April 22, 2021

Guangzhou Mei Yi Kang Medical Technology CO., LTD.
% Cassie Lee
Official Correspondent
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District
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Re: K203646
Trade/Device Name: Disposable Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 31, 2021
Received: April 5, 2021

Dear Cassie Lee:

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 Ryan Ortega, Ph.D.
Acting 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)*
K203646

Device Name
Disposable Medical Face Mask

Indications for Use *(Describe)*
Disposable Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. This face mask is 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.
Models: MK-34, DY 95, DY 96, DY 97

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 for K203646

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor Name: GUANGZHOU MEI YI KANG MEDICAL TECHNOLOGY CO., LTD.
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Application Correspondent:

Contact Person: Ms. Cassie Lee
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2. Date of the summary prepared: April 21, 2021

3. Subject Device Information

Type of 510(k): Traditional
Classification Name: Mask, Surgical
Common name: Surgical Mask
Trade Name: Disposable Medical Face Mask
Model Name: MK-34, DY 95, DY 96, DY 97
Review Panel: Surgical Apparel
Product Code: FXX
Regulation Number: 878.4040
Regulatory Class: II

4. Predicate Device Information

Predicate Device:

Sponsor: Skypro Medical Supplies Company

Trade Name: Skypro, SP01 Mask

Classification Name: Mask, Surgical

Common name: Surgical Mask

510(K) Number: K152197

Review Panel: Surgical Apparel

Product Code: FXX

Regulation Number: 878.4040

Regulatory Class: II

5. Device Description

The Disposable Medical Face Mark is blue color, and flat pleated type mask, utilizing ear loops or tie-on way for wearing, and has nose strip design for fitting the facemask around the nose. The colorant used in the mask outer layer is blue: Copper phthalocyanine/ CAS number: 147-14-8).

The proposed device is manufactured with three layers, the inner and outer layers made of spunbond polypropylene, and the middle layer is made of melt blown polypropylene filter.

The model DY 96, tie-on, is held in place over the user's mouth and nose by four straps welded to the facemask. The straps are made of Spun-bond polypropylene. Its dimension is 17.5x9.5cm, strap is 38 cm, nose strip is 9.5±0.5 cm.

The models MK-34, DY 95 and DY 97, ear loops, are held in place over the user's mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are made of Nylon and Spandex, not made with natural rubber latex. The dimension of MK-34 is 14.5x9.5cm, ear loop is 13cm, nose strip is 9.5±0.5 cm. The dimension of DY 95 and DY 97 is 17.5x9.5cm, ear loop is 13 cm, nose strip is 9.5±0.5 cm.

The nose strip contained in the proposed device is in the layers of facemask to allow the user to fit the facemask around their nose, which is made of PE and galvanized iron wire.

The device is sold non-sterile and are intended to be single use, disposable device.

The difference between the 4 models as below:

Model	Materials	Contact classification	colorants	Size	Style differences
MK-34	Outer layer: spunbond polypropylene, Inner layer: melt blown polypropylene, Nose strip: PE and galvanized iron wire, Ear loops: Nylon and Spandex	Less than 24 hours	Copper phthalocyanine/ CAS number: 147-14-8).	145x95mm	Ear loop style, the ear loop is welded on the outer layer.

DY 95	Outer layer: spunbond polypropylene, Inner layer: melt blown polypropylene, Nose strip: PE and galvanized iron wire, Ear loops: Nylon and Spandex	Less than 24 hours	Copper phthalocyanine/ CAS number: 147-14-8).	175x95mm	Ear loop style, the ear loop is welded on the outer layer.
DY 96	Outer layer: spunbond polypropylene, Inner layer: melt blown polypropylene, Nose strip: PE and galvanized iron wire, Ties: Spun-bond polypropylene	Less than 24 hours	Copper phthalocyanine/ CAS number: 147-14-8).	175x95mm	Tie-on style
DY 97	Outer layer: spunbond polypropylene, Inner layer: melt blown polypropylene, Nose strip: PE and galvanized iron wire, Ear loops: Nylon and Spandex	Less than 24 hours	Copper phthalocyanine/ CAS number: 147-14-8).	175x95mm	Ear loop style, the ear loop is welded on the inner layer.

6. Intended Use / Indications for Use

Disposable Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. This face mask is 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.

7. Comparison of Technological Characteristics

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Comparison in Detail(s):

Elements of Comparison	Subject Device	Predicate Device	Results
Company	GUANGZHOU MEI YI KANG MEDICAL TECHNOLOGY Co., Ltd.	Skypro Medical Supplies Company	--
510 (k)	K203646	K152197	--
Trade Name	Disposable Medical Face Mask	Skypro, SP01 Mask	--
Classification Name	Mask, Surgical	Mask, Surgical	Same
Classification	Class II	Class II	Same
Product Code	FXX	FXX	Same
Intended use	Disposable Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. This face mask is 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.	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.	Same
Materials			
Outer layer	Spunbond Polypropylene	Polypropylene	Same
Middle filter layer	Melt blown Polypropylene	Meltblown	Same
Inner layer	Spunbond Polypropylene	Polypropylene	Same
Nose strip	PE and galvanized iron wire	Metal wires embedded in polyester or non-woven ties	Similar Note 1
Ear loops for MK-34, DY 95, DY 97	Nylon and Spandex	--	Note 1
Straps for DY 96	Spun-bond polypropylene	--	Note 1
Ear attachment	Eastic earloop (for models MK-34, DY 95, DY 97) or Ties (for model DY 96)	Eastic earloop or Ties	Same

Color	Blue	White	Different Note 1
Dimensions	MK-34: 145x95mm DY 95, DY96, DY 97: 175x95mm	Gent loop mask size: 175x95mm Lady loop mask size: 145x95mm Tie on mask size: 175x95mm	Similar
Mask style	Flat pleated	Flat pleated	Same
Design features	3 layers of non---woven fiber with fiber web in the middle	3 layers of non-woven fiber with fiber web in the middle	Same
Sterile	Non-Sterile Single use	Non-Sterile Single use	Same
Shelf Life	2 years	Not publicly available	Note 2
Fluid Resistance Performance	Pass at 120 mm Hg	Pass at 120 mm Hg	Same
Particulate Filtration Efficiency	Model MK-34, DY 95 and DY 97: 98.9% Model DY 96: 99.3%	99.28%	Similar Note 3
Bacterial Filtration Efficiency	Model MK-34, DY 95 and DY 97: 99.8% Model DY 96: 99.9%	99.66%	Similar Note 3
Differential Pressure	Model MK-34, DY 95 and DY 97: 4.2 mm H2O/cm^2 Model DY 96: 4.0mm H2O/cm^2	3.72 mm H_2O/cm^2	Similar Note 3
Flammability	Class 1	Class 1	Same
Latex	Not made with natural latex	Not made with natural latex	Same
Biocompatibility			
Cytotoxicity	Under the conditions of the study, Non-cytotoxic	Non-cytotoxic	Same
Irritation	Under the conditions of the study, Non-irritating	Non-irritating	Same
Sensitization	Under the conditions of the study, Non- sensitization	Non- sensitization	Same

Note 1:
Although the “Nose strip”, “Ear loop”, “Straps” and “Color” is a little different from the predicate devices, but it met the ISO 10993 standards and ASTM F2100 level II required. So, the differences between the subject device and the predicate device will not affect the safety and effectiveness.

Note 2:

Although the "Shelf life" of subject device is different from predicate device, but they all met the ASTM F2100 standard level II required after 81 days accelerated aging under 60℃, so the difference between subject device and predicate device will not affect the safety and effectiveness.

Note 3: Although the "Particulate Filtration Efficiency ", "Bacterial Filtration Efficiency ", and "Differential Pressure" of subject device is a little different from predicate device, but they all met the ASTM F2100 standard level II required. So, the differences between the subject device and predicate device will not affect the safety and effectiveness.

8. Summary of Non-Clinical Performance Testing

- Performance Testing summary

Test item (Performance Level 2 according to ASTM F2100)	**Test method**	**Pass criteria**	**Test results**
Bacterial filtration efficiency	ASTM F2101-14 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus according to ASTM F2100:2019	≥ 98%	Model MK-34, DY 95 and DY 97: 99.8% Model DY 96: 99.9% Pass
Differential pressure (Delta-P)	EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019	<6.0 mm H_2O/cm^2	Model MK-34, DY 95 and DY 97: 4.2 mm $H2O/cm^2$ Model DY 96: 4.0mm $H2O/cm^2$ Pass
Sub-micron particulate filtration efficiency at 0.1 μm of Polystyrene Latex Spheres	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 according to ASTM F2100:2019	≥ 98%	Model MK-34, DY 95 and DY 97: 98.9% Model DY 96: 99.3% Pass
Resistance to	ASTM F1862/F1862M-17	Fluid	Fluid Resistant

penetration by synthetic blood, minimum pressure in mm Hg for pass result	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) according to ASTM F2100:2019	resistant claimed at 120 mm Hg	Pass at 120 mm Hg Pass
Flame spread	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Class 1	Class 1 Pass

- Biocompatibility Testing

According to ISO 10993-1:2009, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is A-Limited (≤24h). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

Test Item	Test Method	Proposed device	Result
Cytotoxicity	ISO 10993-5: 2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	PASS
Irritation	ISO 10993-10: 2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	PASS
Sensitization	ISO 10993-10: 2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	PASS

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10. Final Conclusion：

The conclusion drawn from the nonclinical test demonstrates that the subject device in 510(K) submission K203646, the Disposable medial face mask is as safe, as effective, and performs as well as or better than the legally marketed predicated device cleared under K152197.