October 12, 2023

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: K230707
Trade/Device Name: Skypro, Surgical Gown 6021
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: September 14, 2023
Received: September 14, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bifeng Qian -S

BiFeng Qian, M.D., Ph.D.
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)*
K230707

Device Name
Skypro, Surgical Gown 6021

Indications for Use *(Describe)*
"Skypro, Surgical Gown 6021" are intended to protect both surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. They are classified as Level 3 surgical gowns in accordance with ANSI/AAMI PB70 and used in healthcare facilities. The gown is single use, disposable, and provided 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.

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510(k) Summary
K230707

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

Ⅰ. Submitter

Company: Skypro Medical Supplies Company
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1-33 Cheung Tat Road, Tsing Yi, New Territories, Hong Kong, P. R. China
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Date Prepared: October 12, 2023

US Agent and Correspondent of the Submitter:
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

Ⅱ. Device

Device Manufacturer: SPRO Medical Products (Xiamen) Co., Ltd
Address: No.139 Factory Building, TongAn Garden, TongAn Industrial Area,
Xiamen, Fujian Province, 361100, P. R. China
Device Trade Name: Skypro, Surgical Gown 6021
Regulation Name (Number): Surgical Apparel (21 CFR 878.4040)
Class: Class II
Classification Panel: General and Plastic Surgery
Product Code: FYA
Device Common Name/ Classification Name: Surgical Gown

Ⅲ. Predicate Device

K162442
This predicate has not been subject to a design-related recall.
Device Trade Name: ComfortGuard Surgical Gown, i500
Regulation Name (Number): Surgical Apparel (21 CFR 878.4040)
Class: Class II
Classification Panel: General and Plastic Surgery
Product Code: FYA
Device Common Name/ Classification Name: Surgical Gown

Ⅳ. Device Description

"Skypro, Surgical Gown 6021" are sterile, disposable, and intended for single use. They are fundamentally made of blue non-woven spunbond-meltblown-spunbond (SMS) polypropylene fabrics, and come in a variety of sizes (XS, S, M, L, XL, and XXL). The gown features white elastic cuffs, a hook-and-loop tap for closing the neck, and four waist belts for closing the back.

"Skypro, Surgical Gown 6021" is constructed in accordance with AAMI PB70 Level 3 specifications. The major raw material of the surgical gown is non-woven SMS polypropylene fabric, which is a trilaminate non-woven fabric with a densely packed structure (i.e., small micron pore sizes) to provide tortuous paths to block the penetration of particulate matter. The hydrophobic nature of the fabric can effectively prevent the absorption and penetration of liquids and body fluids. The joints and seam regions of the surgical gown are sealed via ultrasonic vibration- assisted welding to avoid the penetration of liquids through joints and seam stitching. The whole of the surgical gown exhibits a barrier performance of Level 3.

V. Indications for Use/ Intended Use

"Skypro, Surgical Gown 6021" are intended to protect both surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. They are classified as Level 3 surgical gowns in accordance with ANSI/AAMI PB70 and used in healthcare facilities. The gown is single-use, disposable, and provided sterile.

VI. Comparison of Technological Characteristics with the Predicated Device

Description	Predicate Device K162442 "ComfortGuard Surgical Gown, i500"	Subject Device K230707 "Skypro, Surgical Gown 6021"	Comparison
Indications for Use	ComfortGuard Surgical Gown, i500 are single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. ComfortGuard Surgical Gown, i500 have been tested and are classified as Level 3 in the critical zones per AAMI Standard PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.	"Skypro, Surgical Gown 6021" are intended to protect both surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. They are classified as Level 3 surgical gowns in accordance with ANSI/AAMI PB70 and used in healthcare facilities. The gown is single-use, disposable, and provided sterile.	Similar
Design	Neck binder, hook-and-loop neck closures, belt	Raglan sleeves, hook-and-loop neck closures, and tie waist	Same

	ties, removable transfer accessory, and cuffs.	closures	
Material	Single-layer nonwoven SMS polyolefin fabrics throughout the entire gown, with no additional reinforcement	Non-woven SMS polypropylene fabrics throughout the entire gown, with no additional reinforcement	Same
Color	Blue	Blue	Same
Performance Characteristics			
AAMI PB 70 Classification	Level 3	Level 3	Same
Tensile Strength (ASTM D5034 or ASTM D5035)	Body/sleeve material: - MD: 82.8 N - CD: 58.54 N Back material: - MD: 89.52 N - CD: 56.32 N	Warp yarns torn (MD): 179.7 N Weft yarns torn (CD): 103.7 N	Similar
Seam Strength (ASTM D16836/D1683M-17)	Sleeve seam: ≥ 15 N Armhole seam: Experimental data are not available Shoulder seam: Experimental data are not available	Sleeve seam: 113.3 N Armhole seam: 73.2 N Shoulder seam: 111.1 N	Different Data is not available for the predicate device. Data demonstrates subject device complies with ASTM F2407.
Tearing Strength (ASTM D5587)	Body/sleeve material - MD:19.01 N - CD: 28.14 N Back material - MD: 21.19 N - CD: 37.00 N	Warp yarns torn (MD): 53.9 N Weft yarns torn (CD): 29.2 N	Similar
Lint Generation (ISO 9073-10)	Not stated	Side A (face): - Total linting: 140.9 - Coefficient of linting: 2.15 Side B (back): - Total linting: 242.2 - Coefficient of linting: 2.38	Different Data is not available for the predicate device.
Evaporative Resistance (ASTM F1868-17)	Not stated	0.00215 $kPa \cdot m^2/W$	Different Data is not available for the predicate device.
Water Resistance: Hydrostatic Pressure (AATCC 127 and ANSI/AAMI PB70)	Base material: 657 mmH2O Sleeve seam: 760 mmH2O Tie attachments: 668 mmH_2O	Base material: > 50 cmH_2O Sleeve Seam: > 50 cmH_2O Tie attachment with/without film: > 50 cmH_2O	Similar

Water Resistance: Impact Penetration (AATCC 42 and ANSI/AAMI PB70)	Base material: 0.04 g Sleeve seam: 0.04 g Tie attachments: 0.02 g No penetration can be observed	Base material: 0 g Sleeve Seam: 0 g Tie attachment with/without film: 0 g No penetration can be observed	Similar
Flammability Class 16 CFR Part 1610	Class 1	Class 1	Same
Biocompatibility			
Cytotoxicity	Under conditions of the testing, non-cytotoxic	Under conditions of the testing, non-cytotoxic	Same
Sensitization	Under conditions of the testing, not a sensitizer	Under conditions of the testing, not a sensitizer	Same
Primary Skin Irritation	Under conditions of the testing, not an irritant	Under conditions of the testing, not an irritant	Same
Sterility and Shelf Life			
Sterilization	Sterile; single-use	Sterile; single-use	Same
Sterility Assurance Level	Not stated	10^{-6}	Different Data is not available for predicate device. Data demonstrates subject device has acceptable sterility assurance level.
Sterilization modality	Ethylene Oxide	Ethylene Oxide	Same
Sterilant Residuals	Not stated	EO: < 4 mg /device ECh: < 9 mg / device	Different Data is not available for predicate device. Data demonstrates subject device does not have excessive sterilant residuals.
Shelf Life	Not stated	2 years	Different The predicate does not have a stated shelf life.

The differences in the Indications For Use do not impact the safety or effectiveness of the gown. The additional data provided for the subject gown, including the tensile properties

of the armhole and shoulder seam, the lint generation and evaporative resistance, and the Sterility Assurance Level and sterilant residuals provide additional confidence in gown safety and performance. Designation of a shelf life provides confidence that the subject device will maintain performance properties throughout its listed shelf life.

VII. Summary of Non-Clinical Testing

Test Performed	Purpose	Criteria	Result
1. ASTM F2407-20, Section 7.2 Tensile Strength ASTM D5034-09(R17)	To evaluate the tensile strength of the gown material	≥ 30N	Pass
2. ASTM F2407-20, Section 7.2 Seam Strength ASTM D1683/D1683M-22	To evaluate the tensile strength of the gown seam	≥ 30N	Pass
2. ASTM F2407-20, Section 7.2 Tearing Strength ASTM D5733-99	To evaluate the tear strength of the gown material	≥ 10N	Pass
3. ASTM F2407-20, Section 7.3 Lint Generation ISO 9073-10:2003	To evaluate the potential for linting of the gown	Documentation only	Pass
4. ASTM F2407-20, Section 7.3 Evaporative Resistance ASTM F1868-17	To evaluate the evaporative resistance of the gown	Documentation only	Pass
5. Water Resistance: Hydrostatic Pressure AATCC 42:2017	To evaluate the hydrostatic water resistance of the gown	≥ 50cmH_20	Pass
6. Water Resistance: Impact Penetration AATCC 127:2018e	To evaluate the water spray resistance of the gown	≤ 1.0g	Pass
7. ASTM F2407-20, Section 6.3 Flame Spread 16 CFR 1610	To evaluate the flame resistance of the gown	Class 1	Pass
8. Cytotoxicity Test: MEM Elution ISO 10993-5:2009	To evaluate the cytotoxic potential of the gown	Under conditions of the testing, non-cytotoxic	Pass
9. Sensitization Test: Kligman Maximization Test ISO 10993-10:2021	To evaluate the sensitization potential of the gown	Under conditions of the testing, not a sensitizer	Pass
10. Primary Skin Irritation Test: Intracutaneous Injection Test ISO 10993-10:2021	To evaluate the skin irritation potential of the gown	Under conditions of the testing, not an irritant	Pass
11. Sterilant Gas Residue Analysis ISO 10993-7	To verify low levels of residual ethylene oxide and ethylene chlorohydrin	EO: < 4 mg /device ECh: < 9 mg / device	Pass
12. Seal Peel Test ASTM F88	To evaluate the force necessary to open the sterile barrier seals	0.375 lbf (average)	Pass
13. Dye Migration Test	To verify the integrity	No leakage	Pass

ASTM F1929	of the sterile barrier		
14. Simulated Aging Test ASTM F1980	To verify the ability of the sterile barrier to maintain integrity during its shelf life	Meets performance specifications after accelerated aging, no visually apparent change	Pass

VIII. Clinical Testing

No clinical testing was performed in support of this submission.

IX. Conclusions

The conclusions drawn from the non-clinical tests demonstrate that the subject device, Skypro, Surgical Gown 6021, is as safe, as effective, and performs as well as or better than the legally marketed predicate device K162442.