September 17, 2021

Ningbo Ouhan Medical Device Co., Ltd.
℅ Rafi Wong
Manager
Pacific Fortune Management Inc.
2350 Mission College BLVD, STE 475
Santa Clara, California 95054

Re: K203418
Trade/Device Name: Surgical Mask (Procedure Mask) (Models: OH02-01, OH02-01 (Bandage))
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 19, 2021
Received: August 25, 2021

Dear Rafi Wong:

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, 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)*
K203418

Device Name
Surgical Mask (Procedure Mask) (Models: OH02-01, OH02-01 (Bandage))

Indications for Use *(Describe)*
Surgical Mask (Procedure Mask) (Models: OH02-01, OH02-01 (Bandage)) 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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510K SUMMARY of K203418

Date of Summary Prepared: September 16, 2021

510K Number: K203418

1. Submitter Information

Submitter Contact:

Ningbo Ouhan Medical Device Co., Ltd.

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Designated Submission Correspondent:

Name: Rafi Wong

Phone Number: +1 (408) 646-6537

Email: rafi.wong@pfmfinance.com

2. Device Name:

Surgical Mask (Procedure Mask) (Models: OH02-01, OH02-01 (Bandage))

3. Regulatory Information

Classification Name: Mask, Surgical

Common Name: Surgical Apparel Apparel

Classification: Class II

Product Code: FXX

Regulation Number: 21 CFR 878.4040

4. Predicate Device

5. Intended Use/Indications for use

Surgical Mask (Procedure Mask) (Models: OH02-01, OH02-01 (Bandage)) 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. Device Description

The proposed Surgical Mask (Procedure Mask) body is a multi-layer construction of a Spun- bond polypropylene outer layer, meltblown middle layer and Spun-bond polypropylene inner layer. Nose clip is made of Aluminum plastic wire. There are two models of the proposed Surgical Mask (Procedure Mask), OH02-01 and OH02-01(Bandage). The main difference between each model is their wearing method, i.e. mask band part. For OH02-01 model, mask band part is made of non-woven fabric ear loops. For OH02-01(Bandage) model, mask band part is made of non-woven fabric ties. However, the raw materials of the two models devices are exactly the same. And have been tested according to ASTM F2100-19 Standard Specification For Performance Of Materials Used In Medical Face Masks. Surgical Mask (Procedure Mask) is a single use, disposable medical device that will be provided in non-sterile packaging configurations.

7. Summary of Comparison and Technological Characteristics

Table I - General Comparison

Items	Proposed Device	Predicate Device	Comparison
Product Common Name	Surgical Mask (Procedure Mask)	Single-use Surgical Mask	Difference
Manufacturer	Ningbo Ouhan Medical Device Co., Ltd.	BYD Precision Manufacturer Co.Ltd.	-

510K Number		K203418	K200923	-
Product Code		FXX	FXX	Same
Classification		Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)	Same
Intended Use/Indications for Use		Surgical Mask (Procedure Mask) (Models: OH02-01, OH02-01 (Bandage)) 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 Single-use Surgical Masks (Model:FE2311) 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		Flat earhook type, 3 layers / Tie-on type, 3 layers	Ear loop, Flat Pleated, 3 layers	Similar
Materials	**Outer Layer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle Layer	Meltblown polypropylene filter	Melt blown polypropylene filter	Same
	Inner Layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose Piece	Aluminum plastic wire	Metal Core Plastic	Similar
	Ear Loops/Ties	Non-woven fabric	Polyester	Difference
Color		Blue And White	Blue	Similar
Dimension (Width)		17.5 cm +/- 0.5 cm	17.5 cm +/- 0.4 cm	Similar
Dimension (Length)		9.5 cm +/- 0.5 cm	9.5 cm +/- 0.4 cm	Similar
OTC Use		Yes	Yes	Same

Single Use		Yes	Yes	Same
Sterile		No	No	Same
Sterilization modality		-	-	Same
ASTM F2100-19 Level		Level 3	Level 3	Same
Performance Testing	**Fluid Resistance Performance ASTM F1862**	32 out of 32 Pass at 160 mmHg	32 out of 32 Pass at 160 mmHg	Same
	Particulate Filtration Efficiency ASTM F2299	Pass at 99.12%	Pass at 99.67%	Similar
	Bacterial Filtration Efficiency ASTM F2101	Pass at 99.79%	Pass at 99.95%	Similar
	Differential Pressure (Delta P) MILM-36954C	3.57 mmH_2O/cm^2	5.62 mmH_2O/cm^2	Similar
	Flammability 16 CFR 1610	Class 1 (16 CFR 1610)	Class 1 (16 CFR 1610)	Same
Biocompatibility Testing (ISO 10993-1)	**Cytotoxicity ISO 10993-5: 2009**	Non-Cytotoxic	Non-Cytotoxic	Same
	Irritation ISO 10993-10: 2010	Non-Sensitizing	Non-Sensitizing	Same
	Sensitization ISO 10993-10: 2010	Non-Irritating	Non-Irritating	Same

*The difference in the materials and colors 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 construction materials and color additives.

8. Non-clinical Tests Performed on the Proposed Device

The proposed device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 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 (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.
- 16 CFR 1610, Standard For The Flammability Of Clothing Textiles.
- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices – Part 5: Tests For In Vitro Cytotoxicity.
- 10993-10: 2010 Biological Evaluation Of Medical Devices – Part 10: Tests For Irritation And Skin Sensitization.

Table II - Performance Testing Comparison Table

Item	Purpose	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862	In order to verify whether the subject device meets the performance requirements of ASTM F2100 level 3, Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result: Fluid resistant claimed at 160 mm Hg	Fluid resistant claimed at 160 mm Hg	32 out of 32 Pass at 160 mmHg (Average of 3 lots with 32 samples per lot) Pass
Particulate Filtration Efficiency ASTM F2299	In order to verify whether the subject device meets the performance	≥ 98%	Pass at 99.12% (Average of 3 lots with 32 samples per lot)

	requirements of ASTM F2100 level 3, Sub-micron particulate filtration efficiency at 0.1 µm of Polystyrene Latex Spheres: ≥ 98%		Pass
Bacterial Filtration Efficiency ASTM F2101	In order to verify whether the subject device meets the performance requirements of ASTM F2100 level 3, Bacterial filtration efficiency: ≥ 98%	≥ 98%	Pass at 99.79% (Average of 3 lots with 32 samples per lot) Pass
Differential Pressure (Delta P) MILM-36954C	In order to verify whether the subject equipment meets the performance requirements of ASTM F2100 level 3, Differential pressure (Delta-P): <6.0 mm H_2O/cm^2	<6.0 mm H_2O/cm^2	3.57 mmH_2O/cm^2 (Average of 3 lots with 32 samples per lot) Pass
Flammability 16 CFR 1610	In order to verify whether the subject equipment meets the performance requirements of ASTM F2100 level 3, Flame spread: Class 1	Class 1	Class 1 (Average of 3 lots with 32 samples per lot) (16 CFR 1610) Pass

Table III - Biocompatibility Testing Comparison Table

Item	Purpose	Acceptance Criteria	Result
Cytotoxicity **ISO 10993-5:2009**	Under the research conditions, determine whether the target device extract is cytotoxic.	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Non-Cytotoxic
Irritation ISO **10993-10: 2010**	Under the research conditions, determine whether the non-polar and polar extracts of the target device are sensitive.	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Non- Sensitizing
Sensitization **ISO 10993-10: 2010**	Under the research conditions, determine whether the non-polar and polar extracts of the target device are irritating.	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Non-Irritating

9. Clinical Test

There is no clinical study included in this submission.

10. Conclusion

The conclusions drawn from the non-clinical tests (biocompatibility and physical performance testing) demonstrate that the proposed device Surgical Mask (Procedure Mask) is as safe, as effective, and performs as well as or better than the predicate device, the Single- use Surgical Mask (K200923) manufactured by BYD Precision Manufacturer Co.Ltd.