DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 26, 2016

Skypro Medical Supplies Company
Mr. Cyrus Wong
General Manager
Flat C301, 3/F, Block C, Phase 2, Tsing Yi Industrial Centre,
1-33 Cheung Tat Road, Tsing Yi, New Territories,
Hong Kong

Re: K152197
Trade/Device Name: Skypro, SP01 Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: July 21, 2016
Received: July 25, 2016

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement on last page.*

510(k) Number *(if known)*
K152197

Device Name
Skypro, SP01 Mask

Indications for Use *(Describe)*

The 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. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The mask is a single use, disposable device, provided non-sterile.

| Description | Model No. | Color | Size |
|---|---|---|---|
| Gent loop mask | FP3FNWH | White | 175x95mm |
| Lady loop mask | FL3FNWH | White | 145x95mm |
| Tie on mask | FS3FNWH | White | 175x95mm |

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

# Skypro Medical Supplies Company

Date prepared: 24th Aug, 2016

Manufacturer:
SPRO Medical Products (Xiamen) Co., Ltd
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Official Correspondent and Applicant:
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Device Trade Name: Skypro, SP01 Mask

Device Classification and Product Code
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

Recognized Performance
Predicate Device Pasture 60S Surgical Mask K141875

Labels/ Labeling:
Skypro, SP01 Mask will be marketed as single use disposable procedure mask and this product is not made with natural rubber latex for the Intended Use purpose below

Intended Use:

Skypro, SP01 Mask is a procedure or surgical mask that is indicated as a protective nose and mouth covering for healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids and particulate materials.

Indication for use Statement：

Skypro, SP01 Mask is intended to be worn to protect both 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 of wearer to blood and body fluids. The mask is a single use, disposable device, provided non-sterile.

| Description | Model No. | Color | Size |
|---|---|---|---|
| Gent loop mask | FP3FNWH | White | 175x95mm |
| Lady loop mask | FL3FNWH | White | 145x95mm |
| Tie on mask | FS3FNWH | White | 175x95mm |

Device Description:

Skypro, SP01 Mask, is a flat pleated procedure or surgical mask. It is 3 layers and composed of Polypropylene and Meltblown, with elastic earloops or Ties in either knitted polyester/lycra or non-woven polyester and A malleable nosepiece is placed within the bindings for comfort and individualized fir around the wearer's nose.

Comparison of Predicated Devices:

| Description | Our Device<br>"Skypro SP01 Mask" | Predicate K141875<br>"Pasture 60S Surgical Mask" |
|---|---|---|
| Materials | | |
| Outer layer | Polypropylene | Polypropylene |
| Middle layer-Filter Media | Meltblown | Meltblown |
| Inner layer | Polypropylene | Polypropylene |
| Nose Piece | Metal wires embedded in polyester or non-woven ties | Combination of zinc wires and embedded polyester |
| Ear Attachment | Eastic earloop or Ties | Synthetic elastic |
| Specification and Physical sizes | Gent loop mask size: 175x95mm<br>Lady loop mask size: 145x95mm<br>Tie on mask size: 175x95mm | 184+/-1mmx144+/-1mm |
| Mask Style | Flat pleated | Flat pleated |
| Design Features: | 3 layers of non-woven fiber with fiber web in the middle | 4 layers of non-woven fiber containing a filter web |
| Color | White | Blue |
| Indications for use | The 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. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The mask is a single use, disposable device, provided non-sterile. | Pasture 60S Surgical Mask is a surgical mask indicated to be used by the healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. |
| Technological Characteristics | No new technological characteristics are used of Skypro, SP01 Mask | |

| Performance Characteristics | Skypro SP01 Mask | K141875 |
|---|---|---|
| Fluid Resistance Performance (mmHg) ASTM F1862 | Pass @120mmHg | Pass @120mmHg |
| Particulate Filtration Efficiency Performance ASTM F2299 | 99.28% | 99.4% |
| Bacterial Filtration Efficiency Performance ASTM F2101-07 | 99.66% | 99.76% |
| Differential Pressure(Delta-P) MIL-M-36954C | 3.72 mm H2O/cm2 | 3.33 mm H2O/cm2 |
| Flammability class 16 CFR Part 1610 | Class 1 | Class 1 |
| Biocompatibility Test ISO 10993 | | |
| Cytotoxicity | Non-cytotoxic | Non-cytotoxic |
| Sensitization | Non-sensitization | Non-sensitization |
| Primary Skin Irritation | Non-irritating | Non-irritating |
| Sterile | Non-sterile<br>Single Use | Non-sterile<br>Single Use |

Performance Tests:

| Test Performed |
|---|
| 1. Biocompatibility Test , ISO 10993 |
| 2. Flammability Test , 16 CFR Part 1610 |
| 3. Synthetic Blood Penetration Test , ASTM F1862 |
| 4. Particulate Filtration Efficiency , ASTM F2299 |
| 5. Bacterial Filtration Efficiency , ASTM F2101-07 |
| 6. Differential Pressure Testing , MIL-M-36954C |

Conclusion

The test data submitted in this submission demonstrate that the subject device is as safe and as effective as the predicate and technological characteristics do not raise any new questions of safety and as effectiveness. Skypro, SP01 Mask is substantially equivalent to the predicate cleared in K141875.