June 7, 2021

Dongguan Shin Yi Healthcare Products Factory
% Joyce Yang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, Guangdong 51800
China

Re: K210372
Trade/Device Name: Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX,
Dated: April 25, 2021
Received: May 3, 2021

Dear Joyce Yang:

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,

Clarence W. Murray III -S

Clarence W. Murray, III, PhD
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)*
K210372

Device Name
Disposable Surgical Mask

Indications for Use *(Describe)*
The Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use ,disposable device, provided non-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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

510(k) Number: K210372

Date Prepared: June 5, 2021

1. Submission Sponsor

Manufacturer information	Company: Dongguan Shin Yi Healthcare Products Factory Company address: No. 17 Ban Hu Road, Huang Jiang Town, Dong Guan City, Guang Dong Province, China. Contact person: Zhao Shuge Phone: +86-769-83361381 Fax: +86-769-83631102 E-mail: zhaosg.dg@master-frank.cn

2. Submission correspondent

Name Address	Shenzhen Joyantech Consulting Co., Ltd 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen
Post Code Phone No.	518000
Contact Person	86-755-86069197
Email	Joyce Yang joyce@cefda.com

3. Device Identification

Type of 510(k) submission:	Traditional
Trade Name:	Disposable Surgical Mask
Model:	MFA05004, MFA05005, MFA05007, MFA05008
Classification name:	Mask, Surgical
Review Panel:	Surgical Apparel
Product Code:	FXX
Device Class:	II
Regulation Number:	21 CFR 878.4040

4. Legally Marketed Predicate Device

Trade Name	Single-use Surgical Mask
Regulation number	21 CFR 878.4040
Regulation class	II
Regulation name	Surgical Apparel
510(k) Number	K200923
Product Code	FXX
Manufacturer	BYD Precision Manufacturer Co.,Ltd.

5. Device Description

The proposed devices are single use, three-layer, flat masks with straps and nose piece. The Surgical Masks are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter.

The proposed device is held in place over the user's mouth and nose by two elastic ear loops or four ties welded to the face mask. The elastic ear loops are not made with natural rubber latex.

The nose piece contained in the proposed device is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of Malleable aluminum wire.

The proposed devices are sold non-sterile and are intended to be single use, disposable devices.

6. Intended Use/ Indications for Use

The Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

7. Technological characteristics comparison

Comparison item	Subject Device: Disposable Surgical Mask(K210372)	Predicate Device: Single-use Surgical Mask (K200923)	Comments
Product Code	FXX	FXX	Same
Regulation Number	21 CFR § 878.4040	21 CFR § 878.4040	Same
Classification	Class II	Class II	Same
OTC use	Yes	Yes	Same
Intended use &	The Surgical Masks are	The Single-use Surgical	Same

Comparison item	Subject Device: Disposable Surgical Mask(K210372)	Predicate Device: Single-use Surgical Mask (K200923)	Comments
Indications for Use	intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use ,disposable device, provided non-sterile.	Face Masks are 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 to blood and body fluids. This is a single use ,disposable device, provided non-sterile.	
Design feature	Ear-loop, Tie-on	Ear-loop	Similar (Issue 1)
Usage	Single use	Single use	Same
Color	Blue	Blue	Same
Size	(18±1)cm×(9±1)cm (14.5±1)cm×(9±1)cm	(17.5±1)cm×(9.5±1)cm	Similar (Issue 2)
Sterile	Non-sterile	Non-sterile	Same
Material	Outer layer: Spun-bond polypropylene	Outer layer: Spun-bond polypropylene	Same
	Middle layer: Melt blown polypropylene filter	Middle layer: Melt blown polypropylene filter	Same
	Inner layer: Spun-bond polypropylene	Inner layer:Spun-bond polypropylene	Same
	Nose piece:Malleable aluminum wire	Nose piece:Metal Core Plastic	Different (Issue 3)

Comparison item	Subject Device: Disposable Surgical Mask(K210372)	Predicate Device: Single-use Surgical Mask (K200923)	Comments
	Ear-loops: Elastic fiber Tie-on:Spun-bond polypropylene	Ear-loops:Polyester	Similar (Issue 3)
ASTM F 2100 Level	Level 3	Level 3	Same
Fluid Resistance Performance ASTM F 1862-13	Pass at 160 mmHg	Pass at 160 mmHg	Same
Particulate Filtration Efficiency ASTM F 2299	> 98%	> 98%	Same
Bacterial Filtration Efficiency ASTM F 2101	> 98%	> 98%	Same
Differential Pressure (Delta P) EN 14683:2019+ AC：2019	< 6.0mmH_2O/cm^2	< 6.0mmH_2O/cm^2	Same
Flammability 16CFR 1610	Class 1	Class 1	Same
Cytotoxicity	Comply with ISO 10993-5 Non cytotoxic	Comply with ISO 10993-5 Non cytotoxic	Same
Irritation	Comply with ISO 10993-10 Non irritating	Comply with ISO 10993-10 Non irritating	Same
Sensitization	Comply with ISO 10993-10 Non sensitizing	Comply with ISO 10993-10 Non sensitizing	Same

Issue 1: Compared to the predicate device, the subject device has an additional design feature “Tie-on”. The difference in design feature do not affect the performance of the face mask.

Issue 2: The sizes of proposed device are a little smaller than the size of predicate device. The small size is to apply to the population with thin face, and there is no difference in performance.

Issue 3: The nose piece is used to allow the user to fit the face mask around their nose. The difference of materials of nose piece between subject device and predicate device could not affect the performance of the face mask.
The Ear-loops of the proposed device are made by elastic fiber, which of the predicate device is made by polyester. The major chemical composition of the elastic fiber is segmented polyurethane-urea, which is similar to polyester.
In addition, the proposed devices have been tested for biocompatibility, and the test results confirm that the device is biocompatible.

8. Summary of Non-clinical Testing

Non-clinical tests were conducted and conformed to the following standards and the requirements state in the Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submission issued on March 05, 2004.

Standards:

- ASTM F2100-19 Standard Specification For Performance of Materials used in Medical Face Masks.
- ASTM F1862-13 Standard Test Method For Resistance of Medical Face Masks to Penetration by Synthetic Blood.
- ASTM F2299-03 Stand Test Method For Determining The Initial Efficiency Of Materials Used In Medical Face Masks To Penetration By Particulates Using Latex Spheres.
- 16 CFR 1610 Standard For The Flammability Of Clothing Textiles.
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ANSI/AAMI/ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Requirements for Development, validation, and routine control of a sterilization process for Medical devices
- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices – Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices – Part 10: Tests For Irritation And Skin Sensitization.

Table 2: Performance Characteristic

Test Methodology	Purpose	Acceptance Criteria	Results
Fluid Resistance Performance (ASTM F1862)	For evaluating the ability of the mask's material to resist the penetration of blood and body fluids.	Pass at 160 mmHg	Pass at 160 mmHg

Test Methodology	Purpose	Acceptance Criteria	Results
Particulate Filtration Efficiency (ASTM F2299)	For evaluating a submicron efficiency performance	> 98%	> 98%
Bacterial Filtration Efficiency (ASTM F2101)	For evaluating the ability of the mask's material to prevent the passage of aerosolized bacteria	> 98%	> 98%
Differential Pressure (EN 14683:2019)	For evaluating the breathability and comfort of the surgical mask	< 6.0mmH_2O/cm^2	< 6.0mmH_2O/cm^2
Flammability (16 CFR 1610)	For evaluating the flammability of the material	Class 1	Class 1

Table 3: Biocompatibility

Test Methodology	Purpose	Acceptance Criteria	Results
Cytotoxicity	For evaluating the cytotoxicity of the materials	Non-cytotoxicity	Under the conditions of the study, non-cytotoxicity effect
Irritation	For evaluating the skin irritation of the materials	Non-irritation	Under the conditions of the study, non-irritation
Sensitization	For evaluating the sensitization of the materials	Non-sensitization	Under the conditions of the study, non-sensitization

9. Brief discussion of clinical tests

No clinical tests were performed.

10. Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission K210372, the Disposable Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K200923.