June 2, 2021

RFX+CARE Manufacturing Co., Ltd.
% James Tsai
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K203190
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 27, 2020
Received: October 27, 2020

Dear James Tsai:

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 and Part 809); 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,

Ryan Ortega, 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)*
K203190

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
The surgical face mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate materials. This face mask is 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 as 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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510(k) Summary

K203190

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

1. Administrative Information

Date of Summary prepared	April 23, 2021
Manufacturer information	Company: RFX+CARE Manufacturing Co., Ltd. Company address: No. 7 Lanjiang Road, Yuecheng District, Shaoxing, Zhejiang, People's Republic of China Contact person: Zhou Xiufeng Phone: +86-13575509137 E-mail: xiufeng.zhou@rfx-care.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen Contact person: James Tsai E-Mail: james_tsai@cefda.com; field@cefda.com

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Surgical face mask
Common name:	Surgical face mask
Classification name:	Surgical Face Mask, Apparel
Review Panel:	General and plastic surgery devices
Product Code:	FXX
Device Class:	II
Regulation Number:	878.4040

3. Predicate Device Information

Sponsor:	Wuhan Dymex Healthcare Co., Ltd.
Trade name:	Surgical face mask
Common name:	Surgical face mask
Classification name:	Surgical Face Mask, Apparel
Review Panel:	General and plastic surgery devices
Product Code:	FXX

Device Class:	II
510(K) Number:	K182515
Production regulation:	21 CFR §878.4040

4. Device Descriptions

The surgical face mask is provided as sterile, single use, 3 layers, flat-pleated style with ear loops and nose-piece. The outer layer and inner layer of face mask consist of Spunbond Polypropylene, and the middle layer consists of Melt-blown fabric (polypropylene). Each mask contains ear loops to secure the mask over the user's face and mouth with nose-piece to firmly fit over the nose. This device is not made from any natural rubber latex.

5. Indications for Use

The surgical face mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate materials. This face mask is 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 as sterile.

6. Summary of Technological Characteristics

Comparison item	Proposed Device	Predicate Device	Remark
Manufacturer	RFX+CARE Manufacturing Co., Ltd.	Wuhan Dymex Healthcare Co., Ltd.	/
510k number	K203190	K182515	/
Product name	Surgical face mask	Surgical face mask	Same
Product Code	FXX	FXX	Same
Classification	Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)	Same
Intended use & Indications for Use	The surgical face mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate materials. This face mask is 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 as sterile.	The Surgical 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.	Same

Model and features	D20108 Ear Loops, Flat Pleated, 3 layers	Ear Loops, Flat Pleated, 3 layers	Same
Outer layer	Spunbond polypropylene	Spunbond polypropylene	Same
Middle layer	Melt-blown fabric (polypropylene)	Melt blown polypropylene	Same
Inner layer	Spunbond polypropylene	Spunbond polypropylene	Same
Nose piece	Polyethylene	Malleable polyethylene wire	Different
Ear loops	Polyester & polyurethane filament	Spandex	Different
Color	Blue	Yellow	Different
Dimension	Mask body: 17.5cm*9.5cm Nose-piece: 8cm-15cm Ear loop: 16.5cm-18cm	Mask body: 17.5cm*9.5cm	Similar
OTC use	Yes	Yes	Same
Sterility	Sterile	Non-sterile	Different
Sterilization method and S.A.L.	Sterilized by ethylene oxide gas, SAL=10^{-6}	Not applied	Different
Use	Single-use, disposable	Single-use, disposable	Same
ASTM F2100 level	Level 2	Level 2	Same
Fluid Resistance Performance	32 out of 32 pass at 120 mmHg (ASTM F1862)	32 out of 32 pass at 120 mmHg	Same
Particulate Filtration Efficiency	Pass at 99.69% -99.98% (ASTM F2299)	Pass at 99.7%	Similar
Bacterial Filtration Efficiency	Pass at 99.6%-99.8% (ASTM F2101)	Pass at 99.9%	Similar
Differential Pressure (Delta-P)	Pass at 4.14-5.90 mmH_2O/cm^2 (EN 14683)	Pass at 4.0 mmH_2O/cm^2	Similar
Flammability 16 CFR 1610	Class I (16 CFR Part 1610)	Class I	Same
Biocompatibility	Conform with ISO10993-1; Non-cytotoxic, Non-sensitizing, Non-irritating	Conform with ISO10993-1; Non-cytotoxic, Non-sensitizing, Non-irritating	Same

From the comparison table and the gap analysis above, the differences in the materials, colors and sterility status will not raise additional issue for safety and

effectiveness. Physical performance tests and biocompatibility evaluation have been carried out on the finished devices which include all construction materials and color additives; EO sterilization validation has also been provided to prove the product sterility and performance.

7. Non-clinical Test performed on the proposed device

The following performance data of surgical face mask were provided in support of the substantial equivalence determination:

7.1 Biocompatibility testing

The biocompatibility evaluation for the surgical face mask was conducted in accordance with the International Standard ISO 10993-1: 2018 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process,” as recognized by FDA. The outer layer, inner layer and ear loops are considered to be contacted with patient’s intact face skin for duration of less than 24 hours. And the biocompatibility evaluation included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Pass
Skin Sensitization	Under the conditions of the study, the device is non-sensitizing.	Pass
Skin Irritation	Under the conditions of the study, the device is non-irritating.	Pass

7.2 Physical performance testing

Physical performance was conducted, and the results show that the proposed device complies with the following standards:

- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks

Item	Subject device	Acceptance criteria	Result
Fluid Resistance Performance (mmHg) (ASTM F 1862-17)	32 out of 32 pass at 120 mmHg (Statistics of three lots)	29 out of 32 pass at 120 mmHg	Pass
Bacterial Filtration Efficiency Performance (%) (ASTM F2101-19)	99.6%-99.8% (Statistics of three lots)	≥ 98%	Pass
Differential Pressure	4.14-5.90 mmH_2O/cm^2	< 6.0mmH_2O/cm^2	Pass

(Delta-P) (mm H2O/cm2) (EN 14683: 2019)	(Statistics of three lots)		
Particulate Filtration Efficiency Performance (%) (ASTM F2299-2007)	99.69% -99.98% (Statistics of three lots)	≥ 98%	Pass
Flammability (16 CFR Part 1610)	Class I (Statistics of three lots)	Class I	Pass

7.3 Ethylene oxide Sterilization Validation

The proposed device is also provided for sterility, sterilization validation is performed and the results show that the proposed device complies with the following standards:

- ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

7.4 Clinical Test Conclusion

No clinical study is included in this submission.

8. Conclusions

The conclusion drawn from the non clinical tests demonstrates that the subject device in 510(K) submission k203190 for the Surgical face mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K182515.