January 25, 2018

V&Q Manufacturing Corporation
% Tracy Che
Registered engineer
Feiying Drug & Medical Consulting Technical Service Group
B-3F 3005, Bldg.1, Southward Ruifeng Business Center, No 22
Guimiao Road
Shenzhen, 518000 CN

Re: K173062
Trade/Device Name: Non Woven Face Mask (Models: VQN0185W (earloop) and VQN0185B (ties))
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 3, 2018
Received: January 5, 2018

Dear Tracy Che:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173062

Device Name
Non Woven Face Mask (Model: VQN0185W(earloop) and VQN0185B(ties))

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510 (k) Summary

K173062

(1) Applicant information

510 (k) owner's name:	V&Q Manufacturing Corporation
Address:	#B1614 optical valley time square, Wuhan, Hubei, CHINA
Contact person:	Jacky Jin
Phone number:	86-27-87680925
Fax number:	86-27-87680926
Email:	jackyj@chinavqmc.com
Date of summary prepared:	2018.01.24

(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.