March 2, 2021

Huizhou Foryou Medical Devices Co., Ltd
Guosheng Tan
Development Engineer
No. 1 Shangxia North Road, Dongjiang Hi-tech Industry Park
Huizhou, Guangdong 516005
China

Re: K201852
Trade/Device Name: Surgical Mask-Model Number: Ear Loop, Flat-Pleated
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 27, 2021
Received: February 1, 2021

Dear Guosheng Tan:

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, 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: 0MB No. 0910-0120
Expiration Date: *0613012020*
See PRA Statement below.

510(k) Number *(if known)*
K201852

Device Name
Surgical Mask

Indications for Use *(Describe)*
The Surgical 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 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) **X** 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

This 510(k) Summary information is being submitted in accordance with the requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K201852

1. Submitter:

Huizhou Foryou Medical Devices Co., Ltd.

Address:	No.1 Shangxia North Road, Dongjiang Hi-tech Industry Park, Huizhou, Guangdong, China
Phone:	+86-0752-5302185
Fax:	+86-0752-5302020
Contact Person:	Guosheng Tan
Date Prepared:	March 2, 2021

2. Subject Device:

Trade Name:	Surgical Mask
Common Name:	Surgical Mask
Classification Name:	Mask, Surgical
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR §878.4040
Device Class:	Class II

3. Predicate Device:

K182515

Surgical Face Mask

Wuhan Dymex Healthcare Co., Ltd

4. Device Description:

The Surgical Mask is a single use, Flat Pleated mask with ear loops and nose piece. The Surgical Mask is consisting of three layers, the inner and outer layers are made of spunbonded polypropylene, and the middle layer is made of melt blown polypropylene filter. The Surgical Mask uses different colors to distinguish the inner and outer layers, the inner layer is white and the outer layer is blue. The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the facemask. The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of polypropylene and metal wire. The Surgical Mask is sold non-sterile and is intended to be single use, disposable devices.

5. Indications for Use:

The Surgical 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

6. Technological Characteristics Comparison

Table 5.1 Comparison of technological characteristics between subject device and predicate device

Item	Subject Device (K201852)	Predicate Device (K182515)	Comparison
Intended Use	The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body	The Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body	Same

		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.	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.	
Model		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Flat Pleated, 3 layers	Same
Material	Outer layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nosepiece	Malleable polypropylene and metal wire	Malleable polyethylene wire	Similar
	Ear loops	Spandex	Spandex	Same
Color		Blue/White	Yellow	Different*
Dimension	Length	17.5cm±1cm	17.5cm±0.2cm	Same
	Width	9.5cm±1cm	9.5cm±0.2cm	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level		Level 2	Level 2	Same

*The difference in the color does not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all color additives.

7. Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the subject device met all design specifications as the predicate device. The test results demonstrate that the subject device conforms to the recognized standards ASTM F2100-19, ISO 10993-5 and ISO 10993-10 in addition to the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks–Premarket Notification [510(k)] Submission issued on March 5, 2004. Detailed test results are shown in the table 5.2.

Table 5.2 Summary of Non-clinical Performance Testing

Performance Characteristics	Test Method	Acceptance Criteria	Test Result
Fluid Resistance Performance	ASTM F1862/F1862M-17	29 out of 32 passes at 120mmHg	32 out of 32 passes at 120mmHg
Particulate Filtration Efficiency	ASTM F2299/F2299M-03	≥98%	99.79%
Bacterial Filtration Efficiency	ASTM F2101-19	≥98%	99.70%
Differential Pressure (ΔP)	MIL-M-36954C	<6.0mmH_2O/cm^2	3.813 mm H_2O/cm^2
Flammability	16 CFR 1610	Class 1	Class 1
Cytotoxicity	ISO 10993-5:2009	Under the conditions of the study, the device is non-cytotoxic.	Non-cytotoxic
Irritation	ISO 10993-10:2010	Under the conditions of the study, the device is non-irritating.	Non-irritating
Sensitization	ISO 10993-10:2010	Under the conditions of the study, the device is non-sensitizing.	Non-sensitizing

8. Clinical Performance Test

No clinical study is included in this submission.

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated K182515, Surgical Face Mask, Wuhan Dymex Healthcare Co., Ltd.