August 19, 2021

Ningbo Shun Ye Medical Company, Ltd.
Frank Yu
General Manager
No.5 Industry Road, Zhangqi Industry Zone, Cixi
Ningbo, Zhejiang 315313
China

Re: K210256
Trade/Device Name: CiRx® Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 6, 2021
Received: May 18, 2021

Dear Frank Yu:

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, PhD
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)*
K210256

Device Name

CiRx® Surgical Mask

Indications for Use *(Describe)*

This device is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluid, and particulate materials.

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.

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510(k) Summary
K210256

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SI0(k) SUMMARY

5I0(k) Number: K210256

(Submitted As Required per 21 CFR 807.92)

GENERAL INFORMATION:

Submitter Name:	Ningbo Shun Ye Medical Company,Lt d.
Establishment Registration Number:	3007593903
Submitter Address:	No. 5 Industry Road, Zhangqi Industry Zone, Cixi, Ningbo City 315313 Zhejiang, China
Submitter Telephone Number:	011-86-574-6377-8018
Submitter FAX Number:	011-86-574-6377-8028
Contact Person:	Frank Yu General Manager
Date Prepared:	Jan.20 .2021

DEVICE IDENTIFICATION:

SIO(k) Number:	**K210256**
Proprietary Name:	**CiRx® Surgical Mask**
Common Name:	Surgical Face Mask
Classification Name:	Mask, Surgical
Model Numbers:	

Catalog#	Description
WZ-EN-L-S	Non-sterile Single Use Disposable Surgical Mask, Single Bag Package
WZ-EN-L-T	Non-sterile Single Use Disposable Surgical Mask, 10 Pcs Bag Package

Classification: 21 CFR 878.4040; Class II; Product Code FXX

Legally Marketed Predicate Device(s):

510(k) Number	Predicate Device Name	Predicate Device Manufacturer
K122717	Surgical Mask	Tiger Medical Products Ltd.

INTENDED USE/INDICATIONS

This device is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluid, and particulate materials.

DEVICE DESCRIPTION

The device is single use multi-layer surgical mask with outer layer and inner layer (spunbond plypropylene) that sandwich a meltblown polypropylene filter material. The surgical mask is secured on user via earloops. Earloops are made of polyester and spandex. The nose piece is a plastic covered iron strip. The materials used to make the surgical mask are being used in currently marketed surgical masks.

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TECHNICOLOGICAL CHARACTERISTICS COMPARISON

Feature/ Characteristic	CiRx® Surgical Mask (K210256)	Surgical Mask, K122717 (Tiger Medical Products Ltd.)
Intended Use	This device is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	Surgical mask is Intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates.
Mask Style	Flat pleated	Flat pleated
Design Feature	Earloop	Earloop or tie-on
Dimensions	17.5 cm x 9.5 cm	17.5 cm x 9.5 cm
Color	Blue	Blue
OTC Use	Yes	Yes
Single Use	Yes	Yes
Sterile	No	No
Materials		
Inner Layer	Spunbond polypropylene	Spunbond polypropylene
Middle Layer	Meltblown polypropylene	Meltblown polypropylene
Outer Layer	Spunbond polypropylene	Spunbond polypropylene
Nosepiece (See note below)	Iron strip with PP covering	White aluminum strip with PP covering
Ear Loops	Polyester and spandex fabric	Urethane elastic fiber

Note: The nosepiece material used to make CiRx® Surgical Mask is iron strip with PP covering. The predicate device uses white aluminum strip with PP covering.
The face mask is used to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluid, and particulate materials.
Use of nosepiece allows user to close the gap between the upper edge of a face mask and the bridge of the nose. The nosepiece material should be durable and flexible so that the nosepiece can be molded over the nose and fit individual nose shape. Both iron strip and aluminum strip meet the requirements above and can serve the purpose of nosepiece.

Performance Test		
Fluid Resistance	Fluid resistant (ASTM 1862)	Fluid resistant (ASTM 1862)
Particle Filtration Efficiency (PFE}	Average 99.896% at 0.1 micron (ASTM F2299)	Average 99.54% at 0.1 micron (ASTM F2299)
Bacterial Filtration Efficiency (BFE}	>99.8% (ASTM F2101)	>99.9% (ASTM F2101)
Flammability Class	Class 1 (16 CFR 1610)	Class 1 (16 CFR 1610)
Differential Pressure (Delta-P}	Average 4.62 mmH_2o/cm^2 (ASTM F2100-19)	Average 3.38 mmH_2o/cm^2 (M IL-M -36945C 4.4.1.1.1)
Biocompatibility	No cytotoxicity (ISO 10993-5) No sensitization (ISO 10993-10) No irritation (ISO 10993-10)	No cytotoxicity (ISO 10993-5) No sensitization (ISO 10993-10) No irritation (ISO 10993 -10)

PERFORMANCE TESTING

Performance testing was completed to demonstrate the subject device met the standards and the specifications described in the named standards and test methodology below:

Performance testing

Performance testing was conducted for the proposed device in accordance with requirements of FDA's Guidance: ***Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification {510{k)] Submissions (issued on March 5, 2004).***

Biocompatibility

Biocompatibility verification was performed in accordance with requirements of ISO 10993-1 and FDA's modified ISO guidelines in accordance with FDA's Biocompatibility guidance found at https://www.fda.gov/media/85865/download

All test requirements were met as specified by applicable standards. The CiRx® Surgical Mask was designed in accordance with the applicable standards listed below.

TEST METHODOLOGY/PURPOSE/RESULTS

Test Methodology	Purpose	Acceptance Criteria	Results
Synthetic Blood Penetration Resistance (ASTM F1862)	To evaluate the fluid resistance of surgical mask	29 out of 32 pass at 160 mmHg	Pass at 160 mmHg. Synthetic blood penetration was not seen. Four lots were tested. For each lot, 32 out of 32 passed.
Bacterial Filtration Efficiency (BFE) (ASTM F2101-19)	To determine the filtration efficiency of surgical mask	≥ 98%	Pass ≥99.7% Four lots were tested.
Particle Filtration Efficiency (PFE) (ASTM F2299)	To evaluate the non-viable particle filtration efficiency (PFE) of surgical mask	≥ 98%	Pass ≥99.814% Four lots were tested.
Differential Pressure (Delta P) (ASTM F2100-19)	To determine the breathability of surgical mask	< 5.0 mmH_20/cm^2	Pass ≤ 4.9 mmH_20/cm^2 Four lots were tested.
Flammability (16 CFR 1610)	To evaluate the flammability of surgical mask	Class 1	Pass Four lots were tested.

APPLICABLE STANDARDS

International Standard	Description
ASTM F2100-19	Standard Specification for Performance of Materials Used in Medical Face Masks
ASTM F1862/F1862M-17	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
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

International Standard	Description
ASTM F2101-19	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Surgical Masks Using a Biological Aerosol of Staphylococcus Aureus
16 CFR 1610	Standard for the Flammability of Clothing Textiles
ISO 10993-1:2018	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing with a Risk Management Process
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

CLINICAL TEST CONCLUSION

Clinical tests were not needed for this device.

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K210256, the CiRx ® Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed device predicate cleared under K122717.