September 4, 2020

Shandong Shengquan New Material Co., Ltd.
℅ Shelley Li
Director
Shanghai Landlink Medical Information Technology Co., Ltd.
Room 703, 705, Baohua International Plaza
West Guangzhong Road 555, Jingan
Shanghai 200071
China

Re: K201537
Trade/Device Name: Protective Face Mask for Medical Use
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 4, 2020
Received: June 8, 2020

Dear Ms. Shelley Li:

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,

Elizabeth Claverie, MS
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)*
K201537

Device Name
Protective Face Mask for Medical Use

Indications for Use *(Describe)*
The Protective Face Mask for Medical Use is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The face mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

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.

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510(k) Summary

I. Submitter

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Preparation date: Sept. 02, 2020

II. Proposed Device

Trade Name of Device:	Protective Face Mask for Medical Use
Common name:	Surgical Mask
Regulation Number:	21 CFR 878.4040
Regulatory Class:	Class II
Product code:	FXX
Review Panel	General Hospital

III. Predicate Device

510(k) Number:	K143287
Trade name:	FLUIDSHIELD Surgical Mask with Expanded Chamber
Common name:	Surgical Mask
Classification:	Class II
Product Code:	FXX
Manufacturer	Halyard Health, Inc.

IV. Device description

The Protective Face Mask for Medical Use is a single use, two-panel, flat–folded mask with ear loops and nose piece. The mask is designed into a C-shape when flat-folded. The C-shaped design allows for an expanded chamber for the mask in use.

The mask materials include four layers, the inner and outer layers are made of spun-bond polypropylene, and the two middle layers are melt-blown polypropylene and non-woven polypropylene filters, respectively.

The elastic ear loops are made of spandex and polyester, which are welded to the facemask to hold the mask in place over the users' mouth and nose. The elastic ear loops are not made with natural rubber latex. The nose piece is a malleable aluminum strip covered with sponge, which is welded to the facemask top edge to allow the user to fit the facemask around their nose. The mask is a single use, disposable device, provided non-sterile in white color

V. Indication for use

The Protective Face Mask for Medical Use is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The face mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

VI. Comparison of technological characteristics with the predicate device

Table 1: General Comparison

Item	Proposed device	Predicate device (K143287)	Comparison
Product name	Protective Face Mask for Medical Use	FLUIDSHIELD Surgical Mask with Expanded Chamber	-
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Classification	Class II	Class II	Same
Mask style	Expanded chamber flat-folded, ear loops, 4 layers	Expanded chamber (Duckbill) flat-folded, headband ties, 4 layers	Similar
Indication for use	The Protective Face Mask for Medical Use is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The face mask is intended	The Expanded Chamber Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for	Same

		for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.	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.	
Material	Inner layer	Spun-bond polypropylene	Polyethylene/Polyester	Different
	Middle layer	polypropylene non-woven fabric	Spun-bond polypropylene	Different
		Melt-blown polypropylene	Melt-blown polypropylene	Same
	Outer layer	Spun-bond polypropylene	Top Half: Blue spun-bond polypropylene (w Print) Bottom Half: White spun-bond polypropylene	Similar
	Ear loop/headband	Spandex + Polyester	Polyester spunlace or spun-bond polypropylene	Similar
	Nose piece	Plastic coated aluminum wire covered with sponge strips	Unknown	
Color		White outer layer and gray inner layer	Top Half: Blue Bottom Half: White	Different
Size		Length: 16.5±0.8cm Width: 10.5±0.5cm	Length: 21.0±1.0 cm Width: 19.0± 0.3 cm	Different
OTC use		Yes	Yes	Same
Sterility		Non-sterile	Non-sterile	Same
Use		Single use, disposable	Single use, disposable	Same
ASTM F2100 Level		Level 2	Level 2	Same

VII. Non-Clinical Testing

The proposed 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.

Table 2: Performance testing

Test Items	Acceptance Criteria	Results
Fluid Resistance Performance ASTM F1862M-17	29 out of 32 pass at 120 mmHg	32 out of 32 pass at 120mmHg
Particulate Filtration Efficiency ASTM F2299	>98%	99.22%
Bacterial Filtration Efficiency ASTM F2101-19	>98%	99.89%
Differential Pressure EN 14683:2019 Annex C	<6.0 mm H_2O/cm^2	4.2 mmH_2O/cm^2
Flammability 16 CFR 1610	Class 1 Non-Flammable	Class 1 (not ignited)

Table 3: Biocompatibility testing

Testing Items	Standards	Results
Cytotoxicity	ISO 10993-5:2009	Pass (Non-Cytotoxic)
Irritation	ISO 10993-10:2010	Pass (Non-Irritating)
Sensitization	ISO 10993-10:2010	Pass (Non-Sensitizing)

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated K143287, Halyard Health FLUIDSHIELD Surgical Mask with Expanded Chamber.