Section 9. Summary Report

1. Device Description[1]

1.1. Device Overview

The ClearMask Transparent Surgical Face Mask (or the Device hereafter) incorporates specific design elements that come together to create a transparent face mask that, when secured properly to the wearer's face, (1) blocks the transfer of bodily fluids, microorganisms, and particulates both to and from the wearer, (2) does not fog, (3) is comfortable/breathable, and (4) allows access to facial expressions and visual cues, as well as lip-reading from the sides or at an angle.

This device consists of (1) transparent plastic film, (2) top foam piece and bottom foam piece, and (4) tie-on straps, that contribute to its core functions.

The device uses a transparent plastic film with an anti-fog coating on both surfaces to prevent fogging, allowing for full visual access to the user's face while blocking splashes and sprays. The compressibility of the top and bottom foam pieces allows for a snug fit between the mask and the user, creating a seal at both the top and bottom of the device while maintaining comfort. The foam pieces also allow for sufficient space between the user and the plastic film to maintain airflow both during inhalations (as air is drawn in through the sides of the mask) and exhalations. Lastly, the tie-on straps (see section 3 for detail) allow the user to secure the mask on the face.

1.2. Proposed Intended Use / Indications for Use

See *004_Indication for Use Statement* in this submission package.

1.3. Device Components

1.3.1. Overview

This device consists of the following components:

(1) transparent plastic film, with an anti-fog coating on both sides, allowing for full visual access to the user's face while blocking splashes and sprays

(2) top foam piece and bottom foam piece, creating a comfortable seal between the mask and the wearer and push the plastic film away from the user to maintain comfort and airflow, and

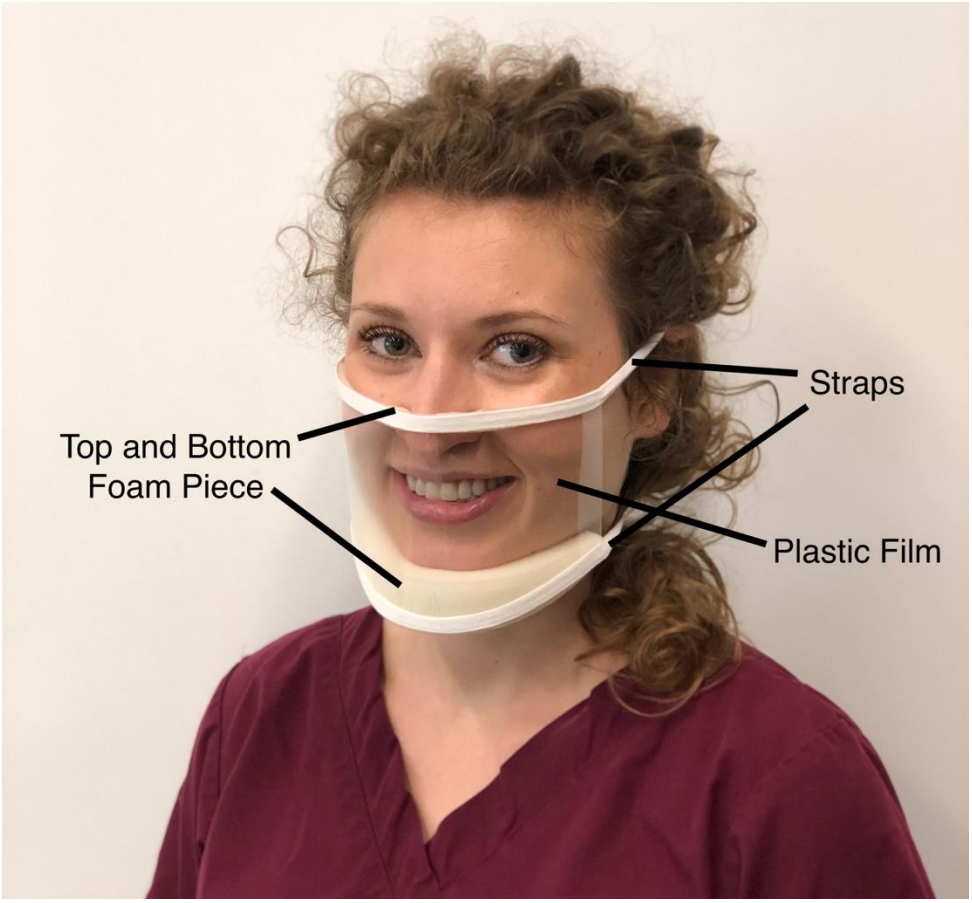
(3) tie-on straps, allowing the user to secure the mask tightly on the face

These components contribute to its core functions of (1) blocking the transfer of bodily fluids, microorganisms, and particulates both to and from the wearer, (2) not fogging, (3) being

[1] As per requirements of section 3 and section 5 of the FDA guidance document Surgical Masks - Premarket Notification [510(k)] Submissions (the Guidance Document hereafter)

comfortable/breathable, and (4) allowing access to facial expressions and visual cues, as well as lip-reading from the sides or at an angle.

See sub-sections below for detailed description on each component.



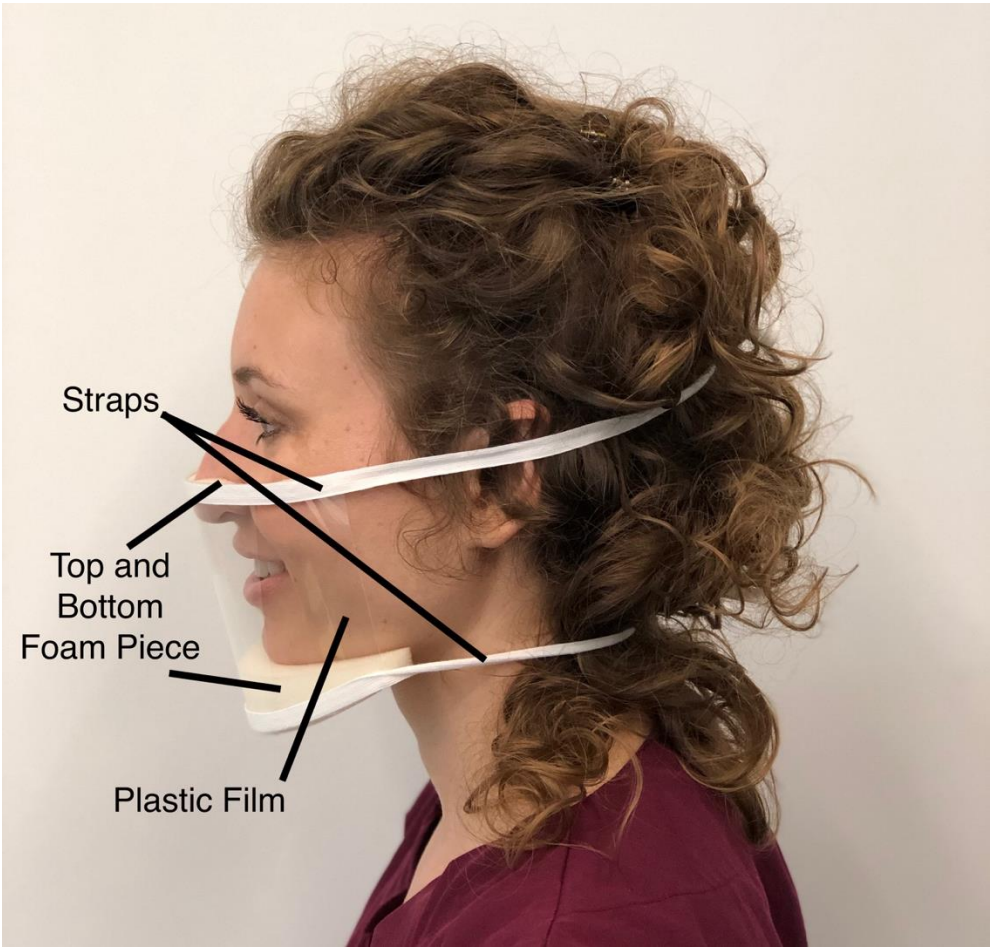


Figure 1. (A) Photo of the device being worn (B) Photo of the device being worn, side view

1.3.2. Component 01 - Plastic Film

The device utilizes an ultra-clear polyester film with an anti-fog coating on both surfaces to reduce surface tension and therefore prevent the formation of condensation (fogging) from the user's breath. The transparency of the film allows for full visual access to the user's face and nose and mouth area, particularly for the purposes of lip-reading and viewing facial expressions. The plastic film shape is designed, when attached to the top and bottom foam pieces, to create space between the user and the plastic film, increasing breathability and comfort. The bottom curve of the plastic film enables the mask to follow the user's jawline, creating a better seal on the bottom of the mask.

Figure 2. Image of the Device, with Plastic Film labelled.
The plastic film is ultra-clear, allowing for full visual access to the user's face.

1.3.3. Component 02 - Top Foam Piece and Bottom Foam Piece

The top foam piece and bottom foam piece are made from polyurethane foam. The shape of the top and bottom foam pieces enable them to push the plastic film away from the wearer's face, preventing the wearer's lips from touching the inside of the mask while speaking, and creating an air pocket that facilitates air exchange.

The top foam piece rests comfortably across the face on the nose level, while also creating a seal along the top of the mask. The divot in the center is designed to fit a variety of nose shapes and sizes. This prevents fogging of wearer's eyeglasses, while also minimizing the warping of the plastic film, which could prevent a clear view of the face.

The bottom foam piece rests on the user's chin, allowing the jaw to move freely while preventing the ClearMask from shifting on the face. The bottom foam pieces tapers as it moves outward from midline, creating a comfortable seal that follows the natural curve of the jawline.

Figure 3. Image of the Device, with Top Foam Piece labelled.
The long, flat edge of the top foam (7.5 in side) should align with the top edge of the plastic piece, and the thickness of the straps (5/16 in) should align with the thickness of the foam piece in the 3rddimension (not shown in above diagram).

Figure 4. Image of the Device, with Bottom Foam Piece labelled.
The bottom curve of the bottom foam aligns with the bottom curve of the plastic piece, and the thickness of the straps (5/16 in) should align with the edge of the foam piece. The thickness of foam should be 0.7 in (for 3rddimension).

1.3.4. Component 03 - Tie-on Straps

The straps allow the user to attach the device securely to the face. The tie-on straps consist of a top and bottom pair of straps, which are tied behind the user's head (one pair running above the ears, and the other pair running below the ears).

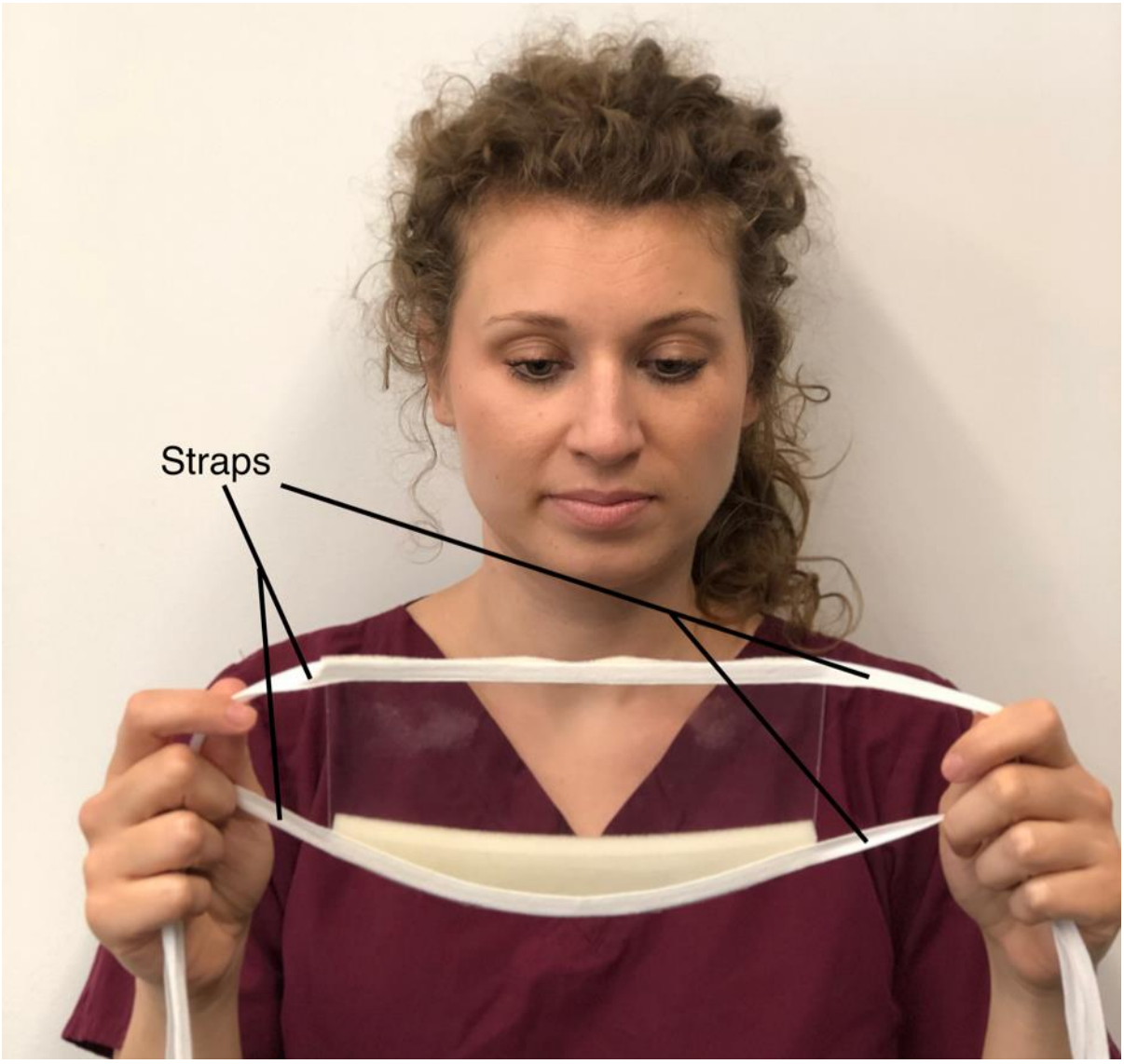


Figure 5. Image of the Device, with Straps labelled.

1.4. Material Specifications

Component Name	Material used	Supplier	Model #	Specifications and MSDS
Plastic Film	Polyester film	MITSUBISHI POLYESTER FILM, INC.	Hostaphan 4FOG	Appendix 9-A
Top and Bottom Foam Piece	Polyurethane foam	FXI	Z100MA	Appendix 9-B

1.5. Device and Predicate Device Descriptions

1.5.1. Proposed Predicate Device

We propose Safe N' Clear Surgical Face Mask (K171162) as predicate device (the Predicate Device) for our device. See table below for general information regarding the Predicate Device.

General Information	
Predicate Device Name	Surgical Earloop Face Mask With Bottom Gap Shield And Surgical Tie-On Face Mask With Bottom Gap Shield (Safe N' Clear)
Predicate Device Manufacturer	Prestige Ameritech
510(K) Number	K171162
510(k) Decision Date	08/15/2017
Device Classification Name	Mask, Surgical
Product Code	FXX
Regulation#	878.4040
Classification	2
Review Panel	General Hospital

1.5.2. Summary of Similarities and Differences

1.5.2.1. Similarities

The ClearMask device is similar to the Predicate Device in that:

- Is a single-use, non-sterile, disposable device intended for use in healthcare settings
- Protects both the patient and provider by blocking the transfer of splashes and sprays
- Has a plastic window for viewing the face (made of a polyester film material)
- Uses tie-on straps to secure the mask to the face

1.5.2.2. Differences

The ClearMask device is different from the Predicate Device in that:

- The transparent window makes up the entirety of the mask, rather than three layers of material (cellulose or spunbonded polypropylene, meltblown polypropylene filter material, medical grade tissue or spunbonded polypropylene), allowing for improved visualization of the user's face
- Does not have an aluminum nosepiece strip, but rather a uniquely shaped top foam piece that allows for the mask to conform to the face while maintaining comfort
- Uses adhesives in place of ultrasonics to bind the materials together

1.5.2.3. Conclusion

There are many similarities between the devices in comparison regarding intended use. The limited differences in technology and device characteristics do not raise new safety or effectiveness concerns for the restricted intended use. We therefore concluded that the proposed device is substantially equivalent to the predicate device in function and intended use.

See Comparison Tables in the section below for a detailed item-by-item comparison between ClearMask Transparent Surgical Face Mask and the Predicate Device.

1.5.3. Substantial Equivalence Comparison Table

1.5.3.1. Overview

Comparison Items	ClearMask	Predicate	Comparison
Product Code	FXX	FXX	Same
Regulation	21 C.F.R Section 878.4040	21 C.F.R Section 878.4040	Same
Classification	Class II	Class II	Same
Intended use	The ClearMask Transparent Surgical Face Mask is intended for use in healthcare settings, such as in operating rooms, or in other medical procedures such as dental, isolation and veterinary procedures during which a face mask is necessary to protect both patient and healthcare personnel from transfer of body fluids, microorganisms, and particulate material. The device allows for full view of the face and facial expressions, particularly the nose and mouth areas. The device is indicated to be over-the-counter use. The device is disposable and is indicated for single use. The device is not provided sterile.	Single use disposable devices intended to be worn in the operating room as well as dental, isolation, and other medical procedures to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material.	Similar
Mask Style	Flat	Flat pleated	Similar
Material Used	Anti-fog Polyester film Polyurethane foam	Cellulose, spunbonded polypropylene, or meltblown Polypropylene Polyester or Polypropylene film	Different The use of the material does not affect the safety or effectiveness of the device
Physical Dimension	7.5 in x 4.3 in x 0.7 in	7.4 in x 3.9 in x 0.25 in (not listed, estimated)	Same
Use Environment	Healthcare or related settings	Healthcare or related settings	Same
Single-use / Multiple-use	Single-use	Single-use	Same
Sterilization	No	No	Same

1.5.3.2. Effectiveness / Performance

Comparison Items	ClearMask	Predicate	Comparison
Performance of Materials Used in	6-254 ASTM F2100-11	6-254 ASTM F2100-11	Same

Comparison Items	ClearMask	Predicate	Comparison
Medical Face Masks			
Bacterial Filtration Efficiency (BFE)	N/A.	6-335 ASTM F2101-14	Different – see section 3.2 under "Inadequate barrier for bacteria"
Particulate Filtration Efficiency (PFE)	N/A.	ASTM F2299	Different – see section 3.2 under "Inadequate barrier for bacteria"
Fluid Resistance	6-406 ASTM F1862/F1862M-17	6-406 ASTM F1862/F1862M-17	Same
Air Exchange and Breathability	Usability Study	MIL-M-36945C (Differential Pressure Test)	Different

1.5.3.3. Safety

Comparison Items	ClearMask	Predicate	Comparison
Biocompatibility for Patient-contacting materials	Biocompatibility evaluation performed based on ISO 10993-1: 2009 and FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued in June 2016	Biocompatibility evaluation performed based on ISO 10993-1: 2009 and FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued in June 2016	Same
Flammability	CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles	CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles	Same

2. Description of Design Requirements[2]

The design and development of the device follows 21 C.F.R Section 820.30 regarding design controls. Design requirements for the device consist of the following sections:

- Device construction and basic dimension
- Primary functions
- Device safety
- Usability
- Others

Sub-sections below summarize Primary Functions, Device Safety and Usability part of the design requirements that are related to the safety and effectiveness of the device.

2.1. Primary Functions

Requirement#	Requirement Item	Note
DR-001-0001	The device shall adequately resist fluid and shall be able to prevent fluid from	

[2] As required by section 3 of the Guidance Document

Requirement#	Requirement Item	Note
	penetrating the mask and reaching to user's skin covered by the device	
DR-001-0002	The device shall provide adequate barrier for bacteria	
DR-001-0003	The device shall allow adequate air exchange to ensure ease of breathing for the user	

2.2. Device Safety

Requirement#	Requirement Item	Note
DR-002-0001	The device shall not cause user skin irritation, allergy or other discomfort after contact less than 24 hours on intact facial skin	
DR-002-0002	The device shall not be flammable (Class 1 in 16 CFR 1610)	
DR-002-0003	The device shall be single-use and shall not be re-processed for re-use	
DR-002-0004	The device shall not be provided sterile	

2.3. Usability

Requirement#	Requirement Item	Note
DR-003-0001	The orientation (up and down) shall be distinguishable by the user	
DR-003-0002	The device shall be able to be secured on user's face; the device shall be secured enough for the user to perform normal surgical operations with no or little relative motion between the device and user's face	
DR-003-0003	The device shall allow clear visual on user's face	This is unique requirements for this device comparing to other surgical masks with fabrics
DR-003-0004	The device shall provide adequate instruction for use (IFU) for the user to understand the use of the device as well as risks (through warning and precautions) associated with the use of the device	

3. Device's Risks, Mitigations and Testing[3]

3.1. Overview

Risk management activities were performed along with the design and development process. Company's standard operation procedure (SOP) is followed for all risk management activities. The risk management process of the device is performed in compliance with ISO 14971:2012 standard. The risks to health described in Section 6 of the Guidance Document were considered and referenced in the risk management process of the devices.

Please see **sub-sections below** for detailed analysis including **identified risks, mitigation measures, and test method(s)**.

3.2. Risks Listed in the Guidance Document

Identified Risk	Test Method	Device Characteristics / Test Criteria	Test Plan / Test Result	Clarification / Justification for V&V
Inadequate fluid resistance	6-406 ASTM F1862 / F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood	• Fluid resistance on a pass/fail basis at three velocities corresponding to the range of human blood pressure (80, 120, 160 mm Hg) • Fluid resistance at 160 mmHg is needed for a Level 3 Medical Face Mask	**To be Verified by 3rd Party Test Lab** Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 +1 (800) 826-2088 See **Appendix 9-C** for Nelson Labs accreditations. **Test Plan:** Applicable conformity verification testing will be conducted on pilot production unit / device sample demonstrating acceptance criteria are met before the device is marketed.	As recommended in the Guidance document

[3] As required by section 3 and section 6 of the Guidance Document

Identified Risk	Test Method	Device Characteristics / Test Criteria	Test Plan / Test Result	Clarification / Justification for V&V
Inadequate barrier for bacteria / Particulate	N/A.	**N/A.**	N/A.	The test protocols for the Bacterial Filtration Testing (ASTM F2101-01) specifies a flow rate of 1 CFM (28.3 LPM) for testing. As confirmed by the 3rd Party Testing Lab (Nelson Labs), for the test systems to work properly, a vacuum is used to maintain the flow rate. If flow through a mask is not possible (close to 0 CFM), the vacuum is not effective in creating the necessary flow rate. For the Particle Filtration Efficiency testing, the standard (ASTM F2299-03) specifies airflow test velocities of 0.5 to 25 cm/s. The way the test system is set up, air flow through the system from the particle generation point is required for particle counters to function. Due to the fact that the bacterial and particle filtration efficiency of a solid plastic film should be 100%, as nothing should pass through a solid plastic film, and the inability of the test method to be physically conducted with a mask that is non-porous, Bacterial Filtration and Particle Filtration tests are not necessary and will not be performed. See Section 3.3 under "Overall performance and construction of the device" for testing performed to cover this risk item.
Inadequate air exchange (differential pressure)	Usability study	Equal to or greater than that of existing approved Level 3 medical face mask	To be validated by the human factor / usability study See **Section 10** of this submission package for detail.	This test method recommended in the Guidance Document, typically used as a measure of breathability, was not used because the airflow through the mask (differential pressure) is not representative of the breathability of this device. Instead, a usability study was conducted to measure breathability of this device.
Flammability	CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles	Class 1 Rating	**To be Verified by 3rd Party Test Lab** Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 +1 (800) 826-2088 See **Appendix 9-C** for Nelson Labs accreditations.	As recommended by the Guidance Document

Identified Risk	Test Method	Device Characteristics / Test Criteria	Test Plan / Test Result	Clarification / Justification for V&V
			Test Plan: Applicable conformity verification testing will be conducted on pilot production unit / device sample demonstrating acceptance criteria are met before the device is marketed.	
Parts that have prolonged contact with intact skin	Biocompatibility evaluation according to ISO 10993 series and FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"	See **Chapter 3.4** below for detail	See **Chapter 3.4** below for detail	As recommended by the Guidance Document.

3.3. Risks Specific to this Device

Identified Risk	Device Characteristics Address the Risk	Test Method	Test Plan / Test Result	Clarification / Justification for V&V
Overall performance and construction of the device	Overall device design, material selection and construction	6-254 ASTM F2100-11 Standard Specification for Performance of Materials Used in Medical Face Masks (Bacterial filtration part is excluded – see details in Section 3.2 under "Inadequate barrier for bacteria")	**To be Verified by 3rd Party Test Lab** Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 +1 (800) 826-2088 See **Appendix 9-C** for Nelson Labs accreditations. **Test Plan:** Applicable conformity verification testing will be conducted on pilot production unit / device sample demonstrating acceptance criteria are met before the device is marketed.	As listed as recognized consensus standard under FDA **Product Code FXX**
The device is incorrectly donned by the user – upside down or not secure	Device's form factor design and labeling design and provision.	Usability study	To be validated by usability study See **Section 10** of this submission package for detail.	Usability study to confirm that the user will be able to, after reading through the provided instruction for use (IFU) document, don the device correctly and securely.
The Device cannot be worn by the user stably and securely – fitness to the user's face	Foam piece design	Usability study	To be validated by usability study See **Section 10** of this submission package for detail.	Usability study to confirm that device's design will ensure the mask will stay on user's face

3.4. Biocompatibility Risks

3.4.1. Biocompatibility Risk Assessment and Identification

According to device's intended use, materials of the device that will come in contact with human body are assessed according to FDA guidance document Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process issued on June 16, 2016 (the Biocompatibility Guidance Document) as well as the International Standard ISO 10993-1 Biological Evaluation of Medical Devices – Part1: Evaluation and Testing Within a Risk Management Process.

Characteristics of material contact, and evaluation methods (according to Table A.1 of the Biocompatibility Guidance Document) are as follows:

Component Name	Material used	Nature of Body Contact	Contact Duration	Biological effects to be evaluated
Plastic Film	Polyester film	Surface - Intact skin	<= 24 hours	• Cytotoxicity • Sensitization • Irritation or Intracutaneous Reactivity
Top and Bottom Foam Piece	Polyurethane foam	Surface - Intact skin	<= 24 hours	• Cytotoxicity • Sensitization • Irritation or Intracutaneous Reactivity

3.4.2. Biocompatibility Study Summary

3.4.2.1. Plastic Film

See information in the table below regarding biocompatibility testing performed on the plastic film material.

Material Name	Hostaphan 4FOG Polyester Film
Material Specifications (MSDS)	See for Appendix 9-A
Test Performed by	Edwards Lifesciences LLC.
Test Items and Conclusions	• Guinea Pig Maximization Test: Pass • Primary skin irritation test: Pass
Standards Used for Testing	USP 26
Test Summary/Report	See for Appendix 9-D for test summary

3.4.2.2. Foam

See information in the table below regarding biocompatibility testing performed on the foam material.

Material Name	**ZM100MA Polyurethane foam**
Material Specifications (MSDS)	See Appendix 9-B
Test Performed by	• North American Science Associates Incorporated • Toxikon
Test Date Range	• 12/2/2009 – 3/15/2010
Test Items	• Cytotoxicity Test • Guinea Pig Maximization Test
Standards Used for Testing	• ISO 10993- 5 • ISO 10993-10
Test Conclusions	• Cytotoxicity - MEM Elution: Pass • Intracutaneous Injection: Pass • Kligman Maximization: Pass
Test Summary/Report	See Appendix 9-E

3.4.3. Biocompatibility Risk Conclusion

The two materials used in this device is the exact same material that went through and passed biocompatibility testing. In addition, manufacturing of the device will only involve cutting and holing in a clean and ISO 13485:2016 certified facility with proper production controls, we believe that no foreign substance will be introduced to the materials during production processes, including packing and shipping.

Given the above-mentioned aspects as well as the fact that the risk level of adverse skin reaction is relatively low (limited exposure), we concluded that the plastic film and foam pieces, as skin-contacting components of the device, will not pose unacceptable biocompatibility related risk to the user.

Appendix 9-A Plastic Film Material Spec and Safe Handling Guide

See attached.

Appendix 9-B Z100MA Foam Specifications and Material Safety Data Sheet (MSDS)

See attached.

Appendix 9-C Nelson Labs LLC Certifications

See attached.

Appendix 9-D Plastic Film Material Supplier Statement and Test Summary Report

See attached.

Appendix 9-E Z100MA Foam Supplier Statement and Test Report List

See attached.