



June 18, 2025

Winner Medical Co., Ltd.  
Jiali Liu  
Regulatory Affairs  
Winner Industrial Park, No.660 Bulong Road, Longhua District  
42nd Floor Building No 2, Huilong Business Center  
Shenzhen, Guangdong 518109  
China

Re: K250082

Trade/Device Name: Procedure mask/Surgical mask/Face mask  
Regulation Number: 21 CFR 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: Class II  
Product Code: FXX  
Dated: May 22, 2025  
Received: May 22, 2025

Dear Jiali 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Bifeng Qian -S**

Bifeng Qian, M.D., Ph.D.  
Assistant Director  
DHT4C: Division of Infection  
Control Devices  
OHT4: Office of Surgical and  
Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K250082

Device Name

Procedure mask/Surgical mask/Face mask

Indications for Use (Describe)

The Procedure mask/Surgical mask/Face mask is 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 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Summary

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

The assigned 510(k) Number: K250082

1. Date of Preparation: June 06, 2025
2. Sponsor Identification

**Winner Medical Co., Ltd.**

42F, Building No.2, HBC Huilong Business Center, North Station Community, Minzhi Street,  
Longhua District, 518131 Shenzhen, China

Contact Person: Jiali Liu

Position: Regulatory Affairs

Tel: +86-755-28138888

Email: lea.liu@winnemedical.com

## 3. Identification of Subject Device

Trade Name: Procedure mask/Surgical mask/Face mask

Regulatory Information

Classification Name: Mask, Surgical;

Classification: II;

Product Code: FXX;

Regulation Number: 21CFR 878.4040;

Review Panel: General Hospital;

## Indications for use:

The Procedure mask/Surgical mask/Face mask is 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 blood and body fluids. This is a single-use, disposable device, provided non-sterile.

## Device Description:

The subject device is a three-layer, single-use, flat-pleated mask. The inner and outer layers of the mask are made of polypropylene nonwoven, and the middle layer is made of polypropylene melt-blown nonwoven. The subject device is available in one type, ear loop. The ear loops are made of polyester and spandex. The ear loops model is held in place over the users' mouth and nose by two elastic ear loops welded to the mask. The nose clip is made of Iron and polypropylene. Users can adjust the nose clip according to the shape of the bridge of the nose, and fix the mask on the bridge of the nose to prevent the mask from falling off. The ear loop masks are available in two size, 17.5 × 9.5 cm and 14.5 × 9.5 cm. And the colors for the ear loop mask are yellow, blue and white. The ear loop masks are available in level 1, level 2 and level 3 masks based on ASTM F2100-23. This is a single-use, disposable device, provided non-sterile. All specifications of the subject device are provided in table 1. The product configuration for level 1 yellow & level 1 blue & level 1 white & level 2 blue & level 3 blue face masks are provided in table 2.

Table 1 Procedure mask/Surgical mask/Face mask Description

Product name	ASTM F2100-23 level	Ear strap type	Size (cm)	Color	Layers	Sterilization
Procedure mask/Surgical mask/Face mask	Level 1	Ear loop	17.5 × 9.5	Yellow	3	Non-sterile
				Blue		
				White		
			14.5 × 9.5	Yellow		
				Blue		
				White		
	Level 2	Ear loop	17.5 × 9.5	Blue	3	
			14.5 × 9.5	Blue		
	Level 3	Ear loop	17.5 × 9.5	Blue	3	
			14.5 × 9.5	Blue		

Table 2 Product configuration

Components	Material					Same or Different	Remark
	Level 1 white	Level 1 blue	Level 1 yellow	Level 2 blue	Level 3 blue		
Inner layer of mask	polypropylene nonwoven fabric, white, 25 g/m <sup>2</sup>	Same	Purchased from the same supplier.				
Middle layer of mask	polypropylene melt-blown nonwoven fabric, 25 g/m <sup>2</sup>	polypropylene melt-blown nonwoven fabric, 25 g/m <sup>2</sup>	polypropylene melt-blown nonwoven fabric, 25 g/m <sup>2</sup>	polypropylene melt-blown nonwoven fabric, 30 g/m <sup>2</sup>	polypropylene melt-blown nonwoven fabric, 33 g/m <sup>2</sup>	Different	Purchased from the same supplier. The only difference between them is square meter weight.
Outer layer of mask	polypropylene nonwoven fabric, white, 25 g/m <sup>2</sup>	polypropylene nonwoven fabric, blue, 25 g/m <sup>2</sup>	polypropylene nonwoven fabric, yellow, 25 g/m <sup>2</sup>	polypropylene nonwoven fabric, blue, 30 g/m <sup>2</sup>	polypropylene nonwoven fabric, blue, 35 g/m <sup>2</sup>	Different	Purchased from the same supplier. The differences between them are square meter weight and color.
White ear loop	Polyester and spandex	Same	Purchased from the same supplier.				
Nose clip	Iron and polypropylene	Same	Purchased from the same supplier.				

#### 4. Identification of Predicate Device

K220194 Procedure mask/Surgical mask/Face mask; 21 CFR 878.4040 FXX Mask, Surgical (For level 1 and level 2).

K223232 Procedure mask/Surgical mask/Face mask; 21 CFR 878.4040 FXX Mask, Surgical (For level 3).

#### 5. Summary of Non-Clinical Test

Non clinical tests were conducted to verify that the subject device met all design specifications as was same/similar to the predicate device. The test results demonstrated that the subject device complies with the following standards:

ASTM F1862/F1862M: 2024 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);

ASTM F2101-23 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus;  
 ASTM F2100-23 Standard Specification for Performance of Materials Used in Medical Face Masks;  
 EN 14683: 2019+AC: 2019 Annex C Medical face masks - Requirements and test methods;  
 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;  
 ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process;  
 ISO 10993-5: 2009 Biological evaluation of medical device - Part 5: Tests for in vitro cytotoxicity;  
 ISO 10993-10: 2021 Biological evaluation of medical device - Part 10: Tests for skin sensitization;  
 ISO 10993-23: 2021 Biological evaluation of medical device - Part 23: Tests for irritation.

Table 3 Summary of Performance Testing

Test Methodology	Purpose	Acceptance Criteria	Result
Resistance to Penetration by Synthetic blood	The test was performed in accordance with ASTM F1862/F1862M-24 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) to evaluate the effectiveness of the test article from possible exposure to blood and other body fluids.	Level 1: No penetration at 80 mmHg Level 2: No penetration at 120 mmHg Level 3: No penetration at 160 mmHg	The results for all lots are as follows: Yellow mask (Level 1): Pass at 80 mmHg
			White mask (Level 1): Pass at 80 mmHg
			Blue mask: Level 1: Pass at 80 mmHg Level 2: Pass at 120 mmHg Level 3: Pass at 160 mmHg
Particulate Filtration Efficiency	The test was performed in accordance with ASTM F3502-24 Standard Specification for Barrier Face Coverings to determine the particle filtration efficiency (PFE) of the test article.	Level 1: $\geq 80\%$ Level 2: $\geq 85\%$ Level 3: $\geq 85\%$	<b>Yellow mask (Level 1):</b> greater than 80% efficiency
			<b>White mask (Level 1):</b> greater than 80% efficiency
			<b>Blue mask (Level 1):</b> greater than 80% efficiency  <b>Blue mask (Level 2):</b> greater than 85% efficiency  <b>Blue mask (Level 3):</b>

			greater than 85% efficiency
Bacterial Filtration Efficiency	The test was performed in accordance with ASTM F2101: 23 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, using a Biological Aerosol of Staphylococcus aureus to determine the bacterial filtration efficiency (BFE) of the test article.	Level 1: $\geq 95\%$ Level 2: $\geq 98\%$ Level 3: $\geq 98\%$	<b>Yellow mask (Level 1):</b> greater than 95% efficiency
			<b>White mask (Level 1):</b> greater than 95% efficiency
			<b>Blue mask (Level 1):</b> greater than 95% efficiency  <b>Blue mask (Level 2):</b> greater than 98% efficiency  <b>Blue mask (Level 3):</b> greater than 98% efficiency
Differential Pressure	The test was performed in accordance with EN 14683:2019+AC: 2019 Annex C Medical face masks - Requirements and test methods to determine the differential pressure of the test article.	Level 1: $< 5.0 \text{ mmH}_2\text{O}/\text{cm}^2$ Level 2: $< 6.0 \text{ mmH}_2\text{O}/\text{cm}^2$ Level 3: $< 6.0 \text{ mmH}_2\text{O}/\text{cm}^2$	<b>Yellow mask (Level 1):</b> less than $5.0 \text{ mmH}_2\text{O}/\text{cm}^2$
			<b>White mask (Level 1):</b> less than $5.0 \text{ mmH}_2\text{O}/\text{cm}^2$
			<b>Blue mask (Level 1):</b> less than $5.0 \text{ mmH}_2\text{O}/\text{cm}^2$  <b>Blue mask (Level 2):</b> less than $6.0 \text{ mmH}_2\text{O}/\text{cm}^2$  <b>Blue mask (Level 3):</b> less than $6.0 \text{ mmH}_2\text{O}/\text{cm}^2$
Flammability	The test was performed in accordance with 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles to evaluate the flammability of the test article.	Class 1	The results for all Lot es are as follows: Yellow mask (Level 1): Class 1
			White mask (Level 1): Class 1
			Blue mask: Level 1: Class 1 Level 2: Class 1 Level 3: Class 1

Cytotoxicity	The test was performed in accordance with ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity to evaluate the cytotoxicity of the test article.	The cell culture test system is suitable if the observed responses to the negative control is grade 0 and to the positive control is at least grade 3. The sample meets the requirements of the test if the response to the sample is not greater than grade 2.	Under the conditions of this study, the cytotoxicity result was grade 0. The test article would be considered no cytotoxic potential. The negative controls, blank controls, and the positive controls performed as anticipated.
Sensitization	The test was performed in accordance with ISO 10993-10 Fourth Edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization to evaluate the sensitization of the test article.	Grades of 1 or greater in the test group generally indicated sensitization, provided grades of less than 1 are seen in the control animals. If grades of 1 or greater were noted in control animals, the reactions of test animals which exceeded the most severe reaction in control animals are presumed to be due to sensitization.	Under the conditions of this study, the guinea pig showed no sensitization reaction after the induction of test extracts and the positive rate is 0%. There was no evidence that the test article extracts would cause sensitization on guinea pig.
Irritation	The test was performed in accordance with ISO 10993-10 Fourth Edition 2021-11 Biological evaluation of medical devices - Part 23: Tests for irritation to evaluate the irritation of the test article.	The cumulative irritation indices in the range of 0 to 0.4 were determined to be in the irritation response category of "Negligible" .	Under the conditions of the test, the cumulative stimulus value is 0.0, the test article caused no skin irritation to rabbits. The test article met the test requirements.

## 6. Clinical Test Conclusion

No clinical study is included in this submission.

## 7. Technological Characteristics Comparison

Table 4 Comparison of Procedure mask/Surgical mask/Face mask-Level 1 and Level 2

ITEM	Subject Device K25002	Predicate Device K220194	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indications for Use	The Procedure mask/Surgical mask/Face mask is intended to be worn to protect both the patient	The Procedure mask/Surgical mask/Face mask is intended to be worn to protect both the patient	Same

	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 blood and body fluids. This is a single-use, disposable device, provided non-sterile.		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 blood and body fluids. This is a single-use, disposable device, provided non-sterile		
Mask style	Flat pleated		Flat pleated		Same
Design feature	Ear loop		Ear loop / Tie-on		Same
Dimension	Body: 175 mm × 95 mm, nose clip: 110 mm, Ear-loop: 178 mm Body: 145 mm × 95 mm, nose clip: 85 mm, Ear-loop: 145 mm		Ear loops: Body: 175 mm × 95 mm, nose clip: 110 mm, Ear-loop: 178 mm Body: 145 mm × 90 mm, nose clip: 85 mm, Ear-loop: 145 mm Tie-on: Body: 175 mm × 95 mm, nose clip: 110 mm, Ear-loop: 900 mm		Different
ASTM F2100 Level	Level 1	Level 2	Level 1	Level 2	Same
Fluid Resistance	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 80 mmHg	Pass at 120 mmHg	Same
Particulate efficiency level	<b>Yellow mask (Level 1):</b> The min result is 90% <b>White mask (Level 1):</b> The min result is 85% <b>Blue mask (Level 1):</b> The min result is 85%	<b>Blue mask (Level 2):</b> The min result is 91%	Blue mask: Pass at 96.05% Black mask: Pass at 96.03%	Blue mask: Pass at 98.78% Black mask: Pass at 98.75%	Different
Bacterial filtration level	<b>Yellow mask (Level 1):</b> The min result is 99.6% <b>White mask (Level 1):</b> The min result is 99.4% <b>Blue mask (Level 1):</b> The min result is 99.5%	<b>Blue mask (Level 2):</b> The min result is 99.9%	Blue mask: Pass at 98.25% Black mask: Pass at 98.25%	Blue mask: Pass at 98.72% Black mask: Pass at 98.73%	Different
Differential pressure	<b>Yellow mask (Level 1):</b> The max result is 3.8 mmH <sub>2</sub> O/cm <sup>2</sup> <b>White mask (Level 1):</b>	<b>Blue mask (Level 2):</b> The max result is 5.1 mmH <sub>2</sub> O/cm <sup>2</sup>	Blue mask: Pass at 3.5 mmH <sub>2</sub> O/cm <sup>2</sup> Black mask: Pass at 3.5	Blue mask: Pass at 3.5 mmH <sub>2</sub> O/cm <sup>2</sup> Black mask: Pass at 3.6	Different

	The max result is 4.6 mmH <sub>2</sub> O/cm <sup>2</sup> <b>Blue mask (Level 1):</b> The max result is 4.5 mmH <sub>2</sub> O/cm <sup>2</sup>		mmH <sub>2</sub> O/cm <sup>2</sup>	mmH <sub>2</sub> O/cm <sup>2</sup>		
Flammability	Class 1		Class 1		Same	
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same	
Materials						
Ear loop	Polyester and spandex		Polyester and spandex			
Nose clip	Iron and polypropylene		Iron and polypropylene			
Mask body	Outer material	25 g/m <sup>2</sup> polypropylene nonwoven	30 g/m <sup>2</sup> polypropylene nonwoven	25 g/m <sup>2</sup> polypropylene nonwoven	30 g/m <sup>2</sup> polypropylene nonwoven	Different
	Middle material	25 g/m <sup>2</sup> polypropylene melt-blown nonwoven	30 g/m <sup>2</sup> polypropylene melt-blown nonwoven	25 g/m <sup>2</sup> polypropylene melt-blown nonwoven	30 g/m <sup>2</sup> polypropylene melt-blown nonwoven	
	Inner material	25 g/m <sup>2</sup> white polypropylene nonwoven	25 g/m <sup>2</sup> white polypropylene nonwoven	25 g/m <sup>2</sup> polypropylene nonwoven	30 g/m <sup>2</sup> polypropylene nonwoven	
Colors	Yellow; Blue; White	Blue	Blue; Black		Different	
Biocompatibility						
Cytotoxicity	Under the conditions of the study, the device was non-cytotoxic.		Under the conditions of the study, the device was non-cytotoxic.		Same	
Sensitization	Under the conditions of the study, the device was non-sensitizing.		Under the conditions of the study, the device was non-sensitizing.		Same	
Irritation	Under the conditions of the study, the device was non-irritating.		Under the conditions of the study, the device was non-irritating.		Same	
Sterilization						
Method	Single use, Non-sterile, No shelf life claimed		Single use, Non-sterile, No shelf life claimed		Same	

#### Different - Dimension

The dimension for the subject device is different from predicate device, it is only minor size adjustments have been made, this difference in dimension will not affect the safety and effectiveness of the subject device.

#### Different - Particulate efficiency

The test method and test result for particulate filtration efficiency for the subject device is different from the predicate device. The difference in test method and test result is not a result of a change in the product, but rather a difference caused by the update of the standard from ASTM-F2100-19 to ASTM-F2100-23. However, the test result for the subject device can meet the requirements of level 1/level 2 mask based on ASTM F2100-23. Thus, this difference will not affect the safety and effectiveness of subject device.

#### Different - Bacterial filtration efficiency

The test result for bacterial filtration efficiency for the subject device is different from the predicate device. However, the test

result for the subject device can meet the requirements of level 1/level 2 mask based on ASTM F2100-23. Thus, this difference will not affect the safety and effectiveness of subject device.

#### Different - Differential pressure

The test result for differential pressure for the subject device is different from the predicate device. However, the test result for the subject device can meet the requirements of level 1/level 2 mask based on ASTM F2100-23. Thus, this difference will not affect the safety and effectiveness of subject device.

#### Different - Materials

The material for the subject device is different from predicate device. Only the grammage of the inner polypropylene nonwoven of the level 2 masks is different, the rest of the masks are not different. By changing the grammage, the biocompatibility test has been performed on the subject device, the test result for the subject device can meet the requirements based on ASTM F2100-23 and the result does not show any adverse effect. Thus, this difference in materials will not affect the safety and effectiveness of the subject device.

#### Different - Colors

The colors of subject device are provided in yellow, blue and white, while the predicate device is blue and black. However, the biocompatibility test has been conducted and test results did not show any adverse effects. Thus, this difference will not affect the safety and effectiveness of the subject device.

Table 5 Comparison of Procedure mask/Surgical mask/Face mask-Level 3

ITEM	Subject Device K250082	Predicate Device K223232	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indications for Use	The Procedure mask/Surgical mask/Face mask is 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 blood and body fluids. This is a single-use, disposable device, provided non-sterile.	The Procedure mask/Surgical mask/Face mask is 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 blood and body fluids. This is a single-use, disposable device, provided non-sterile	Same
Mask style	Flat pleated	Flat pleated	Same
Design feature	Ear loop	Ear loop / Tie-on	Same
Dimension	Ear loops: Body: 175 mm × 95 mm, nose clip: 110 mm, Ear-loop: 178 mm Body: 145 mm × 95 mm, nose clip: 85 mm,	Ear loops: Body: 175 mm × 95 mm, nose clip: 110 mm, Ear-loop: 178 mm Body: 145 mm × 90 mm, nose clip: 85 mm,	Different

	Ear-loop: 145 mm	Ear-loop: 145 mm  Tie-on: Body: 175 mm × 95 mm, nose clip: 110 mm, Ear-loop: 900 mm	
ASTM F2100 Level	Level 3	Level 3	Same
Fluid Resistance	Pass at 160 mmHg	Pass at 160 mmHg	Same
Particulate efficiency level	<b>Blue mask (Level 3):</b> The min result is 92%	Blue mask: Pass at 99.87% Black mask: Pass at 98.90%	Different
Bacterial filtration level	<b>Blue mask (Level 3):</b> The min result is 99.8%	Blue mask: Pass at 99.75% Black mask: Pass at 99.03%	Different
Differential pressure	<b>Blue mask (Level 3):</b> The max result is 5.3 mmH <sub>2</sub> O/cm <sup>2</sup>	Blue mask: Pass at 4.8 mmH <sub>2</sub> O/cm <sup>2</sup> Black mask: Pass at 3.7 mmH <sub>2</sub> O/cm <sup>2</sup>	Different
Flammability	Class 1	Class 1	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
<b>Materials</b>			
Ear loop	Polyester and spandex	Polyester and spandex	Different
Nose clip	Iron and polypropylene	Iron and polypropylene	
Mask body	Outer material 35 g/m <sup>2</sup> blue polypropylene nonwoven	35 g/m <sup>2</sup> polypropylene nonwoven Blue Masterbatch (ratio: 0.8%)	
	Middle material 33 g/m <sup>2</sup> polypropylene melt-blown nonwoven	33 g/m <sup>2</sup> polypropylene melt-blown nonwoven	
	Inner material 25 g/m <sup>2</sup> white polypropylene nonwoven	25 g/m <sup>2</sup> polypropylene nonwoven	
Colors	Blue	Blue; Black	Similar
<b>Biocompatibility</b>			
Cytotoxicity	Under the conditions of the study, the device was non-cytotoxic.	Under the conditions of the study, the device was non-cytotoxic.	Same
Sensitization	Under the conditions of the study, the device was non-sensitizing.	Under the conditions of the study, the device was non-sensitizing.	Same
Irritation	Under the conditions of the study, the device was non-irritating.	Under the conditions of the study, the device was non-irritating.	Same
<b>Sterilization</b>			
Method	Single use, Non-sterile, No shelf life claimed	Single use, Non-sterile, No shelf life claimed	Same

#### Different - Dimension

The dimension for the subject device is different from predicate device, it is only minor size adjustments have been made, this difference in dimension will not affect the safety and effectiveness of the subject device.

#### Different - Particulate efficiency

The test method and test result for particulate filtration efficiency for the subject device is different from the predicate device. The difference in test method and test result is not a result of a change in the product, but rather a difference caused by the update of the standard from ASTM-F2100-19 to ASTM-F2100-23. However, the test result for the subject device can meet the requirements of level 3 mask based on ASTM F2100-23. Thus, this difference will not affect the safety and effectiveness of subject device.

#### Different - Bacterial filtration efficiency

The test result for bacterial filtration efficiency for the subject device is different from the predicate device. However, the test result for the subject device can meet the requirements of level 3 mask based on ASTM F2100-23. Thus, this difference will not affect the safety and effectiveness of subject device.

#### Different - Differential pressure

The test result for differential pressure for the subject device is different from the predicate device. However, the test result for the subject device can meet the requirements of level 3 mask based on ASTM F2100-23. Thus, this difference will not affect the safety and effectiveness of subject device.

#### Different - Materials

The material for the subject device is different from predicate device. The outer material of the subject device is 35 g/m<sup>2</sup> blue polypropylene nonwoven and the predicate device is 35 g/m<sup>2</sup> polypropylene nonwoven Blue Masterbatch (ratio: 0.8%). By changing the outer material, biocompatibility test has been performed on the subject device, the test result for the subject device can meet the requirements based on ASTM F2100-23 and the result does not show any adverse effect. Thus, this difference in materials will not affect the safety and effectiveness of the subject device.

## 8. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K220194 and K223232.