November 30, 2021

Anhui Cleanpro Pharmpack Co., Ltd.
Chong Xiuming , Regulatory Manager
Yeshan Industrial Zone
Tianchang, Anhui 239300
CHINA

Re: K211696
Trade/Device Name: Disposable Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 20, 2021
Received: October 25, 2021

Dear Chong Xiuming:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211696

Device Name
Disposable Surgical Face Mask

Indications for Use *(Describe)*
The Disposable Surgical Face Masks are 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 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.

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

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

Date prepared: October 20.2021

1. Submitter Name and Address:

Owner Name: Anhui Cleanpro Pharmpack Co., Ltd.
Establishment Registration Number : 3016771217
Address: Yeshan Industrial Zone, Tianchang City, Anhui, China.
Post Code: 239300
Contactor Name: Chong Xiuming
TEL: +86-550-7981778
E-mail: carlchong@126.com

Manufacturer Name: Anhui Cleanpro Pharmpack Co., Ltd.
Address: Yeshan Industrial Zone, Tianchang City, Anhui, China.
Post Code: 239300

US Agent:
US Agent: LI QIAN
Address: 4319 Abbotts Bridge Rd STE 3 Duluth Duluth, GA US 30097
TEL: 404 4261248 Ext
Email : Li@Carelifeusa.Com

2. Submission Devices Information:

Trade/Proprietary Name: Disposable Surgical Face Mask
Common Name: Disposable Surgical Face Mask
Classification name: Surgical Apparel.
Class: II.
Product codes: FXX
Submission Type: 510(K)
Regulation Number: 21 CFR 878.4040

3. Predicate Devices Information:

Company Name: BH Medical Products Co., Ltd.
Address: No.90 Zhangjia Industrial Area, Xiling, Changzhou, Jiangsu, China 213024
Trade Name: Surgical Face Mask
Class: II.

510(K) Number: K133070
Product codes: FXX
Submission Type: 510(K)
Regulation Number: 21 CFR 878.4040

4.Devices Description:

The proposed device(s) are Blue color, and Flat Pleated type mask, utilizing Tie-On or Ear Loops way for wearing, and they all has Nose Piece design for fitting the face mask around the nose.

The outer layer is blue, and the colorant material is identified as Phthalocyanine Blue , CAS number: 147-14-8.

The proposed device(s) are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter.

The model of proposed device, tie-on, is held in place over the uers's mouth and nose by four ties welded to the face mask. The tie is made of spun-bond polypropylene.

The model of proposed device, ear loops, is held in place over the uers's mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex.

The nose piece contained in the proposed device(s) is in the layers of facemask to allow the user to fit the facemask around their nose, which is made of malleable aluminum wire.

The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

5. Indications for use:

The Disposable Surgical Face Masks are 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 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.

6. Comparison of technological characteristics with the predicate:

The primary components of The Disposable Surgical Face Masks are manufactured to identical or similar specifications of the predicated devices listed above. The intended use, basic design, function and materials used are identical or similar to the predicate devices.

Table 1 General Comparison

Element of Comparison		**Submission Device**	**Predicate Device K133070**	**Comparison**
Manufacturer		**Anhui Cleanpro Pharmpack Co., Ltd.**	**BH Medical Products Co., Ltd.**	/
510 (k)		**K211696**	**K133070**	/
Proprietary or Model Name		Surgical Face Mask, Ear Loops, Model:CRWKE001 Surgical Face Mask, Tie-on, Model:CRWKT001	Surgical Face Mask, Ear Loops, Model 101B, 101G, 136B, 136G, 137B, 137G Surgical Face Mask, Tie-on, Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G, 151B, 151G.	Similar
Classification		Class II Device, FXX (21CFR878.4040)	Class II Device, FXX (21CFR878.4040)	Same
Intended use/Indications for Use		The Disposable Surgical Face Masks are 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 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.	The Surgical Face Masks are 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 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.	Same
Ear loop model and Tie-on model		Ear Loops, Tie-On	Ear Loops, Tie-On	Same
Mask styles		Flat Pleated, 3 layers	Flat Pleated, 3 layers	Same
Materials	**Outer Facing Layer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle Layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner Facing Layer	Spun-bond polypropylene	Spun-bond polypropylene	Same

	Tie-on	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose Piece	Malleable aluminum wire	Malleable aluminum wire	Same
	Ear Loops	Polyester	Polyester	Same
Design features		Color : Blue	Color : Blue, Green	Similar
Dimension (Length)		17.5 cm +/- 0.5cm	6.8”+/-0.25”	Similar
Dimension (Width)		9.5 cm +/- 0.5cm	3.5”+/-0.25” 4.2”+/-0.25”	Similar
OTC use		Yes	Yes	Same
Single Use		Yes	Yes	Same
Sterile		No	No	Same
ASTM F2100 Level		Level 3	Level 1、Level 2、 Level 3	Similar

Table 2 Performance Characteristic Comparison

Element of Comparison	Submission Device	Predicate Device K133070	ASTM F2100 Requirements for Level 3 Classification	Comparison
Fluid Resistance Performance ASTM F1862	1、LOT NO.: CR202101 1~32,32 out of 32 pass at 160 mmHg 2、LOT NO.: CR202102 33~64,32 out of 32 pass at 160 mmHg 3、LOT NO.: CR202103 65~96,32 out of 32 pass at 160 mmHg	Pass	29 out of 32 pass at 160 mmHg	Same
Particulate Filtration Efficiency ASTM F2299	1、LOT NO.: CR202101 1~32：≥ 99% 2、LOT NO.: CR202102 33~64：≥ 99% 3、LOT NO.: CR202103 65~96：≥ 99%	≥ 98%	≥ 98%	Same
Bacterial Filtration Efficiency ASTM F2101	1、LOT NO.: CR202101 1~32：≥ 99% 2、LOT NO.: CR202102 33~64：≥ 99% 3、LOT NO.: CR202103 65~96：≥ 99%	≥98%	≥98%	Same
Differential Pressure (DeltaP) MIL-M-36954C	1、LOT NO.: CR202101 1~32：<6.0 mmH_2O/cm^2 2、LOT NO.: CR202102 33~64：<6.0 mmH_2O/cm^2 3、LOT NO.: CR202103 65~96：<6.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	Same
Flammability 16 CFR 1610	1、LOT NO.: CR202101 1~32：IBE 2、LOT NO.: CR202102 33~64：IBE 3、LOT NO.: CR202103 65~96：IBE	Class 1 Non Flammable	Class 1 （Burn time ≥3.5 seconds, IBE, or DNI）	Same

Table 3 Biocompatibility Comparison

Element of Comparison	Submission Device	Predicate Device K133070	Comparison
Cytotoxicity	Under the conditions of the study, not cytotoxicity effect（Comply with ISO 10993-5）	Under the conditions of the study, not cytotoxicity effect（Comply with ISO 10993-5）	Same
Irritation	Under the conditions of the study, not an Irritant（Comply with ISO 10993-10）	Under the conditions of the study, not an Irritant（Comply with ISO 10993-10）	Same
Sensitization	Under conditions of the study, not a sensitizer.（Comply with ISO 10993-10）	Under conditions of the study, not a sensitizer.（Comply with ISO 10993-10）	Same

7.Summary non-Clinical Test:

Discussion of Non-Clinical Tests Performed:
The performance tests of surgical face masks were conducted.

Test Methodology	Test Methodology Purpose	Acceptance Criteria	Results
ASTM F2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres	To evaluate the effectiveness of the test article in protecting the user from possible exposure to body fluids.	≥98%	Passed
ASTM F1862-17 Standard Test Method For Resistance Of Medical Face Masks To Penetration By Synthetic Blood (Horizontal Projection Of Fixed Volume At A Known Velocity)	To evaluate the effectiveness of the test article in protecting the user from possible exposure to particulates.	Level 3, No penetration at 160mmHg	Passed
ASTM F2101-19 Standard Test Method For Evaluating The Bacterial Filtration Efficiency (Bfe) Of Medical	To evaluate the bacterial filtration efficiency (BFE) of mask.	≥98%	Passed

Face Mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus. (General Plastic Surgery/General Hospital)			
MIL-M-36954C Military Specification - Mask, Surgical, Disposable 16 CFR Part 1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES	To evaluate the flammability of mask.	Class 1, Resist ignition or flame （Burn time ≥3.5 seconds, IBE, or DNI）	Passed
Differential Pressure (Delta P) EN14683:2019, Annex C and ASTM F2100-19	To measure the differential pressure of mask which is related to breathability.	<6.0 mmH_20/cm^2	Passed
ISO 10993-5: 2009, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)	To evaluate the biological safety of the product which has direct contact with intact skin.	The test article should not have potential toxicity to L-929 in the MTT method.	Passed
ISO 10993-10: 2010, Biological Evaluation Of Medical Devices-Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility)	To evaluate the biological safety of the product which has direct contact with intact skin.	The test article should not cause delayed dermal contact sensitization in the guinea pig. The dermal irritation response category in the rabbit should be negligible.	Passed Passed

Discussion of Clinical Tests Performed: None

8. Conclusion:

Based on the comparison and analysis above, the Anhui Cleanpro Pharmpack Co., Ltd. Disposable Surgical Face Mask is as safe, as effective, and performs as well as the legally marketed predicate device, BH Medical Products Co., Ltd. Surgical Face Mask cleared under K133070.

END