January 12, 2021

Tianjin Saiyuan Technology CO., LTD
% Wang Yanhong
RA Engineer
Andon Health Co., Ltd
No. 3 Jin Ping Street, Ya An Road, Nankai District
Tianjin, Tianjin 300190
China

Re: K201625
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: October 23, 2020
Received: October 26, 2020

Dear Wang Yanhong:

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 CAPT Elizabeth Claverie, MS
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)*
K201625

Device Name
Disposable Medical Surgical Mask (rectangular)

Indications for Use *(Describe)*

The Disposable Medical Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, blood, body fluids and particulate material. This surgical mask is intended for use in infection control practices to reduce 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

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

1.0 submitter's information

Name: TIANJIN SAIYUAN TECHNOLOGY CO.,LTD
Address: 18 DongJiu Street, Zhongxin Road, Pilot Free Trade Zone (Airport Economic Area) , Tianjin, CN 300308

Phone number: 86-22-60406905
Fax number: 86-22-60406912
Contact: Hong Cai
Date of Preparation: 1/11/2021

2.0 Device information

Trade name: Disposable Medical Surgical Mask (rectangular)
Common name: surgical mask
Regulation Name: Surgical Apparel

3.0 Classification

Production code: FXX
Regulation number: 21 CFR §878.4040
Classification: II
Panel: General Hospital

4.0 Predicate device information

Manufacturer: WUHAN DYMEX HEALTHCARE CO., LTD
Device: SURGICAL FACE MASK
510(k) number: K182515

5.0 Intended use

The Disposable Medical Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, blood, body fluids and particulate material. This surgical mask is intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

6.0 Device description

The Disposable Medical Surgical Mask (rectangular) is single use, three-layer, flat-folded masks with ear loops and nose piece. The Surgical Mask is 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. The mask is held in place by the elastic ear loops. The nose piece in the layers of surgical mask is to allow the user to fit the mask around their nose, which is made of malleable polyethylene wire. The mask is a single use, disposable device, provided non-sterile.
This device is not made from Natural Rubber Latex.

7.0 Summary comparing technological characteristics with predicate device

Item	Subject Device	Predicate Device (K182515)	Comparison
Manufacturer	TIANJIN SAIYUAN TECHNOLOGY CO.,LTD	WUHAN DYMEX HEALTHCARE CO., LTD	Different note 1
510K number	K201625	K182515	Different note 2
Product name	Surgical mask	Surgical face mask	Different note 3
classification	Class II device, FXX (21 CFR 878.4040)	Class II device, FXX (21 CFR 878.4040)	Same
Indications for Use	The Disposable Medical Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, blood, body fluids and particulate material. This surgical mask is intended for use in infection control practices to reduce	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	Same

	potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.	reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	
Model	rectangular	Ear loops, flat pleated, 3 layers	Different note 4
materials	Outer facing layer: Spun-bond polypropylene	Outer facing layer: Spun-bond polypropylene	Same
	Middle facing layer: Melt blown polypropylene filter	Middle facing layer: Melt blown polypropylene filter	Same
	Inner facing layer: Spun-bond polypropylene	Inner facing layer: Spun-bond polypropylene	Same
	Nose piece: Malleable polyethylene wire	Nose piece: Malleable polyethylene wire	Same
	Ear loops: Spandex and nylon	Ear loops: Spandex	Different note 5
Color	Outside: Blue Inside: white	Yellow	Different note 6
Dimension(Width)	9.5cm±1cm	9.5cm±1cm	Same
Dimension(Length)	17.0cm±1cm	17.5cm±1cm	Different note 7
Mask style	flat-folded	flat-folded	Same
OTC use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level	Level 3	Level 2	Different note 8

Note 1-4: the manufacturer is different, so the device name, 510K number and model number is different. The performance test conform that the new device is the same safe and effective as the predicate device.

Note 5: There is nylon material in the ear loop of the proposed device, which is different from the predicate device, however, Nylon is a popular material used in cloths, and the biocompatibility test also demonstrated the material is as safe as the predicate device.

Note 6: The color of the outer facing layer is different from the predicate device, but the biocompatibility test also demonstrated the material is as safe as the predicate device.

Note 7: Dimension of width is the same as the predicate device, while dimension of length of is different, the performance test proves the device is the same safe and effective as the predicate device.

Note 8: The new device is level 3 according to ASTM F2100 standard, the performance test conform that, the difference does not raise any new performance questions.

8.0 Discussion of non-clinical test performed

Non-clinical tests were conducted to verify that the proposed device met all design specifications as the predicate device. The test results demonstrate that the proposed device conforms to the recognized standards ASTM F2100-19, ASTM F1862, ASTM F2101, and ISO 10993 in addition to the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004.

ASTM F2100 Level	Level 3	Level 2	Different note 8

Performance testing

Item	Proposed device	Acceptance criteria	Result
Fluid Resistance Performance ASTM F1862	≥160 mmHg	29 out of 32 pass at 160 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	≥ 98%	≥ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101	≥ 98%	≥ 98%	Pass
Differential Pressure (Delta P) MIL-M-36954C	< 6.0mmH_2O/cm^2	< 6.0mmH_2O/cm^2	Pass
Flammability 16 CFR 1610	Class 1 Non Flammable	Class 1	Pass
Barrier protection level	Level 3	Level 3	Pass

Biocompatibility testing

Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Pass
Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Pass
Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Pass

9.0 Clinical Test Conclusion

No clinical study is included in this submission.

10.0 Comparison to the predicate device and the conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission K201625, Disposable Medical Surgical Mask (rectangular), is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K182515.