December 24, 2021

Skypro Medical Supplies Company
Cyrus Wong
General Manager
C301, Tsing Yi Industrial Centre Phase 2,
1-33 Cheung Tat Road, Tsing Yi, N.T.
Hong Kong,
China

Re: K202255
Trade/Device Name: Skypro, SP02 Mask (Level 3)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 9, 2021
Received: December 13, 2021

Dear Cyrus Wong:

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,

For 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)*
K202255

Device Name
Skypro, SP02 Mask (Level 3)

Indications for Use *(Describe)*
"Skypro, SP02 Mask (Level 3)" is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. It is intended for infection control practices to reduce the potential exposure of the wearer to blood and body fluids. It is a non-sterile, single-use, and disposable device.

Description	Item No.	Color	Size
Earloop mask	L3RELX	Blue	175 mm x 95 mm
Earloop mask	L3MELX	Blue	145 mm x 95 mm
Tie-on mask	L3RTOX	Blue	175 mm x 95 mm

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
K202255

Skypro Medical Supplies Company

Date of Submission: 9th December, 2021
Date of Preparation: 9th December, 2021

1. Manufacturer

Company: SPRO Medical Products (Xiamen) Co., Ltd
Address: No.139 Factory Building, TongAn Garden, TongAn Industrial Area, Xiamen, Fujian Province, 361100, P. R. China

2. Official Correspondent and Applicant

Contact Person: Cyrus Wong (General Manager)
Company: Skypro Medical Supplies Company
Address: Flat C301, 3/F, Block C, Phase 2, Tsing Yi Industrial Centre, 1-33 Cheung Tat Road, Tsing Yi, New Territories, Hong Kong, P. R. China
Phone No.: 852-27110882
Fax No.: 852-27110116
Email: cyrus@skypro-med.com

3. US Agent and Correspondent

Company: SKYPRO MEDICAL SUPPLIES USA LTD COMPANY
Address: 5722 Kendall Hill Ln, Sugar Land, TX 77479
Contact Person: Eve Luo
Email: Eve@1masks.com
Phone No.: 832-312-2668
EIN/TAX ID: 851587593

4. Details of Device

Device Trade Name: Skypro, SP02 Mask (Level 3)
Classification Name: Mask, Surgical (21 CFR 878.4040)
Class: Class II
Classification Panel: General and Plastic Surgery
Product Code: FXX
Device Common Name/ Classification Name: Surgical Mask
Predicate Device: Skypro, SP01 Mask (K152197)

Labels/ Labeling:
"Skypro, SP02 Mask (Level 3)" is marketed as a single-use and disposable surgical or procedure mask. It is a prescription device.

Intended Use:
"Skypro, SP02 Mask (Level 3)" is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. It is intended for infection control practices to reduce the potential exposure of the wearer to blood and body fluids. It is a non-sterile, single-use, and disposable device.

Device Description:
"Skypro, SP02 Mask (Level 3)" is a flat-pleated surgical or procedure mask. It is composed of 4-layer spunbond/meltblown polypropylene fabrics, elastic earloops or ties, and a moldable nose clip.

No.	Item No.	Description
1	L3RELX	The face mask (size: 175 mm x 95 mm) is composed of four-layer non-woven polypropylene fabrics, a moldable nose clip, and earloops. The earloops are attached to the corners of mask blank. Seam sealing is applied to the edge of mask blank.
2	L3RTOX	The face mask (size: 175 mm x 95 mm) is composed of four-layer non-woven polypropylene fabrics, a moldable nose clip, and ties. Seam sealing is applied to the edge of mask blank.
3	L3MELX	The face mask (size: 145 mm x 95 mm) is composed of four-layer non-woven polypropylene fabrics, a moldable nose clip, and earloops. The earloops are attached to the corners of mask blank. Seam sealing is applied to the edge of mask blank.

Note: The details of each item have been indicated in the relevant "Product Drawing" files.

Technological Characteristic Comparison with Predicated Device:

Description	Predicate K152197 "Skypro, SP01 Mask"	Subject Device K202255 "Skypro, SP02 Mask (Level 3)"		Comparison
Materials				
Outer Layer	Spunbond polypropylene	Spunbond polypropylene		Similar
Middle Layer	Meltblown polypropylene	1st	Spunbond polypropylene	Similar
		2nd	Meltblown polypropylene	Similar
Inner layer	Spunbond polypropylene	Spunbond polypropylene		Similar
Nose Piece	Metal wire(s) coated with polyethylene	Metal wire(s) coated with polyethylene		Similar
Ear Attachment	Elastic latex-free earloops or ties	Elastic latex-free earloops or ties		Similar
Specification and Physical Sizes	Earloop mask: 175 mm x 95 mm; 145 mm x 95 mm; Tie-on mask: 175 mm x 95 mm	Earloop mask: 175 mm x 95 mm; 145 mm x 95 mm; Tie-on mask: 175 mm x 95 mm		Similar
Mask Style	Flat-pleated	Flat-pleated		Similar

Design Features	3 layers of non-woven fabrics with a dense fiber	4 layers of non-woven fabrics with a dense fiber web as one	Similar

	web as the middle layer	of the middle layers	Similar
Color	White	Blue	Different
Indications for Use	"Skypro, SP01 Mask" is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. It is intended for infection control practices to reduce the potential exposure of the wearer to blood and body fluids. It is a non-sterile, single-use, and disposable device.	"Skypro, SP02 Mask (Level 3)" is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. It is intended for infection control practices to reduce the potential exposure of the wearer to blood and body fluids. It is a non-sterile, single-use, and disposable device.	Similar
Performance Characteristics			
Fluid Resistance Performance (mmHg)	Pass @ 120 mmHg	Pass @ 160 mmHg	Different
Particulate Filtration Efficiency Performance	99.28%	98.59%	Similar
Bacterial Filtration Efficiency Performance	99.66%	99.24%	Similar
Differential Pressure (Delta P)	3.72 mmH_2O/cm^2	4.04 mmH_2O/cm^2	Similar
Flammability Class	Class 1	Class 1	Same
Biocompatibility Test			
Cytotoxicity	Under the conditions of the study the sample was found to be non-cytotoxic	Under the conditions of the study the sample was found to be non-cytotoxic	Same
Sensitization	Under the conditions of the study the sample was found to be non-sensitizing	Under the conditions of the study the sample was found to be non-sensitizing	Same
Primary Skin Irritation	Under the conditions of the study the sample was found to be non-irritating	Under the conditions of the study the sample was found to be non-irritating	Same
Sterilization	Non-sterile; single-use	Non-sterile; single-use	Same

Summary of Non-Clinical Testing:

Test Methodology	Purpose	Acceptance Criteria	Result
1. Biocompatibility Test			
- Cytotoxicity Test: MEM Elution GLP Report;	To determine if the mask may cause cytotoxic effects	Non-cytotoxic	Non-cytotoxic
- Sensitization Test: Kligman Maximization Test – ISO (GLP)	To determine if the mask may cause skin sensitization	Non-sensitizing	Non-sensitizing
- Primary Skin Irritation Test: Intracutaneous Injection Test – ISO (GLP)	To determine if the mask may cause skin irritation	Non-irritating	Non-irritating
2. Fluid Resistance Test	To determine the capability of mask to resist the penetration of fluids	Pass @ 160 mmHg	Pass
3. Particle Filtration Efficiency Test	To measure the filtration efficiency of mask for particulates	$\geq$ 98%	98.59%
4. Bacterial Filtration Efficiency (BFE) Test	To measure the filtration efficiency of mask for bacteria	$\geq$ 98%	99.24%
5. Differential Pressure (Delta P) Test	To measure how easily air is passed from one side of the mask to the other, which can function as an indicator of air permeability or breathability	$<$ 6 mmH_2O	4.04 mmH_2O/cm^2
6. Flammability Test	To determine if the mask ignites easily when exposed to or used near fire or heat	Class 1	Class 1

Clinical Performance Test: No clinical testing was performed.

5. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(K) submission K202255, the “Skypro, SP02 Mask (Level 3)” is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K152197.