Performance testing - Bench

The performance testing was determined according to "ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks" to demonstrate the effectiveness of device.

Table 2 Summary of Performance Testing

Test	Purpose	Acceptance Criteria per ASTM F2100-19 Level 3 (AQL=4.0%)	Subject Device Test Results	
			ASTM F2100-19 Level 3	Average
Fluid Resistance (ASTM F1862)	Determine synthetic blood penetration resistance.	Pass at 160 mmHg	Pass at 160 mmHg (96/96) 32 Samples each from 3 non-consecutive lots	N/A
Bacterial filtration efficiency (BFE) (ASTM F2101)	Determine the bacterial filtration efficiency.	⩾ 98%	Pass (96/96) 32 Samples each from 3 non-consecutive lots	99.9%
Particulate filtration efficiency (PFE) (ASTM F2299)	Determine submicron particulate filtration efficiency at 0.1 micron.	⩾ 98%	Pass (96/96) 32 Samples each from 3 non-consecutive lots	99.8%
Differential pressure (Delta-P) (EN 14683)	Determine breathing resistance or differential pressure.	< 6.0 mmH_2O/cm^2	Pass (96/96) 32 Samples each from 3 non-consecutive lots	4.5 mmH_2O/cm^2
Flammability (16 CFR 1610)	Determine flammability or flame spread.	Class 1	Pass (96/96) 32 Samples each from 3 non-consecutive lots	N/A

8. Clinical Testing

No clinical study is included in this submission.

9. Conclusions

The proposed device has the same indication for use and similar technological characteristic as the predicate device. Non-clinical testing demonstrates that the proposed device performs as safe and effective as the predicate device.