Food and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification 510(k) Review

Date: March 5, 2021

Reviewer:

Subject: Traditional 510(k)#

Applicant: Co.,Ltd.

Device Trade Name: Disposable Medical Face Mask

Contact Name: .

Contact Title: Consultant

Correspondent Firm:

Phone: **Email:**

Received Date: February 8, 2021

Due Date: March 12, 2021

Pro Code(s): FXX **Class:** II **Reg #:** 878.4040

Reg Name: Surgical Apparel

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
	FXX	Disposable Surgical Face Mask	

Recommendation

I recommend that the Disposable Medical Face Mask is/are Substantially Equivalent (SESE)

Review Summary

The substantive review of this 510(k) was completed by . I reviewed the AINN response in S001.

The subject device is a Surgical Apparel with the following Indications for Use: "The Disposable Medical 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 mask 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." It is for OTC use.

Due to the following major deficiencies identified in the submission, I recommend AINN at this stage:

1. The test female animals in biocompatibility testing (sensitization) were not specified the pregnancy status
2.
3. Sampling plan and lot-to-lot variation in performance testing were not sufficiently addressed.

Following submission of S001 and interactive review, the above deficiencies were resolved. Therefore, I recommend that the subject device is substantially equivalent to the proposed predicate.

Review Team

Lead Reviewer (Office Location)

I. Purpose and History

TPLC Information Recall Information Historyfalls

This traditional pre-market submission of Disposable Medical Face Mask from [redacted] Co.,Ltd. is seeking the Agency's clearance on substantial equivalence to the predicate device [redacted]

08/25/2020 DCC received original submission
09/08/2020 Acceptance review notification (RTAA) letter was sent to sponsor

Following substantive review, the file was put on AINN hold on 10/22/20. The sponsor submitted their response under S001 on 2/8/21, which was assigned to me on 2/12/21.

II. 510(k) Summary/Statement

510(k) Summary/Statement		
Was a 510(k) Summary or Statement provided?	**Summary**	Undo
The 510(k) Summary is complete.		

Reviewer comments:
Due to the following issues, the 510(k) summary is not considered acceptable at this stage
1) A summary for each non-clinical testing was not provided in this summary.
2) Multiple major deficiencies were identified in biocompatibility study and performance testing,

S001:

Reviewer comment: *Following submission of S001, the above deficiencies were resolved. See section **XVI** for more details.*

Reviewer Recommendation
The 510(k) Summary/Statement is acceptable.

III. Device/System Description

Is there a new intended use, or different technology that raises different questions of S&E?	Undo	**No**

Device Description Information	{Red} = Inadequate or Unanswered [Yellow] = Marked
Device is life-supporting or sustaining: No	
There are direct/indirect tissue contacting components: Yes	
• **Device or a component is an implant:** No	
Device uses software/firmware: No	
Device or component packaged as sterile: No	
Use/Reuse information: SUD (Packaged Sterile/Not Sterile)	
Environments of Use: Professional Healthcare Facility	
Combination Product Type: N - Not a Part 3 Combination Product	
The Device/System is electrical: No, the device is not electrical	
Device Attributes	
Nanotechnology present: No	

Device Description Information	Red = Inadequate or Unanswered	Yellow Marked

Reprocessed SUD: No

Medical Counter Measures: Yes

Animal-Derived Material(s): No

The proposed devices are single use, three-layer, flat masks with ear-loops and nose piece. The Disposable Medical Face Masks are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter.
The model of proposed device, [redacted], is held in place over the user's mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are not made with natural rubber latex. The nose piece contained in the proposed device is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of Polyethylene and iron.
The proposed devices are sold non-sterile and are intended to be single use, disposable devices.

Dimensions:

- Length x width: (175±10) mm×(95±10)mm
- Length of nose piece: 120mm
- Length of ear loops: (155 ±10) mm
- Length of ear ties: (not applicable)

Material Composition

- Each layer of mask (3 layers): the inner and outer layers are made of Spun-bonded polypropylene, and the middle layer is made of melt blown polypropylene filter,
- Ear loops: the ear loop is made of elastic fiber (The provided MSDS indicated the ear loop is made of [redacted] however, no such description was included in the document of "001_Device Description.pdf.")
- Nose piece: the nose clamp is made of Polyethylene with iron
- Colorant for mask (blue, pink, etc.): the provided MSDSs indicated the color of the outer layer is blue, the inner layer is white. However, no colorant description was included in the document of "001_Device Description.pdf."

The structure of product is as follows:

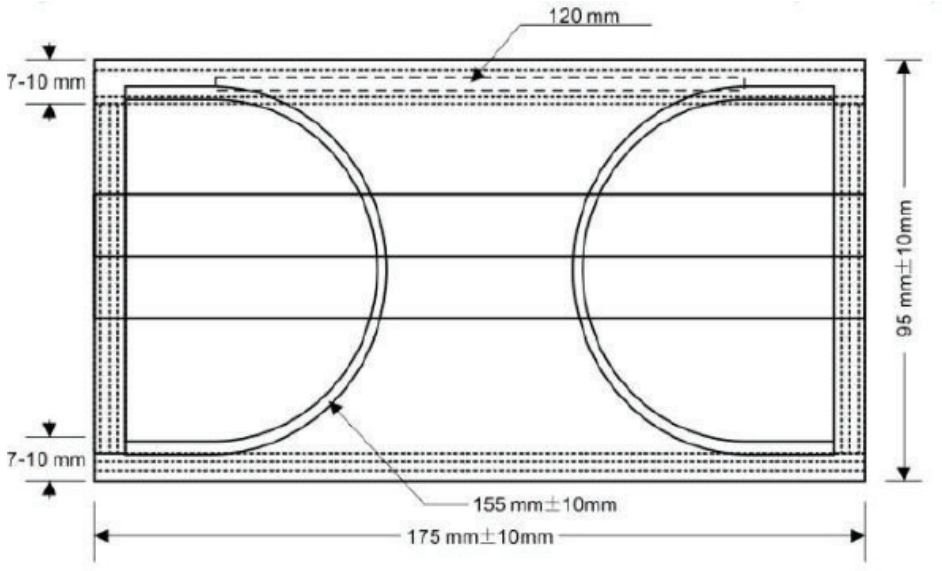


Figure 1. Size of Disposable Medical Face Mask

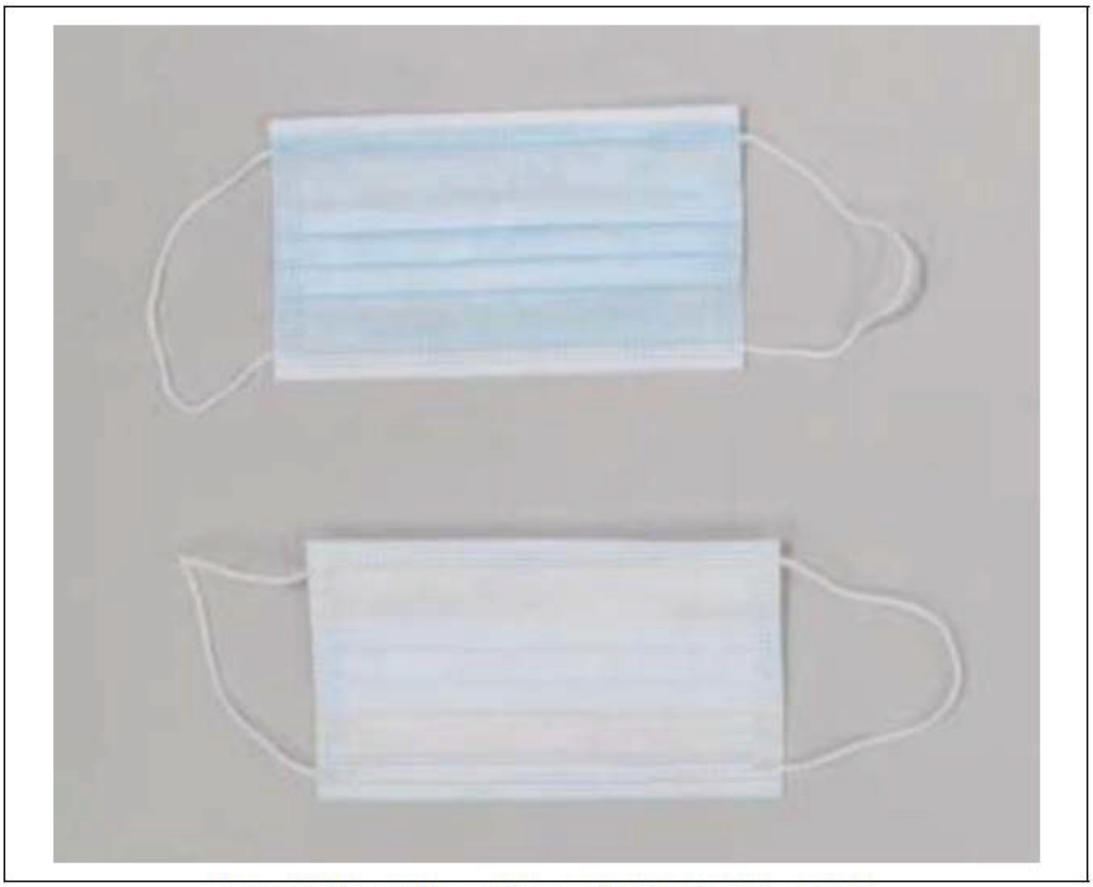


Figure 2.The picture of Disposable Medical Face Mask

Style: Plane Ear-loop type

Working Principle

A standard surgical face mask basically contains 3 layers: the outer layer has a function of against water and dust; the melt-blown material always used as the filter (the middle layer) that stops microbes from entering or exiting the mask, which has a function of filtration; the inner layer's function is moisture absorption. In general, filtration contains 5 main mechanisms: Brown motion, interception, inertial impact, gravitational attraction, electrostatic attraction. Among them, Brown motion and electrostatic attraction lead to more obvious filtration effect to smaller particle; and for intercept, inertial impact and gravitational attraction, the larger size of particle, the stronger filtration effect. When particle size is more than 1μm, the effect of intercept, inertial impact and gravitational attraction are enhanced, and for particles with size less than 0.6μm, Brown motion and electrostatic attraction result in increased filtration efficiency. For a table of device characteristics, see "Comparison of Technology to Predicate Devices" below.

Structure and materials

The structure and materials information are as following:

Table 2 Structure and Materials

No.	Composition	Materials	Major chemical composition	Material safety data sheet	Supplier	CAS number
1.	Outer Layer	Non-woven fabric	Spun-bond polypropylene	Refer to 002_MSDS-Outer layer		
2.	Inner Layer	Non-woven fabric	Spun-bond polypropylene	Refer to 003_MSDS-Inner layer		
3.	Middle Layer	Melt blown Fabric	Melt blown polypropylene	Refer to 004_MSDS-Meltblown		
4.	Nose piece	PE+Steel wire	Polyethylene and iron	Refer to 005_MSDS-Nose-piece		
5.	Straps: Ear - loops	Elastic fiber	Elastic fiber	Refer to 006_MSDS-Ear-loop		

Materials /components in contact with the human body

The structure of Disposable Medical Face Mask contains straps, outer layer, nose piece, filter, inner layer. As the nose piece and filter are enclosed between inner layer, so they are not contacting with skin directly. Other components are contacting with human skin-hands and face.

For a table of device characteristics, see "Comparison of Technology to Predicate Devices" below.

Reviewer comments:

1) The provided MSDSs indicated that the color of the outer layer is blue, the inner layer is white. However, no colorant description was included in the document of "001_Device Description.pdf." A clarification is needed from sponsor for colorant description.
2) The provided MSDS indicated the ear loop is made of , however, no such description was included in the document of "001_Device Description.pdf." A clarification is needed from sponsor for colorant description

S001:

Reviewer comment: *Following submission of S001, the above deficiencies were resolved. See section* ***XVI*** *for more details.*

Reviewer Recommendation

The Device Description is acceptable.

IV. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: Rx/OTC: OTC

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes								
No								
Unknown	☒	☒	☒	☒	☒	☒	☒	☒

Indications for Use: The Disposable Medical 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 mask 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.

Predicate(s)

Submission#: Rx/OTC: OTC

Intended Population: Unknown

Indications for Use: The Disposable 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 blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

The indications for use statement are almost identical for both subject and predicate devices.

Reviewer Recommendation

The Comparison of the Indications for Use is acceptable.

V. Comparison of Technology to Predicate Devices

Device & Predicate Device(s):		
General Device Characteristics		
Indications for use	The Disposable 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 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.	The Disposable 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 blood and body fluids. This is a single use, disposable device(s), provided non-sterile.
Design feature	Ear-loop [*1]	Ear-loop, Tie-on
Usage	Single use	Single use

Color	Blue	Blue
Size	(175±10) mm×(95±10)mm	(17.5±1) cm×(9.5±1)cm
Sterile	Non-sterile	Non-sterile
Materials	Outer layer: Spun-bond Polypropylene Middle layer: Melt blown polypropylene filter Inner layer: Spun-bond Polypropylene Nose piece: PE+ Steel wire *2 Ear-loops: Elastic fiber *3	Outer layer: Spun-bond Polypropylene Middle layer: Melt blown polypropylene filter Inner layer: Spun-bond Polypropylene Nose piece: Malleable aluminum wire Ear-loops: Elastic fiber
ASTM F 2100 Level	Level 2	Level 2
Fluid Resistance Performance ASTM F 1862-13	Meet the ASTM F2100 Requirements for Level 2 Classification	Meet the ASTM F2100 Requirements for Level 2 Classification
Particulate Filtration Efficiency ASTM F 2299	Meet the ASTM F2100 Requirements for Level 2 Classification	Meet the ASTM F2100 Requirements for Level 2 Classification
Bacterial Filtration Efficiency ASTM F 2101	Meet the ASTM F2100 Requirements for Level 2 Classification	Meet the ASTM F2100 Requirements for Level 2 Classification
Differential Pressure (Delta P) EN 14683:2019+ AC:2019	Meet the ASTM F2100 Requirements for Level 2 Classification	Meet the ASTM F2100 Requirements for Level 2 Classification
Flammability 16CFR 1610	Class 1	Class 1
Cytotoxicity	Comply with ISO 10993-5 Non cytotoxic	Comply with ISO 10993-5 Non cytotoxic
Irritation	Comply with ISO 10993-10 Non irritating	Comply with ISO 10993- 10 Non irritating
Sensitization	Comply with ISO 10993-10 Non sensitizing	Comply with ISO 10993- 10 Non sensitizing

*1: Issue 1: The design feature of the proposed device is covered by the predicate device.
*2: Issue 2： The nose piece of the proposed device is made by PE + Steel wire, which of the predicate device is made by Malleable aluminum wire. The Nose piece is between the inner and outer layers of the mask, which does not contact with the human body directly when used. Moreover, the whole product has been tested for biocompatibility, and the test results confirm that they have good biocompatibility, so their differences will not cause new safety risks.
*3: Issue 3: The Ear-loops of the proposed device are made by elastic fiber, which of the predicate device is made by polyester. The major chemical composition of the elastic fiber is segmented polyurethane-urea, which is similar to polyester. In addition, the proposed devices have been tested for biocompatibility, and the test results confirm that they have good biocompatibility, so their differences will not cause new safety risks.

Reviewer comments:
A sampling plan and lot size were not specified for the tests of PFE, BFE, and differential pressure (see details in section XI performance testing), a clarification is needed from the sponsor.

S001

Reviewer comment: *Following submission of S001, the above deficiencies were resolved. See section **XVI** for more details.*

Reviewer Recommendation

The Comparison of the Technology to Predicate Devices is acceptable.

VI. Labeling

Labeling Review Needed?	**Yes**	Undo
Usability Consult Needed?	Undo	**No**

Labeling Information	**{Red} = Inadequate or Unanswered [Yellow] Marked**
Prescription statement included: Inapplicable	
Adequate OTC instructions: Yes	
Indications for Use consistent with IFU page: Yes	
Appropriate Contraindications, Warnings, Precautions & Adverse Events: Yes	
Instructions in accordance with guidance: Yes	
Appropriate labeling inside device: Inapplicable	
[Appropriate labeling outside device: No]	
Appropriate instructions for use labeling: Yes	
Appropriate Home Use information: Inapplicable	
MR Status according to labeling: Not Evaluated and Not Needed	

Instruction for use (in original submission with statement of

Model:

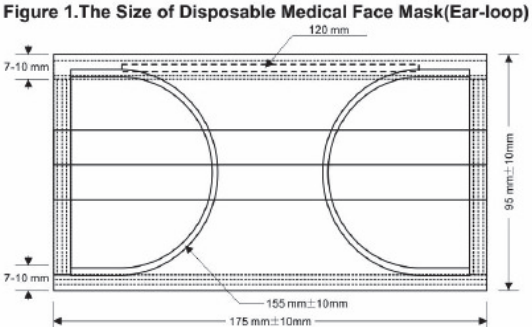
Date of issue: July 05, 2020
Version number: Q0
Please refer to the instructions before use

Instruction

[Product Name] Disposable Medical Face Mask
[Model]
[Style] Flat-Pleated
[Indication for Use] The Disposable Medical Face Mask 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, provided non-sterile.
[Structure and Material]
This mask is manufactured with three layers of non-woven fabric, nose piece and Straps. The inner and outer layer are made of spun-bond polypropylene, the middle layer is made of melt-blown polypropylene.

NO.	Name	Material
1	Straps	Ear-Loop: Elastic fiber
2	Outer layer	Non-woven fabric
3	Nose-piece	PE + Steel wire
4	Filter	Melt-blown fabric
5	Inner layer	Non-woven fabric

Figure 1.The Size of Disposable Medical Face Mask(Ear-loop)



Symbol Description

	Do not re-use
	Consult instructions for use
	Non-sterile
	Do not use if package is damaged
	Manufacturer

NO.	Tests	Results
1	Bacterial filtration efficiency	≥ 98%
2	Sub-micron particulate filtration efficiency	≥ 98%
3	Synthetic blood penetration test	Pass at 120mmHg
4	Differential pressure	< 6.0 mm H_2O
5	Flammability test	Class 1

[Instructions for Use]
Lay the mask flat, nose-piece upward; unfold it; cover it on your face and nose; put the ear-loop on until it perfectly fit your nose and face.

[Cautions]
1. Please discard the mask and replace with a new one if excessive clogging of the mask causes breathing difficulty or the mask is damaged.
2. Please pay attention to the expiry date on the bags (boxes) before use; the mask beyond the period of validity cannot be used.
3. The mask is disposable. Please not reuse.
4. Please do not make the product contact with flame and extremely hot object in order avoid burning.
5. Please check the mask whether its surface is damaged, straps fractured and nose piece exposed before opening the package. If have, do not use.
6. Please refer to the instructions for use when wear.

[Warnings]
1. Not for use in circumstance with immediate dangerous to life or health
2. The mask can be only used for protecting against certain contaminants. It cannot eliminate all the risks of contracting disease or infection.

[Storage Requirements] Shall be stored it in a cool and dry place under normal temperature, please keep away from direct sunlight.
[Expiry date] Please refer to labeling on the bags (boxes).
[Manufacturer]

[Service Line] If you have any questions, please contact with

Disposable Medical Face Mask-Instruction for use

[Product Name] Disposable Medical Face Mask
[Model]
[Style] Flat-Pleated
[Indication for Use] The Disposable Medical Face Mask 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, provided non-sterile.

[Structure and Material]
This mask is manufactured with three layers of non-woven fabric, nose piece and Straps. The inner and outer layer are made of spun-bond polypropylene, the middle layer is made of melt-blown polypropylene.

NO.	Name	Material
1	Straps	Ear-Loop: Elastic fiber
2	Outer layer	Non-woven fabric
3	Nose-piece	PE + Steel wire
4	Filter	Melt-blown fabric
5	Inner layer	Non-woven fabric

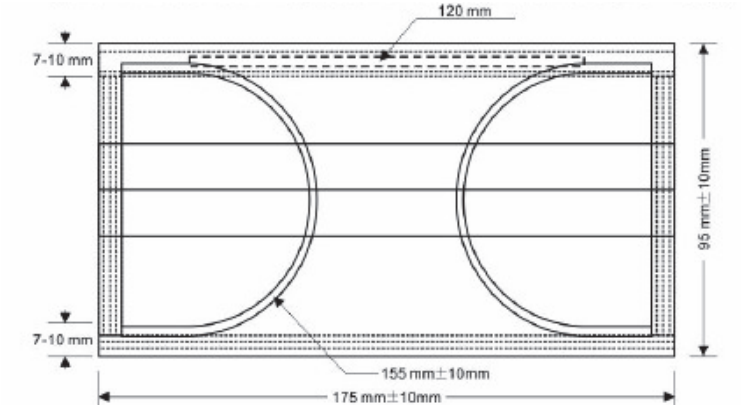


Figure 1.The Size of Disposable Medical Face Mask(Ear-loop)

[Properties]

NO.	Tests	Results
1	Bacterial filtration efficiency	≥ 98%
2	Sub-micron particulate filtration efficiency	≥ 98%
3	Synthetic blood penetration test	Pass at 120mmHg
4	Differential pressure	< 6.0 mm H_2O
5	Flammability test	Class 1

[Instructions for Use]

Please follow the instructions to wear:
1) Lay the mask flat, nose piece upward;
2) Unfold it;
3) Cover it on your face and nose;
4) Put the ear loops on until it perfectly.

[Cautions]
1. Please discard the mask and replace with a new one if excessive clogging of the mask causes breathing difficulty or the mask is damaged.
2. The mask is disposable. Please not reuse.
3. Please do not make the product contact with flame and extremely hot object in order avoid burning.
4. Please check the mask whether its surface is damaged, straps fractured and nose piece exposed before opening the package. If have, do not use.
5. Please refer to the instructions for use when wear.

[Warnings]
1. Not for use in circumstance with immediate dangerous to life or health
2. The mask can be only used for protecting against certain contaminants. It cannot eliminate all the risks of contracting disease or infection.

[Storage Requirements]
Shall be stored it in a cool and dry place under normal temperature, please keep away from direct sunlight.

[Manufacturer]

[Service Line] If you have any questions, please contact with

[Symbol Description]

	Do not re-use
	Consult instructions for use
	Non-sterile
	Do not use if package is damaged

Reviewer comments: The proposed labeling included a claim of [redacted] A justification / clarification is needed from sponsor

S001

Reviewer comment: *Following submission of S001, the above deficiencies have been resolved. See section* ***XVI*** *for more details.*

Reviewer Recommendation
The Labeling is acceptable.

VII. Reprocessing, Sterility and Shelf-Life

No shelf life claimed.

Reviewer Recommendation
Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable.

VIII. Biocompatibility

Biocompatibility Review Needed?	**Yes**	Undo
Biocompatibility Consult Needed?	Undo	**No**

Biocompatibility Information {Red} **Inadequate or Unanswered** [Yellow] **= Focal Point**

There is/are 1 tissue contacting products/components/materials.

Biocompatibility Information {Red} **Inadequate or Unanswered** [Yellow] **= Focal Point**

Material compositions described?: Yes

Device has Special Considerations?: No

Table of Materials and Rationales

Component	Material	Type of Contact	Identical Material & Rationale
Disposable Medical Face Mask(	Spun-bond polypropylene, Elastic fiber	Indirect	No, No Rationale

Rationale

Rationale: No rationale provided.

Biocompatibility Material 1:

Test Component/Material: Disposable Medical Face Mask(/ Spun-bond polypropylene, Elastic fiber

Potential for Repeat Exposure?: No

Type of Tissue Contact: Surface Device: Skin

Duration of Contact: < hours

Cytotoxicity Testing {Red} **= Inadequate or Unanswered** [Yellow] **= Focal Point**

Cytotoxicity testing conducted: Extraction Method (MEM Elution)
Test Article: Disposable medical face mask

Extraction Conditions	Methods	Results	Conclusion and Recommendation

Comments: Report No.:

Sensitization Testing {Red} **= Inadequate or Unanswered** [Yellow] **= Focal Point**

Sensitization testing conducted: Yes,)
Test Article: Disposable medical face mask

Extraction Conditions	Methods	Results	Conclusion and Recommendation

Biocompatibility Information	{Red}	Inadequate or Unanswered	[Yellow]	= Focal Point

Comments: Report Number:

Irritation Testing	{Red}	= Inadequate or Unanswered	[Yellow]	= Focal Point

Irritation testing conducted: Yes, Dermal Irritation Test
Test Article: Disposable medical face mask

Sample Prep / Extract Conditions	Methods	Results	Conclusion and Recommendation

Comments: Report Number:

Reviewer comments: Within sensitization testing, the female animal pregnancy was not specified, which affects result evaluation; also, which is not appropriate and needs sponsor's explanation.

S001:

Reviewer comment: *Following submission of S001, the above concerns were resolved. See section **XVI** for more details.*

Reviewer Recommendation

The Biocompatibility information is acceptable.

IX. Software/Firmware & Cybersecurity/Interoperability

NA

X. EMC, Wireless, Electrical, Mechanical and Thermal Safety & Risk Analysis

NA

XI. Performance Testing

A Bench Testing

Testing facility/lab:

Original Sample Photo

Summary of testing:
With reference to following standard:
• ASTM F2100-19ε1 Standard Specification for Performance of Materials Used in Medical Face Masks Level 2
• ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
• EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods
• ASTM F2299/F2299M-17 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
• ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood
• 16 CFR Part 1610 Wearing Apparel Flammability

1 Differential Pressure (ASTM F2100-19^{e1} , Section 9.2, Testing Refer to EN 14683:2019+AC:2019 Annex C): Air flow: 8 L/min, Test Area Diameter 25 mm, Test Area: 4.9 cm^2 .

Tested Sample	Result (mm H_2O/ $cm^{2)*}$	Performance Requirement for Medical Face Mask (mm H_2O/ cm^2)
		Level 2:

Reviewer comments:
The following information is missing:
- Average DP comparison for subject and predicate
- Any deviations and the justifications

Therefore, a clarification is needed from sponsor.

2 Resistance to Penetration by Synthetic Blood (ASTM F2100-19^{e1}, Section 9.4, Testing Refer to ASTM F1862/F1862M-17):
Synthetic Blood Surface Tension: 0.042 N/m, Distance Between Blow Head Front End and Target Area: 300 mm, Artificial Blood Volumes: 2 mL, Test Pressure: 120 mmHg, Velocity: 550 cm/s, Use a Fixed Target.

Tested Sample/Component	Result	Performance Requirement for Medical Face Mask Pass Pressure at Level 2: 120 mm Hg
[redacted]		

Reviewer comments:
The following information is missing:
- Average blood penetration resistance comparison for subject and predicate
- Any deviations and the justifications

Therefore, a clarification is needed from sponsor.

3 Flammability Test (ASTM F2100-19^{E1}, Section 9.5, Testing Refer to 16 CFR Part 1610 -2008):

X	Plain Surface		Raised Surface

Burn Direction:	☒Length ☐Width	Requirement Class 1
Prelim Plain Surface:		
Length: IBE		
Width: -		
	Original* (seconds)	
1.		
2.		
3.		
4.		
5.		
6.	-	
7.	-	
8.	-	
9.	-	
10.	-	
Average:	-	

Classification:	☒	Class 1, Normal Flammability
	☐	Class 2, Intermediate Flammability, Raised Surface
	☐	Class 3, Rapid and Intense Burning

Explanation of Flammability Results:	
DNI	Did not ignite.
IBE	Ignited but extinguished.

*The disposable fabrics and garments need note to be refurbished in accordance with 16 CFR Part 1610.35 (a)(2).

Reviewer comments:
The following information is missing:
- Any deviations and the justifications

Therefore, a clarification is needed from sponsor.

4 Bacterial Filtiration Effieiency (BFE)

As per ASTM F2100-19^{e1} Standard Specification for Performance of Materials Used in Medical Face Masks Section 9.1 and ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.

Test Item	Results (%)	Performance Requirement for Medical Face Mask (%)
Bacterial Filtration Efficiency (BFE)		Level 2: ≥ 98

Rem

1.
2.
3.
4.
5.
6.
7.

Reviewer comments:
The following information is missing:
- Mean particle size (MPS)
- Average BFE comparison for subject and predicate
- Any deviations and the justifications

Therefore, a clarification is needed from sponsor.

5 Sub-Micron Particulate Filtration (ASTM F2100-19^{E1} , Section 9.3, Testing Refer to ASTM F2299/F2299M-17):
Particle size in Test area: Airflow:
Sampling time:

Tested Sample/Component	Result(%)	Performance Requirement for Medical Face Mask (%)
		Level 2: ≥ 98

Remark: The test was preformed by an approved third party subcontractor laboratory.

Reviewer comments:
The following information is missing:
- Average PFE comparison for subject and predicate
- Any deviations and the justifications

Therefore, a clarification is needed from sponsor.

Also, the information about the calculation of sample size based upon the lot size could not be located in the submission. A clarification is needed from sponsor.

Reviewer comment: *Following submission of S001, the sponsor has resolved the above concerns. See section **XVI** for more details.*

B Animal Testing

C Clinical Testing

Is one or more of the prior clinical investigations subject to requirements governing FDA acceptance of data from clinical investigations?	Undo

Reviewer Recommendation

The Performance Testing [Verification & Validation] is acceptable.

XII. Summary of Benefit-Risk Assessment

In comparison to the predicate device, has the review team or the sponsor identified one of the following scenarios for the subject device: 1	Undo **No**

XIII. Kit Certification

N/A

XIV. References

Standard Code	Title	FDA Recognition number	Tested Result	Options selected
ASTM F2100-19	Standard Specification for Performance of Materials Used in Medical Face Masks	#6-425	Pass	All applicable clauses are met
ASTM F2101-19	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus	#6-427	Pass	All applicable clauses are met
ASTM F1862	Standard Test Method for Resistance of Surgical Mask to Penetration by Synesthetic Blood	#6-406	Pass	All applicable clauses are met
ISO 10993-1:2018	Biological Evaluation of Medical Devices – Part 1: Evaluation And Testing Within A Risk Management Process	#2-258	Pass	All applicable clauses are met
ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	#2-245	Pass	All applicable clauses are met
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	#2-174	Pass	All applicable clauses are met

XV. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
1. Is the predicate device legally marketed?	☒	☐
2. Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device: almost same		
3. Do the devices have the same technological characteristics?	☐	☒
Please describe the different technological characteristics: design feature of ear loop, materials of nose piece and ear loops		
4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?	☐	☒
5a. Are the methods acceptable?	☒	☐
5b. Do the data demonstrate equivalence and support the Indications for Use?	☒	☐

Please explain how the data do or do not demonstrate substantial equivalence:
Testing supported substantial equivalence.

XVI. Original Major Deficiencies

Biocompatibility

1. Based upon the test report provided in the document "003_Skin Sensitization Test Report.pdf," you used female animals for sensitization testing. As described in Section VI.B. of CDRH's 2016 Biocompatibility Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" (https://www.fda.gov/media/85865/download), pregnancy can affect the ability of the model to detect a positive response. Therefore, please provide an amended test report that clarifies the females used in these studies were non-pregnant (e.g., caged by gender at birth).

   Response: The Sensitization Test has been conducted by third party agency, and clarified that the female animals were nulliparous and not pregnant. Please refer to VOL 007 /001_Skin Sensitization Test Report.

   Reviewer comment: The sponsor provided new testing to address deficiency #2. This report supports that the female animals used in the testing were not pregnant. The sponsor has adequately addressed this deficiency.

2. You provided sensitization testing in the document "003_Skin Sensitization Test Report.pdf." However, the provided test report on page 6 of 11 indicates the positive control testing for your sensitization assay was performed [redacted]. Per the Handbook of Toxicology (Third Edition 2014, Edited by Michael J. Derelanko and Carol S. Auletta, Chapter 3. Dermal Toxicology), positive control testing is typically conducted with lower DNCB concentrations (0.1%-0.5% and 0.05%-0.1% w/v, respectively). This confirms that the assay is capable of detecting weak to moderate sensitization responses. Valid sensitization test results are important because exposure to the device (if it includes even a small amount of a sensitizer) can result in sensitization, which can lead to allergic reactions. Therefore, please provide a scientific rationale to support that your method is capable of detecting weak to moderate sensitizers

   Response: The Sensitization Test has been conducted by third party agency, and the positive control testing was conducted with [redacted]). Please refer to VOL 007 /001_Skin Sensitization Test Report.

   Reviewer comment: The sponsor provided new testing using the recommended DNCB concentration. Results continue to support that the subject device is non-sensitizing. The sponsor has adequately addressed this deficiency.

Performance Testing

3. Please note that it is the Agency's expectation for face masks that at least 32 samples per lot are tested for performance testing for synthetic blood penetration resistance per ASTM F1862. Particle filtration efficiency, bacterial filtration efficiency, and differential pressure testing sample sizes are determined based on 4% AQL per ASTM F2100, depending upon the production lot size (i.e., the lot size to be shipped for interstate commerce). Please address the following items.

    a. In your response, you did not provide the calculation of sample size based upon the lot size. Please state the production lot size and provide the calculation of sample size for particle filtration efficiency, bacterial filtration efficiency, and differential pressure, and flammability based on your referenced standard ISO 2859-1 and AQL of 4%. Please also provide performance testing based upon the sample size calculated according to the lot size.

    b. In addition, all of your test samples were from a single lot. The Agency recommends that performance testing be performed on 3 non-consecutive lots. Please provide testing from 3 non-consecutive lots for the performance testing for particle filtration efficiency, bacterial filtration efficiency, differential pressure testing, flammability and synthetic blood penetration resistance testing. Alternatively, you may provide a scientific justification for how you ensure that the subject device's performance is maintained between production lots.

    This information is necessary in order to determine substantial equivalence in safety and effectiveness between the subject and predicate devices

Response: The performance testing has been conducted on 3 non-consecutive lots, and the sample sizes were calculated base on lot size per ISO 2859-1. Please refer to VOL 008.

Reviewer comment: The sponsor provided new testing on 3 non-consecutive lots using 32 samples each. The following summarizes the results:

Item	Test standard	Method and condition	Acceptance criteria	Result	Report
Bacterial filtration efficiency	ASTM F2101-19 And EN 14683:2019, Annex B	The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts up stream of the test article to the bacterial counts downstream. Test side: Inside BFE test area: ~40cm^2 BFE flow rate: 28.3 L/min Conditioning parameters: 85 ± 5%(RH) and 21±5°C for a minimum of 4 hours Test article dimensions: ~174mm*149mm MPS: 3.2 μ m	≥ 98%		VOL_006/ 002_Performance Test Report-20200716, 003_Performance Test Report-20200728, 004_Performance Test Report-20200905
Differential pressure	EN 14683:2019, Annex C	The Delta P test is performed to determine the 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. Test side: Inside Delta P flow rate: 8 L/min Conditioning parameters: 85±5°(RH) and 21±5°C for a minimum of 4 hours	<6.0 mmH$_2$O/cm^2		VOL_006/ 002_Performance Test Report-20200716, 003_Performance Test Report-20200728, 004_Performance Test Report-20200905
Sub-micron Particulate Filtration efficiency	ASTM F2299	This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.	≥ 98%		VOL_006/ 002_Performance Test Report-20200716, 003_Performance Test Report-20200728, 004_Performance Test Report-

Item	Test Standard	Method and condition	Acceptance criteria	Result	Report
		Test side: Inside Area tested: 91.5 cm^2 Particle size: 0.1 μ m Laboratory Conditions: 21.8°C,22% Relative humidity (RH) at 0640; 21.7°C, 22% RH at 0654; 21.8°C, 22% RH at 0905; 22.3°C, 21% RH at 1032			20200905
Resistance to penetration by synthetic blood	ASTM F1862	This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid presentation. The purpose of this procedure is to 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. The distance from the target area surface to the tip of cannula is 30.5 cm. A test volume of 2 mL of the synthetic blood was employed using the targeting plate method. Test side: Outside Pre-conditioning: Minimum of 4 hours at 21 ± 5°C and 85 ± 5° relative humidity (RH) Test conditions: 22.0° C and 22% RH	Pass at 120 mmHg		VOL_006/ 005 Synthetic Blood Penetration Resistance Test Report-3 non-consecutive lots
Flame Spread	16 CFR Part 1610	This procedure was performed to evaluate the flammability of plain surface clothing textiles by	Class 1: Burn time ≥ 3.5 seconds, IBE, or	All of the test article ignited, but extinguished	VOL006/ 002_Performance Test Report-

		measuring the ease of ignition and the speed of the flame spread. The parameter of time is used to separate materials into differn't classes, thereby assisting in a judgement of fabric suitability for clothing and protective clothing material.	DNI		20200716 003-Performance Test Report-20200905 004_Performance Test Report-20200905

After discussing with [redacted] she confirmed using 32 samples for each test is acceptable. The sponsor has adequately addressed this deficiency.

1. Within your performance testing, the following information could not be located:

   a. Data comparison for the subject and predicate devices, such as average differential pressure (DP), average blood penetration resistance, average BFE, and average PFE.
   b. Mean particle size (MPS) of BFE testing
   c. Any deviations and the justifications, if applicable

   Please indicate the locations of or please provide the missing information. This information is necessary in order to determine substantial equivalence in safety and effectiveness between the subject and predicate devices

   Response: The performance testing data have been provided, please refer to VOL 008 / 001_Summary of Performance tests. And the data comparison for the subject and predicate devices were shown in 510(k) Summary and Substantial Equivalence, please refer to VOL 003 /001_510(k) Summary and VOL 005 /001_Substantial Equivalence Comparison.

   Reviewer comment: The sponsor provided the requested MPS (see summary table above) and revised the substantial equivalence discussion to include comparisons of the requested items. The sponsor has adequately addressed this deficiency.

I. Original Minor Deficiencies

Administrative information

1. The document "001_510k Summary.pdf" provides the summary of your submission. However, a summary for each non-clinical testing result could not be located in this document. The summary of Non-clinical tests should be in a tabular format with the following items
   a. Title of the test
   b. Purpose of the test
   c. Acceptance criteria and the source of references
   d. Results

   It applies to biocompatibility tests, performance tests, sterility, and shelf-life. All non-clinical tests. Therefore, please revise this document with additions of the above information. This information is necessary for the accuracy and completion of the 510k summary document.

   Response: The 510(k) Summary has been revised, please refer to VOL 003 / 001_510(k) Summary.

   Reviewer comment: The sponsor provided the requested revisions. The deficiency is resolved.

Device Description

1. The provided MSDSs indicated that the color of the outer layer is blue, the inner layer is white, and the ear loop is made of [redacted] However, no such descriptions were included in the document of "001_Device Description.pdf." Please revise the device description document to include the information of colorant and ear loop materials description for the subject device. This information is necessary for a complete description of the subject device.

Response: The device description document has been revised, please refer to VOL 004 /001_Device Description.

Reviewer comment: The sponsor has clarified that the colorants are [redacted] The biocompatibility testing has addressed the material compatibility of these colorants. The sponsor has adequately addressed this deficiency.

Labeling

2. The document "002_Design drawing of packaging.pdf" provided the labeling information for your subject device, however, we have the following concerns:
   a. The proposed labeling included a claim of [redacted] However, no such evidence and/or clinical studies could be located in the submission. Therefore, please indicate the locations of or please provide the missing information. Alternative, you may revise the labeling with removal of this claim.
   b. To respond to the FDA's RTA comments, you provide the document "002_Design drawing of packaging-Respond to [redacted] However, we found that the section of "Cautions" was also removed in this revised labeling. We consider that the caution information is important for end user safety. Please provide your rationale on this removal or please provide the re-revision to include the caution information.

   This information is necessary to ensure the labeling is accurate and supported within the submission.

Response: The descriptive term [redacted] has been removed and the caution information have been added to the package. Please refer to VOL 006/001_Design drawing of packaging.

Reviewer comment: The sponsor has removed the statements from the labeling and reinstated to cautions section. This deficiency is resovled.

Reviewer comment: Some revisions to the 510(k) summary were needed to complete review. The following revisions were provided interactively:

2. Please revise the device description to contain information on the specific types of colorants present. That is, specify the technical name and not just there is [redacted]

The sponsor has adequately addressed this deficiency.

XVII. Original Additional Considerations

N/A

XVIII. Contact History

09/08/2020	Acceptance review notification (RTAA) letter was sent to sponsor
3/3/2021	Communicated minor revisions to the 510(k) summary.

Digital Signature Concurrence Table (Doc ID: 04500.14.02)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off	2021.03.05 09:22:29 -05'00'