510 (k) Summary

K173062

(1) Applicant information

510 (k) owner's name:	V&Q Manufacturing Corporation
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(2) Proprietary name of the device

Trade name:	Non Woven Face mask (Models: VQN0185W (earloop) and VQN0185B (ties))
Regulation name:	Surgical apparel
Regulation number:	21 CFR 878.4040
Product code	FXX
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(3) Predicate device

Sponsor	Tiger Medical Products Ltd.
Device Name	Face Mask, Surgical Mask, Surgical Face Mask
510(k) Number	K122717
Product Code	FXX
Regulation Number	21 CFR 878.4040
Regulation Class	II

(4) Description/ Design of device

Non Woven Face Mask is a single use multi-layer mask with outer layer and inner layer (spunbond polypropylene) that sandwich a meltblown polypropylene filter material. There are two options for the surgical mask to be secured on users via earloops or ties. Earloops are of urethane elastic fiber and not made with natural rubber latex; and ties are of spunbond polypropylene and also not made with natural rubber latex. The nose piece is a pliable white aluminum strip, covered by polypropylene covering. All of the materials used in the construction of the surgical mask are being

used in currently marketed devices. Non Woven Face Mask has two models which are VQN0185W and VQN0185B. They are basically the same, the only difference is VQN0185W adopts earloops and VQN0185B adopts ties to secure the mask on user.

(5) Indications for use

Non Woven Face Mask (Models: VQN0185W (earloop) and VQN0185B (ties)) is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

(6) Materials

Component of Device Requiring Biocompatibility	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Non Woven Face Mask	Spunbond polypropylene, meltblown polypropylene, urethane elastic fiber, white aluminum strip, blue color master batch.	Surface-contacting device: skin	< 24hours

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

(7) Technological characteristics and substantial equivalence

Item	Subject device	Predicate device	Remark
Trade name	Non Woven Face Mask (Models: VQN0185W (earloop) and VQN0185B (ties))	Face Mask, Surgical Mask, Surgical Face Mask	/
510 (k) number	K173062	K122717	/
Regulation number	21 CFR 878.4040	21 CFR 878.4040	Identical
Regulation description	Surgical apparel	Surgical apparel	Identical

Product code		FXX	FXX	Identical
Class		II	II	Identical
Indications for use/ Intended use		Non Woven Face Mask (Models: VQN0185W (earloop) and VQN0185B (ties)) is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	Surgical mask (with different trade names: Face Mask, Surgical Mask, Surgical Face Mask) is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates.	Similar
Materials	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Similar
	Middle layer	Meltblown polypropylene	Meltblown polypropylene	
	Outer layer	Spun-bond polypropylene	Spun-bond polypropylene	
	Nosepiece	White aluminum strip covered by PP covering	White aluminum strip with PP covering	
	Headband	Urethane elastic fiber or spun-bond polypropylene	Urethane elastic fiber or spun-bond polypropylene	
Mask style		Flat pleated	Flat pleated	Identical
Design feature		Earloop or tie-on	Earloop or tie-on	Identical
Dimensions		175mm×95mm	Approx 170mm×90 mm	Similar
Latex		Not made with natural rubber latex	Latex Free	Identical
Performance test result				
Fluid resistance		Pass at 120mm Hg	Fluid resistant	Similar
Particle Filtration Efficiency		Average 99.74% at 0.1μm	Average 99.54% at 0.1 micron	Similar
Bacterial Filtration Efficiency		Average 99.4%	>99.9%	Similar
Flammability Class		1	1	Identical
Delta – P		Average 2.7 mmH_2O/cm^2	Average 3.38 mmH_2O/cm^2	Difference Note 1
Biocompatibility		ISO10993-5 and ISO10993-10;	ISO10993-5 and ISO10993-10;	Identical

	Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	

- Note 1:
  The Delta-P of the subject device is smaller than that of the predicate device which means user may feel cooler wearing the subject device, since a lower Delta-P translates to increased breathability.

(8) Non-clinical studies and tests performed

The performance tests of Non Woven Face Mask were conducted.

- ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F1862 Standard test method for resistance of medical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity)
- ASTM F 2101-14 Standard Test Method For Evaluating The Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus.
- MIL-M-36954C Military Specification - Mask, Surgical, Disposable
- 16 CFR Part 1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES

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

- ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

(9) Conclusion

Based on the non-clinical tests performed, the subject device is as safe, as effective, and performs as well as the predicate device.