September 16, 2021

Yangzhou Runyi Arts & Crafts CO., LTD.
℅ Helen Nan
General Manager
Wenzhou Cytech Information Service Co., Ltd.
Room302, Building3, Hangqian Mansion, Hangqian Street,
Lucheng District
Wenzhou, Zhejiang 32500
China

Re: K203112
Trade/Device Name: Disposable Medical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 13, 2021
Received: September 13, 2021

Dear Helen Nan:

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,

Liqun Zhao -S

For Clarence W. Murray III, Ph.D.
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)*
K203112

Device Name
Disposable Medical Mask

Indications for Use *(Describe)*
The Disposable Medical 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(s), 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.

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扬州润益工艺品有限公司

YANGZHOU RUNYI ARTS & CRAFTS CO., LTD.

K203112_510(k) Summary
(As required by 21 CFR 807.92)

1.0 Submitter Information

Company:	YANGZHOU RUNYI ARTS & CRAFTS CO., LTD.
Address:	4.NO.87 West Heye Road HanJiang District Yangzhou,Jiangsu,225008,CHINA
Phone:	086-514-82082789
Contact Person:	Li Yu
Title:	Legal Person
E-mail:	yzsunnytoys@aliyun.com

• Date of Preparation: September 15, 2021

2.0 Device Information

Trade/Device Name:	Disposable Medical Mask
Model:	RYSM001
Regulation Description:	Surgical apparel
Device:	Mask, Surgical
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Device Class:	Class II

3.0 Predicate Device Information

Trade/Device Name:	Single-use Medical Face Mask
510k Number:	K203591
Submitter:	Conod Medical Co., Limited

4.0 Device Description

The Disposable Medical Masks are non-sterile, single use, 3 layers, flat-pleated style surgical masks. Each mask contains ear loops made of nylon and spandex to secure the mask over the user's face and mouth with nose piece made of polypropylene to firmly fit over the nose. The size of the mask body is 14 cm×9 cm and the dimension of the ear loop is 8 cm×0.3 cm, the dimension of nose piece is 9.4 cm×0.3 cm. The outer layer and inner facing layer of face mask consists of Spunbond Polypropylene. Color of the inner facing layer of the mask is white and color of the outer facing layer is blue. The middle layer consists of white Melt Blown Polypropylene Filter.

50 masks are packed in a polyethylene plastic bag and placed in the package box made of white cardboard. Outside the package box there is also a PE plastic film cover on the box. This device is not made from any natural rubber latex.

5.0 Indications for Use

The Disposable Medical 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(s), provided non-sterile.

6.0 Summary of Comparison and Technological Characteristics

Device	Predicate Device	Proposed Device	Comparison
Manufacturer	Conod Medical Co., Limited	YANGZHOU RUNYI ARTS & CRAFTS CO., LTD.	N/A
510K Number	K203591	K203112	N/A
Trade/Device Name	Single-use Medical Face Mask	Disposable Medical Mask	N/A
Product Code	FXX	FXX	Same
Classification	Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)	Same
Indications for Use	The Single-use Medical 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(s), provided non-sterile.	The Disposable Medical 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(s), provided non-sterile.	Same
Material			
Outer Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Middle Layer	Melt Blown	Melt Blown	Same

	Polypropylene Filter	Polypropylene Filter	
Inner Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Nose Piece	Malleable aluminum wire	Polyethylene	Different
Mask Style	Flat pleated	Flat pleated	Same
Design feature	Earloop, Tie Coverall, 3 layers	Earloop, 3 layers	Same
Ear loops/Ties	Ear loops: Polyester Tie tapes: Spun-bond Polypropylene	Ear loops: Spandex and nylon	Different
Color	Blue	Blue	Same
Dimension (Length × Width)	Earloop: 17.5 cm × 9.5 cm 16.5 cm × 9.0 cm 14.5 cm × 9.5 cm Tie Coverall: 17.5 cm × 9.5 cm	Earloop: 14 cm × 9 cm	Similar
OTC Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use	Single Use	Same
ASTM F2100 Level	Level 2	Level 2	Same
Non-Clinical Performance Testing			
Fluid Resistance Performance ASTM F1862	32 Out of 32 pass at 120 mmHg (Level 2 Fluid Resistance)	32 Out of 32 pass at 120 mmHg (Level 2 Fluid Resistance)	Same
Particulate Filtration Efficiency ASTM F2299	Average 99.80%	≥99%	Similar
Bacterial Filtration Efficiency	Average 99.77%	≥99%	Similar

ASTM F2101			
Differential Pressure (Delta P) MIL-M-36954C	Average 4.01 mmH_2O/cm^2	< 6.0 mmH_2O/cm^2	Similar
Flammability 16 CFR 1610	Class 1	Class 1	Same
Biocompatibility			
Cytotoxicity ISO 10993-5	Non-Cytotoxic	Non-Cytotoxic	Same
Sensitization ISO 10993-10	Non- Sensitizing	Non- Sensitizing	Same
Irritation ISO 10993-10	Non-Irritating	Non-Irritating	Same

Discussion:
First, the subject device shares the same intended use with the predicate device.

Secondly, the subject device enjoys similar technological characteristics with the predicate device. For example, they enjoy the same fluid resistance level, they are both for OTC use. Although there are differences in physical specifications such as the smaller mask dimensions, it's still similar. Therefore such differences will not affect the core usage of the subject device as a single use surgical mask and the usage effectiveness of the subject device has been verified by the performance tests listed in the comparison table.

Thirdly, the subject device enjoys same mask body materials, but the nose piece and earloop materials are different with the predicate device, the material safety of the subject device have been evaluated by relevant ISO 10993 standards, which further proves that the subject device will be as safe for use as the predicate device.

7.0 Non-Clinical Performance Testing
The following performance data demonstrated in 3 non-consecutive lots were provided demonstrate that the subject device met the specification found in the standard. The results demonstrated that the subject device meets the acceptance criteria found in the standard.

7.1 Conformity to Standards

Standards	Name
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 F2100-19	Standard Specification for Performance of Materials Used in Medical Face Masks
ASTM F2101-19	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials Using a Biological Aerosol of Staphylococcus aureus
MIL-M-36945C	Differential Pressure (Delta-P)
ASTM F2299/F2299M-03	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
16 CFR PART 1610	Standard for the flammability of clothing textiles
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for Irritation and skin sensitization

7.2 Performance Testing-Bench

Standards	Test purpose	Acceptance Criteria	Result
Resistance to penetration by synthetic blood **ASTM F1862**	Testing the efficiency of resistance to penetration by synthetic blood.	Level 2: 29 out of 32 passed in 120 mmHg 3 non-consecutive lots, 32 samples per lot, AQL 4%	Pass
Sub-micron particulate filtration efficiency at 0.1 micron **ASTM F2299**	Testing the efficiency of the filter material in capturing aerosolized particles smaller than one micron.	Level 2: ≥ 98% 3 non-consecutive lots, 32 samples per lot, AQL 4%	Pass
Bacterial filtration efficiency **ASTM F2101-19**	Testing the effectiveness of medical face mask material in preventing	Level 2: ≥ 98% 3 non-consecutive lots, 32 samples	Pass

	the passage of aerosolized bacteria.	per lot, AQL 4%	
Differential pressure **MIL-M-36954**	Measuring the pressure of dropping across a medical face mask material.	Level 2: < 6.0mmH_2O/cm^2 3 non-consecutive lots, 32 samples per lot, AQL 4%	Pass
Flame spread **16 CFR 1610**	Testing the characteristics of a material that pertain to its relative ease of ignition and relative ability to sustain co mbustion.	Class 1 Non-Flammable 3 non-consecutive lots, 32 samples per lot, AQL 4%	Pass

7.3 Biocompatibility Testing

Standards	Proposed Device	Result
Cytotoxicity **ISO 10993-5**	Under the conditions of the study, the device is non-cytotoxic.	Pass
Skin Sensitization Test **ISO 10993-10**	Under the conditions of the study, the device is non-sensitizing.	Pass
Skin Irritation Test **ISO 10993-10**	Under the conditions of the study, the device is non-irritating.	Pass

8.0 Clinical Performance Testing

No clinical study is included in this submission.

9.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.