



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

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

Indications for Use

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.

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510(k) Summary

Skypro Medical Supplies Company

Date prepared: 24th Aug, 2016

Manufacturer:

SPRO Medical Products (Xiamen) Co., Ltd
139 Factory Building, TongAn Garden, TongAn Industrial Area, TongAn Xiamen,
China. 361100

Official Correspondent and Applicant:

Cyrus Wong
General Manager
Skypro Medical Supplies Company
Flat C301, 3/F, Block C, Phase 2, Tsing Yi Industrial Centre,
1-33 Cheung Tat Road, Tsing Yi, New Territories, Hong Kong.
Phone Number: 852-27110882
Fax Number: 852-27110116
cyrus@skypro-med.com

US agent and correspondent

Wilson Lim
165 North Aspan Ave, Azusa, CA 91702
Phone: 1-626-969-7838 Ext 105
Fax: 1-626-969-7823

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 fit around the wearer's nose.

Comparison of Predicated Devices:

Description	Our Device "Skypro SP01 Mask"	Predicate K141875 "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 Lady loop mask size: 145x95mm 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 Single Use	Non-sterile 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.