November 1, 2022

America's Supply Chains
% Prithul Bom
Accredited Person, Reviewer
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K223270
Trade/Device Name: POSE™ Health Care Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 22, 2022
Received: October 24, 2022

Dear Prithul Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223270

Device Name
POSE™ Health Care Surgical Mask

Indications for Use *(Describe)*

The POSE™ Health Care Surgical 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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AMERICA'S SUPPLY CHAINS

510(k) Summary

This summary of 510(k) is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

America's Supply Chains
7555 Warren Pkwy, Unit 486
Frisco, TX 75034 USA

Contact Person: Paul Park
Tel: (617) 800-3602
Email: americasupplychains@gmail.com
Date Prepared: October 05, 2022

II. DEVICE

Name of Device:	POSE™ Health Care Surgical Mask
Common or Usual Name:	Surgical Mask
Classification Name:	Surgical Apparel
Regulatory Class:	Class II (21 CFR §878.4040)
Regulation Medical Specialty:	General & Plastic Surgery
510k Review Panel:	General Hospital
Product Code:	FXX

III. PREDICATE DEVICE

Predicate Manufacturer:	YTS GLOBAL INC
Predicate Trade Name:	Technoweb Surgical Mask
Predicate 510(k):	K172500
Device Classification Name:	mask, surgical
Device Name:	Technoweb Surgical Mask
Regulatory Class:	Class II (21 CFR §878.4040)
Regulation Number:	878.4040
Classification Product Code:	FXX
Decision:	Substantially Equivalent (SESE)
Regulation Medical Specialty:	General & Plastic Surgery
510k Review Panel:	General Hospital
Type:	Traditional

IV. DEVICE DESCRIPTION

POSE™ Health Care Surgical Mask is composed of three-layers and is flat fold. The mask materials consist of an outer cover web (polypropylene spunbond, white), filter web (polypropylene melt-blown, white) and inner cover web (polypropylene thermal-bonded, white). Each mask contains ear loops to secure the mask to the user's face and mouth, as well as a fully enclosed, soft, bendable nose piece to fit over the nose.

This device is not made from natural rubber latex.

V. INDICATIONS FOR USE

POSE™ Health Care Surgical 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following characteristics were compared between the subject device and the predicate device in Table 1 below.

[Table 1: Comparison of Predicate Devices]

AMERICA'S SUPPLY CHAINS

Description	Subject Device POSE™ Health Care Surgical Mask ASTM Level 3	Predicate Device (K172500) Technoweb Surgical Mask	Comparison
Intended Use/ Indications 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
Materials			
Outer Cover Web	Polypropylene Spunbond, white	felt	similar
Filter Web (Middle)	Polypropylene Meltblown, white	felt	similar
Inner Cover Web	Polypropylene Spunbond, white	felt	similar
Nose Piece	Polyethylene Aluminum Wire	Aluminum	similar
Ear Loops	Spandex elastic cord	Nylon	similar
Style	Flat - Fold	Flat - Fold	Same
Multiple Layers	3-Ply	3-Ply	Same
Colors	White	White	Same
Dimension (Width)	180mm	TM-R is 212mm(W) TM-S is 177.8mm(W)	similar

Dimension (Length)	90mm	TM-R is 74mm(H) TM-S is 138mm(H)	similar
OTC Use	Yes	Yes	Same
Sterility	Non-Sterile		Similar
Use	Single Use	Single Use	Same
ASTM F2100 Level	Level 3		Similar

VII. PERFORMANCE DATA

The subject device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004. A summary of the benchtop performance testing results is provided below in Table 2.

[Table 2: Benchtop Performance Testing]

Item	Proposed Device POSE™ Health Care Surgical Mask ASTM Level 3	ASTM Level 3 Mask Standard Acceptance Criteria	Predicate Device (K172500) Technoweb Surgical Mask	Result
ASTM F1862/ISO 22609 Fluid Resistance	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at 160mmHg Lot 1: 32 /32 pass Lot 2: 32 /32 pass Lot 3: 32 /32 pass	AQL 4%, single sampling plan, 29 out of 32 Pass at 160mmHg		Pass
ASTM F2299 Particulate Filtration Efficiency	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥98% Lot 1: 32/32 pass Lot 2: 32/32 pass Lot 3: 32/32 pass	≥ 98%		Pass
Bacterial Filtration Efficiency ASTM F2101	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥98% Lot 1: 32/32 pass Lot 2: 32/32 pass Lot 3: 32/32 pass	≥ 98%		Pass
Differential Pressure ASTM F2100/EN 14683:2019	Three non-sequential lots of 32 (total of 96) passed at <6mmH2O/cm2 MIL-M36954C Lot 1: 32/32 pass Lot 2: 32/32 pass Lot 3: 32/32 pass	AQL 4%, single sampling plan, <6.0 mmH2O/cm2		Pass

Class 1 Flammability 16 CFR 1610	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed Class 1 16 CFR 1610 Lot 1: Class 1, DNI Lot 2: Class 1, DNI Lot 3: Class 1, DNI	Class 1 < 3.5 second burn time		Pass

Sterilization & Shelf-life Testing

Not Applicable (This is a non-sterile device and shelf-life is not applicable to this device because of low likelihood of time-dependent product degradation.)

Biocompatibility Testing

Biocompatibility testing was performed in accordance with ISO 10993-1:2018. Specifically, the following testing endpoints were evaluated.

[Table 3: Biocompatibility Testing]

Biocompatibility Testing Endpoints	Acceptance Criteria	Result
Cytotoxicity – ISO 10993-5 Skin Sensitization – ISO 10993-10 Skin Irritation – ISO 10993-10	Non-Cytotoxic Non- Sensitizing Non-Irritating	Pass Pass Pass

[Table 4: Summary of Non-Clinical Performance Testing]

The following standards have been used to evaluate the High Fluid-Resistant Surgical and Procedure Mask:

ASTM F2101-19/EN 14683:2019	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
ASTM F1862/F1862M-17	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
ASTM F2299-17	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
ASTM F2100/EN	Standard Test Method for Differential Pressure

14683:2019 ANNEX C	Standard Specification for Performance of Materials Used in Medical Face Masks
16 CFR Part 1610 EN 14683:2019 ANNEX C	Standard for Flammability
ISO 10993-5	ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Software Verification and Validation Testing

Not Applicable (Passive Device)

Electrical safety and electromagnetic compatibility (EMC)

Not Applicable (Passive Device)

Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Human Clinical Performance Testing

Clinical testing was not required to demonstrate the safety and effectiveness of the device.

VIII. CONCLUSIONS

The conclusions drawn from the performance data demonstrate that the subject device is as safe, effective, and performs as well as or better than the legally marketed device K172500, Technoweb Surgical Mask manufactured by YTS GLOBAL INC.