December 17, 2021

Topwide Medical Products Manufacturer
% Jimmy Wu
Associate
Lee and Xiao
2600 Mission Street, Suite 206
San Marino, California 91108

Re: K210102
Trade/Device Name: Topwide Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: General Hospital
Regulatory Class: Class II
Product Code: FXX
Dated: October 30, 2021
Received: November 3, 2021

Dear Jimmy Wu:

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,

Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210102

Device Name
TOPWIDE SURGICAL FACE MASK

Indications for Use *(Describe)*

The TOPWIDE surgical face mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The TOPWIDE surgical intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This device is non-sterile and for single use only.

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
K210102

1. **Type of 510(k) submission:** Traditional Submitted on: 12/13/2021

2. **Device Type:** Mask, Surgical

3. **510(k) Submitter/Owner:**

Name: Topwide (Hubei) Medical Products Manufacturer

Address: 19 Xianhong Road, Xin Li Ren Kou
Xiantao, Hubei 433012
CHINA

Phone: 86-728-2714000 Fax: 86-728-2712999

Contact: Jimmy Wu Email: JWU@LEEXIAO.COM

4. **Device:**

Common Name:	Surgical Face Mask
Trade Name:	Topwide Surgical Face Mask
CFR Section:	21 CFR 878.4040
Product Classification:	Class II
Classification Panel:	General Hospital
Product Code:	FXX

5. **Basis for the Submission:** New Device

6. **Predicate Device:** Single-Use Surgical Mask with Ear Loop (K201691)

7. **Indication For Use:**
The TOPWIDE surgical face mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The TOPWIDE surgical intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This device is non-sterile and for single use only.

8. **Device Description:**
The Topwide surgical face mask is with white color outer layer and white inner layer. Subject device is a Flat Pleated type mask, utilizing ear-loop way for wearing, and it has a nose piece design for fitting the facemask around the nose. The mask materials consist of an outer layer (polypropylene spunbond), inner layer (polypropylene spunbond), filter (polypropylene melt-blown) and ear-loops. The mask contains a malleable nosepiece to provide a firm fit over the nose and then to secure the mask over the users' mouth and face. The mask has Level II fluid resistance under ASTM F2100. The mask is a single use, provided non-

sterile.

This product contains no components made with natural rubber latex.

9. Technological Characteristic Comparison

Device	Subject Device - Topwide Surgical Face Mask (K210102)	Predicate Device - Single-Use Surgical Mask with Ear Loop (K201691)	Comparison
Intended Use	The TOPWIDE surgical face mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The TOPWIDE surgical intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This device is non-sterile and for single use only.	The Single-Use Surgical Mask with Ear Loop is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Single-Use Surgical Mask with Ear Loop intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device(s), provided non-sterile. Model: M and L, blue color, and Level 2 barrier level as ASTM F2100.	**Same**
Design feature			
Outer layer	Spun-bond polypropylene	Spun-bond polypropylene	**SAME**
Middle layer	Melt blown polypropylene	Melt blown non-woven fabric	
Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	
Nose piece	Wire, malleable nosepiece, plastic-coated steel	Wire, malleable aluminum nosepiece	**DIFFERENT**
Ear Loops	Polyester and spandex materials	Polyester	**SAME**
Color	White outer layer	Blue	**DIFFERENT**
Mask style	Flat pleated, Ear-Loop	Flat pleated, Ear-Loop	**SAME**
Size	Length: 17.5 cm ± 0.5 cm, Width: 9.5 cm ± 0.5 cm	Large: Length - 18 cm ± 1 cm, Width 9 cm ± 1 cm	**DIFFERENT**

Single Use	Yes	Yes	**SAME**
OTC Use	Yes	Yes	
Sterile	Non-Sterile	Non-Sterile	

Performance			
ASTM F2100 Level	II	II	**SAME**
Fluid resistance (ASTM F1862)	32 out of 32 pass at 16Kpa (120 mmHg)	31 out of 32 pass at 120 mmHg	**SIMILAR**
Particulate Filtration (ASTM F2299)	≥ 99.78%	> 99%	
Bacterial Filtration (ASTM F2101)	≥ 98%	> 99%	
Differential Pressure (Delta-P) (ASTM F2100)	<28.8 pa/cm2 (2.94 mmH2O/cm2)	< 5.0 mmH2O/cm2	
Biocompatibility ISO10993	Irritation (ISO 10993-10), Sensitization (ISO 10993-10), Cytotoxicity (ISO 10993-5)	Irritation (ISO 10993-10), Sensitization (ISO 10993-10), Cytotoxicity (ISO 10993-5)	**SAME**
Flammability	Class 1	Class 1	

10. Summary of Non-Clinical Test

Following performance data has been provided from 3 nonconsecutive lots to demonstrate that the subject device meet the acceptance criteria the standard.

Test Methodology, Standard	Purpose	Acceptance Criteria	Results
ASTM F1862	Resistance to penetration by synthetic blood	120 mm Hg	120 mm Hg
ASTM F2299	Particulate filtration efficiency	≥ 98%	>99%
ASTM F2101	Bacterial filtration	≥ 98%	≥ 98%
16 CFR 1610	Flammability	Class 1	Class 1
ASTM F2100	Differential Pressure (Delta-P)	< 6.0 mm H_2O/cm_2	2.94 mmH2O/cm2
ISO 10993-5, ISO 10993-10	Biocompatibility	Not cytotoxic, irritating or sensitizing under the conditions of the studies	PASSED

11. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.