July 21, 2021

Crown Name Disposable Hygiene Products Fty., Ltd.
Ying Fang
Manager
Chengbei Industrial Zone, Zhucheng Ave, Xinzhou District
Wuhan, Hubei 431400
China

Re: K203534
Trade/Device Name: Surgical face mask (Model: Flat Ear Loop/CN102)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 8, 2021
Received: April 21, 2021

Dear Ying Fang:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203534

Device Name
Surgical face mask (Model: Flat Ear Loop/CN102)

Indications for Use *(Describe)*
The surgical face mask(Model: Flat Ear Loop/CN102) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These 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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510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) Number: K203534

Summary Prepared Date:July 7, 2021

1. Submitter Information

Sponsor Name: Crown Name Disposable Hygiene Products Fty., Ltd.

Address: Chengbei Industrial Zone,Zhucheng Ave,Xinzhou District,Wuhan,Hubei, 431400,CHINA.

- Contact Person (including title): Ying Fang (Manger)
- Phone:+86-27-82761940
- Fax: +86-27-82761339
- E-mail :eric-shi2020@outlook.com

2. Subject Device Information

Type of 510(k):	Traditional
Common Name:	Surgical face mask
Trade Name:	Surgical face mask (Model: Flat Ear Loop/ CN102)
Classification Name:	Mask,Surgical
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	II

3. Predicate Device Information

Predicate Device

Sponsor:	Wuhan Dymex Healthcare Co., Ltd
Common Name:	Surgical Face Mask
Trade Name:	Surgical Face Mask

510(k) number:	K182515
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	II

4. Device Description

The surgical face mask is pleated three-layer mask. The inner and outer layers are made of spun-bond polypropylene.The middle layer is made of melt blown polypropylene filter.only the outer layers' color is blue (colorant: Pigment Blue15:3 /CAS number:147-14-8), which is held to cover the users' mouth and nose by two polyester and spandex elastic bands ultrasonic welded to the surgical face mask. The elastic ear loops are not made with natural rubber latex. The nose piece contained in the surgical face mask is in the middle layer of surgical face mask to allow the user to fit the surgical face mask around their noses, which is made of malleable aluminum wire coated with polypropylene resin.All of the material used in the construction of the new masks are being used in currently marketed devices.

The dimensions of each surgical face mask are length 175±10 mm and width 90±10 mm,The dimensions of nose piece is length 110±10 mm, and the ear loop is length 180±20 mm.

The surgical face mask are sold non-sterile and are intended to be single use,disposable devices.

5. Intended Use / Indications for Use

The surgical face mask(Model: Flat Ear Loop/CN102) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These 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. Comparison with predicate device

Table 1 General Comparison

Elements of Comparison		Subject Device	Predicate Device	Comparison
Manufacturer		Crown Name Disposable Hygiene Products Fty., Ltd.	Wuhan Dymex Healthcare Co., Ltd	--
Product Name		Surgical face mask	Surgical Face Mask	--
K Number		K203534	K182515	--
Product Code		FXX	FXX	Same
Regulation Number		21 CFR 878.4040	21 CFR 878.4040	Same
Intended use/ Indications for Use		The Surgical face mask(Model: Flat Ear Loop/CN102) is indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures.The mask is indicated in any procedure or situation where there is a risk of microorganism, body fluid and particulate aerosol transfer.The product is a single use,disposable device(s), provided non-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
Mask style		Flat pleated, 3 layers.	Flat pleated,3 layers.	Same
Design feature		Ear loop	Ear loop	Same
Material	Outer facing layer	spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose piece	Outer plastic, inner aluminum wire	Malleable polyethylene wire	Different Note 1
	Ear loops	Spandex	Spandex	Same
Color		Blue	Yellow	Different Note 1

Dimension (Width)	17.5cm±1.0cm	17.5cm±0.2cm	Different Note 2
Dimension (Length)	9.0cm±1.0cm	9.5cm±0.2cm	Different Note 2
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level	Level 2	Level 2	Same
Fluid resistance Performance ASTM F1862	Level 2:32 out of 32 pass at 120mmHg,3non-consecutive lots tested.	32 out of 32 pass at 120 mmHg	Similar
Particle Filtration Efficiency ASTM F2299	3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 98.36% Lot B: 98.49% Lot C: 98.43%	98.46%	Similar Note 3
Bacterial Filtration Efficiency ASTM F2101	3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 99.89% Lot B: 99.89% Lot C: 98.87%	98.7%	Similar Note 3
Flammability Class 16 CFR 1610	Class1, 3 non-consecutive lots tested,using a sample size of 32/lot.	Class 1 Non Flammable	Similar
Differential Pressure(Delta –P)	3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 3.3 mm H_2O/cm^2 Lot B: 3.3 mm H_2O/cm^2 Lot C: 3.3 mm H_2O/cm^2 (EN 14683:2019,Annex C)	4.2mmH_2O/cm^2 (MIL-M-36954C)	Similar Note 3
Biocompatibility	ISO10993-5 and ISO10993-10;Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	ISO10993-5 and ISO10993-10; Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	Same

Note 1

The materials of the current nose piece and the colors were different from the predicate device.

The biocompatibility evaluation test of the subject devices have been performed on the final finished device. The test results shows pass the requirements.

Note 2

Compare with the predicate and reference device, the different of the physical feature or size does not affect the intended use of the subject device.

Note 3

For the Performance testing, the test results are not identical to each other, but they are similar and they both meet the requirement of Level 2 medical mask according to the ASTM F 2100.

7. Summary of Non-Clinical Tests Performed

Non-clinical tests were conducted to verify that the proposed device met all design specifications as to the predicate device. The test results demonstrated that the proposed device complies with 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:

- ASTM F2299-03(2017), Standard Test Method for Determining the Initial Efficiency of Materials Used in Surgical face masks to Penetration by Particulates Using Latex Spheres.
- EN 14683:2019,Annex C.Method for determination of breathability (differential pressure)
- ASTM F1862/ASTM F1862M-17, Standard test method for resistance of Surgical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity)

- ASTM F2101-19, Standard Test Method For Evaluating The Bacterial Filtration Efficiency (BFE) Of Surgical face mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus.
- 16 CFR Part 1610, Standard for the flammability of clothing textiles.
- 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.

Table 2:Performance Testing

Test item (Performance Level 2)	**Proposed device**	**Acceptance criteria (Level 2)**	**Test results**
Bacterial filtration efficiency (BFE) ASTM F2101-19	3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 99.89% Lot B: 99.89% Lot C: 98.87%	BFE≥98%.	Pass
Differential pressure, (Delta-P) EN 14683:2019,Annex C	3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 3.3 mm H_2O/cm^2 Lot B: 3.3 mm H_2O/cm^2 Lot C: 3.3 mm H_2O/cm^2 (EN 14683:2019,Annex C)	Delta-P <6.0H_2O/cm^2	Pass
Sub-micron particulate filltration efficiency at 0.1 micron. ASTM F2299	3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 98.36% Lot B: 98.49% Lot C: 98.43%	PFE≥98%.	Pass
Resistance to penetration by synthetic blood ASTM F1862	Level 2:32 out of 32 pass at 120mmHg,3non-consecutive tested.	29 out of 32 pass at 120mmHg	Pass
Flame spread 16 CFR Part 1610	Class1,3 non-consecutive tested,using a sample size of 32/lot.	Class 1:Burn time≥3.5 seconds	Pass

Results: All tests were passed.

Biocompatibility evaluation and test

Biocompatibility evaluation conducted in accordance with the FDA's 2016 guidance and ISO10993-1:2018 supports that the subject devices are biocompatible.

The biocompatibility test includes the following tests:

- In vitro Cytotoxicity Test per ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
- Skin Sensitization Tests per ISO 10993-10:2010 Biological evaluation of medical devices —Part 10: Tests for irritation and skin sensitization
- Skin Irritation Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization.

Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the device is noncytotoxic.	Pass
Irritation	Under the conditions of the study, the device is nonirritating.	Pass
Sensitization	Under the conditions of the study, the device is nonsensitizing	Pass

8. Summary of Clinical Performance Test

No clinical study is included in this submission.

9. Final Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Surgical face mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Surgical Face Masks (K182515).