Establishment Registration & Device Listing

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Proprietary Name:	AIR QUEEN; AIR QUEEN BREEZE; Nano Mask; PURE MASK; TECHNO WEB; TECHNOWEB
Classification Name:	MASK, SURGICAL
Product Code:	FXX
Device Class:	2
Regulation Number:	878.4040
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	NANO FILTER, INC
Registered Establishment Number:	3016766213
Premarket Submission Number:	K172500
Owner/Operator:	TOPTEC Co., LTD.
Owner/Operator Number:	10072713
Establishment Operations:	Contract Manufacturer

Page Last Updated: 06/08/2020

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

510(k) Premarket Notification

Device Classification Name	Mask, Surgical
510(K) Number	K172500
Device Name	Technoweb Surgical Mask
Applicant	YTS GLOBAL INC. 7406 ALBAN STATION CT STE A 108 Springfield, VA 22150
Applicant Contact	Eddie Nguyen
Correspondent	YTS GLOBAL INC. 7406 ALBAN STATION COURT SUITE A108 Springfield, VA 22150
Correspondent Contact	Eddie Nguyen
Regulation Number	878.4040
Classification Product Code	FXX
Date Received	08/18/2017
Decision Date	03/01/2018
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General & Plastic Surgery
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

U.S. FOOD & DRUG ADMINISTRATION

May 18, 2018

Yts Global Inc.
Eddie Nguyen
Senior Logistics Specialist
7406 Alban Station Court Suite A108
Springfield, Virginia 22150

Re: K172500
Trade/Device Name: Technoweb Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 23, 2018
Received: January 29, 2018

Dear Eddie Nguyen:

This letter corrects our substantially equivalent letter of March 01, 2018.

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,

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)*
K172500

Device Name
Technoweb Surgical Mask

Indications for Use *(Describe)*
The Technoweb Sugical Mask is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

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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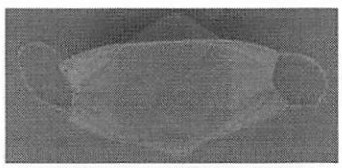
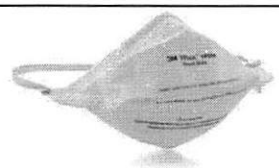
510(k) SUMMARY

The assigned 510(k) number is : K172500

510(k) Owner/Applicant	Finetex EnE, inc
US Correspondent	Eddie Nguyen YTS GLOBAL INC 7406 ALBAN STATION COURT SUITE A108 SPRINGFIELD, VA 22150 (703)340-8178
Date Prepared	February 26, 2018
Trade Name	Technoweb Surgical Mask,
Common Name	Surgical Respirator
Classification Name	Surgical Apparel
Review Panel	General Hospital
Product Code	MSH
Device Classification	Class II per 21 CFR 878.4040
Predicate Device	3M VFlexTM Health Care Particulate Respirator and Surgical Mask, Model 1805/1805S cleared under K121069

Table – Substantial Equivalence Comparison.

Proprietary		Finetex EnE, inc	3M Health Care	Substantial Equivalence
Common Name		TechnoWeb Surgical Mask	3M™ VFlex™ HealTh Care Particulate Respirator and Surgical mask,	SAME
Model Number		TM-R, TM-S	1805/1805S	-
Manufacturer		Finetex EnE, inc	3M Health Care	-
510(k) Reference Number		K172500	K121069	
Intended use		Surgical Mask/Respirator	Surgical Mask/Respirator	SAME
Design				SIMILAR
Single Use		Yes	Yes	SAME
Material	Outside cover web	Felt	Polypropylene spunbond	SIMILAR
	Stiffener web	N/A	Polypropylene spunbond	SIMILAR
	Filter web	Felt	Polypropylene	SIMILAR
	Inner web	Felt	Polypropylene	SIMILAR
	Nose-Clip	Aluminum	Aluminum	SAME
	Staple	N/A	Steel	SIMILAR
	Headband	Nylon	Polyisoprene	SIMILAR
	Nose foam	Plastic coating	N/A	SIMILAR
Dimensions		TM-R is 212mm(W), 74mm(H) and model TM-S is 177.8 mm(W), 138 mm(H).		SIMILAR
Product style		Flat fold	Flat fold	SAME
Design Features		Ear loops	Advanced Electostatic Media	SIMILAR
Fluid Resistance (ASTM F1862)		fluid resistance at 12 mmHg.	YES	SIMILAR

Indication for Use	is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	SAME

Device Description	Technoweb Surgical Mask is a type of surgical mask covers the user's nose and mouth. And provides a physical barrier to fluids and particulate materials. Technoweb Surgical Mask is a flat, pleated tie-on or elastic ear-loop mask consisting of three nonwoven layers; inner and outer cover web with middle different filter web sandwiched in between.
Intended Use	The Technoweb Sugical Mask is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.
Model Numbers	TM-R and TM-S (Different Sizes)
Technological Characteristics	Technoweb Surgical Mask is a type of surgical mask covers the user's nose and mouth. And provides a physical barrier to fluids and particulate materials. Technoweb Surgical Mask is a flat, pleated tie-on or elastic ear-loop mask consisting of three nonwoven layers; inner and outer cover web with middle different filter web sandwiched in between.
Performance Testing	Laboratory testing regarding characteristics was performed on Technoweb surgical mask to verify its safety and performance. A biocompatibility assessment was performed on the patient contact materials of Technoweb surgical mask.
Conclusions	Finetex EnE, inc concludes that the Technoweb surgical mask is as safe and as effective and is substantially equivalent to predicate device, 3M Health Care Particulate Respirator and Surgical Mask,