June 4, 2021

Juntech(Jiaxing)Healthcare Materials Co,.Ltd
% Gamma Zhang
RA Manager
Feiying Drug&Medical Consulting Technical Service Group
Rm 218, Building 2, Yike Intelligent Innovation Park,
No. 232 Kezhu Road, Huangpu, Guangzhou
Guangzhou, Guangdong 510000
China

Re: K203704
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 28, 2021
Received: May 5, 2021

Dear Gamma Zhang:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203704

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
Surgical Face Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

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

This 510(k) Summary is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information

510 (k) owner's name:	Juntech（Jiaxing）Healthcare Materials Co,.Ltd
Address:	No.4 Plant, No1 build of North of Yubei St, and Zhengdong Rd, Yuxin Town Nanhu District, Jiaxing Zhejiang, China
Contact person:	Cam Sun
Phone number:	86-573-83178618
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Email:	cam.sun@juntai-tech.com
Date of summary prepared:	2021-04-27

(2) Proprietary name of the device

Trade name:	Surgical Face Mask
Regulation name:	Surgical apparel
Regulation number:	21 CFR 878.4040
Product code	FXX
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(3) Predicate device

Sponsor	V&Q Manufacturing Corporation
Device Name	Face Mask, Surgical Mask, Surgical Face Mask
510(k) Number	K173062
Product Code	FXX
Regulation Number	21 CFR 878.4040
Regulation Class	II

(4) Description/ Design of device

Surgical Face Mask is single use multi-layer mask with outer layer and inner layer (spun-bond polypropylene) that sandwich a meltblown polypropylene filter material. Earloops are of urethane elastic fiber and not made with natural rubber latex; The nose piece is a white aluminum strip covered by PP covering. All of the materials used in the construction of the surgical mask are being used in currently marketed devices.

(5) Indications for use

Surgical Face Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

(6) Materials

Component of Device Requiring Biocompatibility	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Surgical Face Mask	Spunbond polypropylene, meltblown polypropylene, urethane elastic fiber, Steel wire covered by PP covering.	Surface-contacting device: skin	Prolonged contact: 24 hours to 30 day

The body-contacting material used in the Surgical Face Mask have all passed biocompatibility test. Details can be seen in "Biocompatibility Discussion".

(7) Technological Characteristics Comparison Table

Item	Subject device	Predicate device	Comparison
Trade name	Surgical Face Mask	Non Woven Face Mask	/
510 (k) number	K203704	K173062	/
Regulation number	21 CFR 878.4040	21 CFR 878.4040	Same
Regulation description	Surgical apparel	Surgical apparel	Same
Product code	FXX	FXX	Same
Class	II	II	Same
Indications for use/ Intended use	Surgical Face Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood	Non Woven Face Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against	Same

		and body fluids, and particulate materials.	transfer of microorganisms, blood and body fluids, and particulate materials.	
Materials	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Similar. All the materials of Targeted device are used in Predicate device.
	Middle layer	Meltblown polypropylene	Meltblown polypropylene	
	Outer layer	Spun-bond polypropylene	Spun-bond polypropylene	
	Nosepiece	Steel wire covered by PP covering	White aluminum strip with PP covering	
	Headband	Urethane elastic fiber	Urethane elastic fiber or spun-bond polypropylene	
Mask style		Flat pleated	Flat pleated	Same
Design feature		Earloop	Earloop or tie-on	Same
Dimensions		17.5cm*9cm	175mm×95mm	Same
Latex		Not made with natural rubber latex	Not made with natural rubber latex	Same
Color		Blue (outer layer) and white (inner layer)	Blue (outer layer) and white (inner layer)	Same
Performance test result				
Performance Testing (ASTM F2100-19)		Level 3	Level 2	Different. Note 1
Fluid resistance		3 non-consecutive lots, 1st lot: 30 of 32 samples >99.9% at 0.1μm pass at 160 mmHg; 2nd lot: 29 of 32 samples pass at 160mmHg; 3rd lot: 29 of 32 samples >99.9% at 0.1μm pass at 160mmHg	Pass at 120 mmHg	Similar. Targeted device meets ASTM F2100-19 Requirements for Level 3 Classification and ISO 22609: ≥29 of 32 test articles pass at 160 mmHg
Particle Filtration Efficiency		3 non-consecutive lots, 1st lot: 32 samples >99.9% at 0.1μm; 2nd lot: 32	Average 99.74% at 0.1μm	Similar. Targeted device meets ASTM F2100-19 Requirements for Level 3 Classification: ≥98% at 0.1μm

	samples >99.9% at 0.1μm; 3rd lot: 32 samples >99.9% at 0.1μm		
Bacterial Filtration Efficiency	3 non-consecutive lots, 1st lot: 32 samples >99.9%; 2nd lot: 32 samples >99.9%; 3rd lot: 32 samples >99.9%	99.4%	Similar. Targeted device meets ASTM F2100-19 Requirements for Level 3 Classification: ≥98%
Flammability Class	3 non-consecutive lots, Each lot: 32 samples: Class 1	Class 1	Similar. Targeted device meets ASTM F2100-19 Requirements for Level 3 Classification: Class 1
Delta – P	3 non-consecutive lots, 1st lot: 4.1 to 4.5 mmH_2O/cm^2; 2nd lot: 4.0 to 4.6 mmH_2O/cm^2; 3rd lot: 3.7 to 3.9 mmH_2O/cm^2	Average 2.7 mmH_2O/cm^2	Similar. Targeted device meets ASTM F2100-19 Requirements for Level 3 Classification: <6 mmH_2O/cm^2
Biocompatibility	Under the conditions of the study, the device was found non-cytotoxic", "non-irritating", or "non-sensitizing	Under the conditions of the study, the device was found non-cytotoxic", "non-irritating", or "non-sensitizing	Same

- Note 1:

The surgical masks are divided into three levels against ASTM F2100-19 which Level 3 Barrier is the most demanding. Performance testing was provided in support of that the Surgical Face Mask meets ASTM F2100-19 Requirements for Level 3 Classification.

(8) Summary for Non-clinical Studies

The performance tests of Non Woven Face Mask were conducted.

- ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F1862 Standard test method for resistance of medical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity)
- ASTM F 2101-14 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 Military Specification - Mask, Surgical, Disposable
- 16 CFR Part 1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES

During use, the Non Woven Face Mask will directly contact with user's skin, so we have it tested to demonstrate conformance to the following standards.

- 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

Test Methodology	Purpose	Acceptance Criteria	Results
Performance Testing (ASTM F2100-19)	To test the fluid resistance, particle filtration efficiency, bacterial filtration efficiency, flammability class, Differential Pressure of Surgical Face Mask	Level 3	Level 3
Fluid resistance	To evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration, as well as simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids.	Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.	3 non-consecutive lots, 1st lot: 30 of 32 samples >99.9% at 0.1μm pass at 160 mmHg; 2nd lot: 29 of 32 samples pass at 160mmHg; 3rd lot: 29 of 32 samples >99.9% at 0.1μm pass at 160mmHg
Particle Filtration Efficiency	To evaluate the non-viable particle filtration efficiency (PFE) of the test article	≥98% at 0.1μm	3 non-consecutive lots, 1st lot: 32 samples >99.9% at 0.1μm; 2nd lot: 32 samples >99.9% at 0.1μm; 3rd lot: 32 samples >99.9% at 0.1μm
Bacterial Filtration Efficiency	To determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream.	≥98%	3 non-consecutive lots, 1st lot: 32 samples >99.9% at 0.1μm; 2nd lot: 32 samples >99.9% at 0.1μm; 3rd lot: 32 samples >99.9% at 0.1μm
Flammability Class	To evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread.	Class 1	3 non-consecutive lots, Each lot: 32 samples: Class 1
Delta - P	To determine the	<6 mmH_2O/cm^2	3 non-consecutive lots,

	breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate.		1st lot: 4.1 to 4.5 mmH_2O/cm^2; 2nd lot: 4.0 to 4.6 mmH_2O/cm^2; 3rd lot: 3.7 to 3.9 mmH_2O/cm^2
Biocompatibility ISO 10993-5 and ISO 10993-10	To test In Vitro Cytotoxicity, Irritation and Skin Sensitization of Surgical Medical Mask	non-cytotoxic", "non-irritating", or "non-sensitizing	Under the conditions of the study, the device was found non-cytotoxic", "non-irritating", or "non-sensitizing

(9) Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K203704, Surgical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K173062.