October 24, 2021

Weihai Dishang Medical Technology Co., Ltd
Ricky Xia
Manager
Room 406-409, Block C, No.213 Torch Road, Torch High-Tech
Industrial Development Zone
Weihai, Shandong 264209
China

Re: K210348
Trade/Device Name: Disposable Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 25, 2021
Received: September 3, 2021

Dear Ricky Xia:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210348

Device Name
Disposable Medical Surgical Mask

Indications for Use *(Describe)*
The "Disposable Medical Surgical Mask" is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The 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.

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K210348

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: August 25, 2021

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Weihai Dishang Medical Technology Co.,Ltd
Address:	Room 406-409,Block C,No.213 Torch Road,Torch High-tech Industrial Development Zone,Weihai,Shandong China
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2. Device Identification

510(K) number:	K210348
Trade/Device Name:	Disposable Medical Surgical Mask
Models:	DSAL2-WHITE, DSAL1-WHITE
Common name:	Mask, Surgical
Regulation Number:	878.4040
Regulation Name:	Surgical apparel
Regulation Class:	Class 2
Panel:	General Hospital
Product Code:	FXX

3. Predicate Device

510(K) number:	K202463
Device Name:	Disposable Surgical Mask
Manufacturer:	UNISOURCES GROUP LLC
Common name	Mask, Surgical
Regulation Number:	878.4040
Regulation Name:	Surgical apparel
Regulation Class:	Class 2
Panel:	General Hospital
Product Code:	FXX

K210348

4. Device Description

The “Disposable Medical Surgical Mask” is single use,white color, without face shield, Flat Pleated type, utilizing ear loops for wearing, and it has a Nose clip design for fitting the facemask around the nose. The “Disposable Medical Surgical Mask” is manufactured with three layers. The inner and outer layers are made of Spunbond fabric (Polypropylene), and the middle filter layer is made of a meltblown fabric (Polypropylene). The subject device is held in place over the user’s mouth and nose by two ear loops welded to the facemask. The ear loop is made of Knited nylon and spandex. The nose clip contained in masks is in the layers of the facemask to allow the user to fit the facemask around their nose, which is made of Synthetic iron wire, PP and PE. The “Disposable Medical Surgical Mask” is sold non-sterile and are intended to be single-use, disposable devices.
This product contains no components made with natural rubber latex.

5. Indication for use

The " Disposable Medical Surgical Mask " is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The 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(s), provided non-sterile.

6. Technological Characteristic Comparison to Predicate Device

Comparison to the predicate devices summarized in the following table

SE Comparisons	Proposed Device DSAL2-WHITE K210348	Proposed Device DSAL1-WHITE K210348	Predicate Device K202463	Comparison
Name	Disposable Medical Surgical Mask	Disposable Medical Surgical Mask	Disposable Surgical Mask	/
Model	DSAL2-WHITE	DSAL1-WHITE	FILTECH M201	/
Classification	Class 2	Class 2	Class 2	Same
Intended use	The “Disposable Medical Surgical Mask” is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The 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(s), provided non-sterile.	The “Disposable Medical Surgical Mask” is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The 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(s), provided non-sterile.	The Disposable Surgical Mask, FILTECH M201 is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. The Disposable Surgical 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(s), provided non-sterile.	Same
ASTM F2100 Level	Level 2	Level 1	Level 2	Different Note 1
Mask Styles	Flat Pleated	Flat Pleated	Flat Pleated	Same
Design features	Ear loop	Ear loop	Ear loop	Same
Layers	3	3	3	Same
Color	White	White	Blue outside; white inside	Similar Note 2

Target population	Adults	Adults	Adults	Same
Dimension (length)	175 mm± 5 mm	175 mm± 5 mm	175 ± 5 mm	Same
Dimension (width)	95 mm± 5 mm	95 mm± 5 mm	95 ± 5 mm	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Use	Single use, disposable	Single use, disposable	Single use, disposable	Same
Anatomical site	Nose and mouth	Nose and mouth	Nose and mouth	Same
Technology	Self-suction filter mask	Self-suction filter mask	Self-suction filter mask	Same
Environment of use	OTC	OTC	OTC	Same
Material of Outer layer	Spunbond fabric (Polypropylene)	Spunbond fabric (Polypropylene)	Spunbond polypropylene	Same
Material of middle layer	Meltblown fabric (Polypropylene)	Meltblown fabric (Polypropylene)	Melt blown polypropylene filter	Same
Material of inner layer	Spunbond fabric (Polypropylene)	Spunbond fabric (Polypropylene)	Spunbond polypropylene	Same
Material of ear loops	Knited nylon and spandex	Knited nylon and spandex	Spandex	Similar Note 3
Material of Nose clip	Synthetic iron wire,PP and PE	Synthetic iron wire,PP and PE	Malleable polyethylene wire	Similar Note 3
Colorants	/	/	Polypropylene (PP) master batch	Similar Note 2

Performance					
Test item	**Test standard**	**Proposed Device DSAL2-WHITE K210348**	**Proposed Device DSAL1-WHITE K210348**	**Predicate Device K202463**	**Remark**

BFE	ASTM F2101-19	≥98%	≥98%	≥98%	Same
PFE	ASTM F2299-03(2017)	≥98%	≥98%	≥98%	Same
Differential Pressure	EN 14683 :2019+AC (2019)(E), Annex C	<6.0	<6.0	<6.0	Same
Synthetic Blood Penetration Resistance	ASTM F1862M-17	120mmHg	120mmHg	120mmHg	Same
Flammability	16 CFR Part 1610 (As Amendment In 2008)	Class 1	Class 1	Class 1	Same

Biocompatibility					
Test item	**Test standard**	**Proposed Device DSAL2-WHITE K210348**	**Proposed Device DSAL1-WHITE K210348**	**Predicate Device K202463**	**Remark**
Cytotoxicity	ISO 10993-5:2009	toxicity	toxicity	No Cytotoxicity	Different – Note 4
Acute systemic toxicity	ISO 10993-11:2017	No systemic toxicity	No systemic toxicity	/	
Skin sensitization	ISO 10993-10:2010	No Irritation	No Irritation	No Irritation	Same
Skin irritation		No Sensitization	No Sensitization	No Sensitization	Same

Note 1: In this submission, we propose two model products, one is level 1, another is level 2, both of these models are subjected ASTM F2100-2019 tests.

Note 2: There is a difference in color.

Note 3:

We introduce materials “Knited nylon and spandex” in ear loop and materials “Synthetic iron wire, PP and PE” in nose clip.

Note 4:

We evaluated the In vitro cytotoxicity of surgical mask in accordance with ISO 10993-5:2009, the results showed potential toxicity to L929 cells, additionally we evaluated acute systemic toxicity of surgical mask in accordance with ISO 10993-11:2017, result showed no evidence of systemic toxicity from the extract.

8. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The proposed device Disposable Medical Surgical Mask conducted below testing:

Performance: (Testing was performed using 3 nonconsecutive lots of 32 samples per lot)

1. **ASTM F2100-19** Standard Specification for Performance of Materials Used in Medical Face Masks
2. Bacterial Filtration Efficiency-Determine the bacterial filtration efficiency as directed in Test method **F2101**.
3. Differential Pressure -Determine breathing resistance or differential pressure as directed in **EN 14683:2019,Annex C**.
4. Sub-Micron Particulate Filtration-Determine particulate filtration efficiency as directed in Test Method **F2299**
5. Resistance to Penetration by Synthetic Blood-Determine synthetic blood penetration resistance as specified in Test Method **F1862.**
6. Flammability-Determine flammability as specified in **16 CFR Part 1610.**

Test item	Purpose	Acceptance Criteria	Results
BFE ASTM F2101-19	The purpose of the testing to demonstrate the BFE of the device.	≥98%	Accepted
PFE ASTM F2299-03(2017)	The purpose of the testing to demonstrate the PFE of the device.	≥98%	Accepted
Differential Pressure EN 14683 :2019+AC (2019)(E), Annex C	The purpose of the testing to demonstrate the Differential pressure of the device.	<6.0	Accepted

Synthetic Blood Penetration Resistance ASTM F1862M-17	The purpose of the testing to demonstrate the Synthetic Blood Penetration Resistance of the device	120mmHg	Accepted
Flammability 16 CFR Part 1610 (As Amendment In 2008)	The purpose of the testing to demonstrate the Flammability of the device	(A) There are no burn times; or (B) There is only one burn time and it is equal to or greater than 3.5 seconds; or (C) The average burn time of two or more specimens is equal to or greater than 3.5 seconds.	Class 1

Biocompatibility:

1. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro
2. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
3. ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

Test Method	Purpose	Acceptance Criteria	Results
ISO 10993 -5: 2009 In Vitro Cytotoxicity	In this study, mammalian L-929 cells were cultured in vitro according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article. The test articles and the control material were separately placed in MEM medium containing 10% fetal bovine serum and extracted in a 37℃ incubator for 24 hours. After the end of the extraction, the cell culture medium in the 96-well plate (10^4 cells/well) cultured for 24 hours was removed and replaced with the corresponding extract, cultured in 37℃, 5% CO_2, >90% humidity for 24 hours. After the culture the morphology and cell lysis of the cells were observed under the microscope, and the cytotoxicity of the test	The 50% extract of the test aticle should have at least the same or a higher viability than the 100% extract. Otherwise, the test should be repeated. The lower the Viab. % value, the higher the cytotoxic potential of the test article is. If viability is reduced to <70% of the blank, it has a cytotoxic potential. The Viab.% of the 100% extract of the test article is the final result.	Under the condition of the test, the test article was found to be cytotoxic

	samples was determined by MTT assay.		
Skin Sensitization ISO 10993 -10: 2010	we took guinea pigs to observe the skin sensitization of the test article according to ISO 10993-10: 2010. The test article were extracted in Constant Temperature Vibrator at 50℃, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Mix 50:50 (by volume) stable emulsion of Freund's complete adjuvant with selected solvent. Intradermal induction and topical induction were operated in the clipped intrascapular region of each animal. After the topical induction phase was completed on day 14, all test and control animals were challenged with the test sample. The erythema and edema of the challenge site were observed to test the sensitization response of the test article. According to the Magnusson and Kligman scales, the response to erythema and edema at each application site of the skin was described and scored 24 hours and 48 hours after the challenge phase.	Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals. If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization. If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in test and control animals.	Under the condition of the test, the test article was found to be non-sensitizing
Skin Irritation test ISO 10993 -10: 2010	we took New Zealand white Rabbits to observe the skin irritation of the test article according to ISO10993-10:2010. The test article were extracted in Constant Temperature Vibrator at 50℃, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Apply 0.5 ml extracts of test article or control to 2.5 cm x 2.5 cm absorbent gauze patches, and then apply the patch soaked with	Use only (24±2) h, (48±2) h and (72±2) h observations for calculation. After the 72 h grading, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h were totaled separately for each test article and blank for each animal. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).	Under the conditions of the test, the test article was found to be non-irritating

	the extract of test article or control directly to the skin on each side of each rabbit, and then wrap the application sites with a bandage for a minimum of 4 h.At the end of the contact time, remove the dressing. The describe and score the skin reaction for erythema and oedema for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2)h following removal of the patches.	To obtain the primary irritation index for the test article, add all the primary irritation scores of the individual animals and divide by the number of animals. When blank or negative control was used, calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.	
Acute systemic toxicity ISO 10993 -11: 2017	A single dose of test article extract was injected into the designated group of mice intraperitoneally at the dose level of 50 mL/kg bw. The negative control liquid was injected similarly into the separate group of designated control mice. Mice were observed for any adverse clinical reactions immediately after injection, and then the animals were retuned to their cages. The animals were observed for signs of systemic reactions at4,24,48 and 72 hours after injection and weighed daily for three days after dosing. Any animal found dead or showed abnormal signs were subjected to gross necropsy.	(1) If during the observation period of an acute systemic toxicity test none of the mice treated with the test article extract exhibited a significantly greater biological reactivity than control mice, the test article met the requirements. If two or more animals died, or if abnormal behavior such as convulsions or prostration occurs in two or more animals, or if body weight loss greater than 10 %occurs in three or more animals, the test article did not meet the requirements. (2)If any animals treated with the sample exhibited only slight signs of biological reactivity, andno more than one animal showed gross symptoms of biological reactivity or died, repeat the testing using groups of ten animals. On the repeat test, if all ten animals treated with the test article extract exhibited no scientifically meaningful biological reactivity above the vehicle control animals during the observation period, the test article met the requirements.	Under the condition of the test, the test article was found to be non-systemic toxicity

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210348, the Disposable Medical Surgical Mask (model: DSAL2-WHITE, DSAL1-WHITE), are as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202463.