December 31, 2020

Changzhou Combat Protective Equipment Co., Ltd.
Yanmei Song
Official Correspondent
QingSiTang village, Henglin Town, Wujin District
Changzhou, Jiangsu 213101
China

Re: K202615
Trade/Device Name: Nordiwell Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 23, 2020
Received: November 30, 2020

Dear Yanmei Song:

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 CAPT Elizabeth Claverie, M.S.
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)*
K202615

Device Name
Nordiwell Medical Face Mask

Indications for Use *(Describe)*
When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate matter. This device is non-sterile and for single use only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K202615

510(k) Summary

1. Contact Information

1.1. Applicant

Applicant Name: Changzhou Combat Protective Equipment Co., Ltd.
Address: Qingsitang, Henglin, Changzhou, Jiangsu, 213101 China
Contact Person: Yanmei Song
Title: Sales Manager
Telephone: +86-519-85190068; +86-15051998125
E-mail: xinyaoutdoor08@126.com

1.2. Consultant

Company: Sinow Medical AS
Address: Vestre Fantoftåsen 44, 5072, Bergen, Norway
Contact Person: Huifang Zhao
Telephone: +86 13961151430
Email: zhao@bergemed.com

2. Device information

Trade Name: Nordiwell Medical Face Mask
Common Name: Surgical Face Mask
Regulatory information:
Classification Name: Mask, Surgical
Classification: II
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Review Panel: General Hospital

3. Legally Marketed Primary Predicate Device

Product name: Avianz® Surgical Face Mask
510(k) Number: K200847
Product Code: FXX
Manufacture: MEXPO INTERNATIONAL INC.

4. Indication for use

When properly worn, the medical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate matter. This device is non-sterile and for single use only.

5. Device Description

The Nordiwell Medical Face Masks are composed of 3-layers and are flat-pleated. The mask materials consist of an outer layer (polypropylene spunbond, blue), inner layer (polypropylene spunbond white), filter (polypropylene melt-blown, white) and ear-loops. The mask contains a malleable nosepiece to provide a firm fit over the nose and then to secure the mask over the users' mouth and face. The mask is a single use, provided non-sterile.

This device is not made from Natural Rubber Latex.

Shelf-life of the device is 2 years.

6. Substantially Equivalent (SE) Comparison

Device	**Subject Device (K202615) Nordiwell Medical Face Mask, Model 952001**	**Predicate Device (K200847) Avianz® Surgical Face Mask**	**Comparison**
Intend use	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate matter. This device is non-sterile and for single use only.	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only.	Same
	Material		
Outer Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Filter(Middle layer)	Melt Blown Polypropylene Filter	Melt Blown Polypropylene Filter	Same
Inner Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Nose Wire	Single Galvanize Wire, Coated	Single Galvanize Wire, Coated	Similar

	by Polypropylene	by PE	
Ear Loops	Spandex and Nylon, natural rubber latex free	Not made with natural rubber latex	Same
Design Features			
Colors	Blue	White	Different
Style	Flat - Pleated	Flat - Pleated	Same
Multiple Layers	Yes	Yes	Same
Single Use	Yes	Yes	Same
OTC Use	Yes	Yes	Same
Sterility			
Sterile	Non-Sterile	Non-Sterile	Same
Dimension			
Length	17.5cm ±0.5cm	17.5cm ±0.5cm	Same
Width	9.5cm ±0.5cm	9.0cm ±0.5cm	Similar
Performance			
Fluid Resistance Performance ASTM F1862	32 of 32 pass at 160 mmHg	30 Out of 32 pass at 120 mmHg	Better
Particulate Filtration Efficiency ASTM F2299	> 99.9%	99.9%	Same
Bacterial Filtration Efficiency ASTM F2101	> 99.9%	⩾98%	Better
Differential Pressure (Delta P)	5.6 mmH_20/cm^2 (EN 14683:2019, Annex C and ASTM F2100-19)	3.0 mmH_20/cm^2 (MILM-36954C)	Similar
Flammability 16 CFR 1610	Class 1	Class 1	Same
Biocompatibility			
In Vitro Cytotoxicity Test ISO 10993-5: 2009	Non-Cytotoxic	Non-Cytotoxic	Same
Skin Irritation Test ISO 10993-10:2010	Non-Irritating	Non-Irritating	Same
Skin Sensitization Test ISO 10993-10:2010	Non-Sensitizing	Non-Sensitizing	Same

7. Non-Clinical Test

Non clinical tests were conducted to verify that the proposed device met all design

specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

(1) Performance test:

Bench test was conducted on Medical Face Mask for proposed device to determine substantially equivalence. The bench tests include the following tests:

Item	Proposed Device	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862-17	32 of 32 pass at 160 mmHg	≥29 of 32 pass at 160 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299-17	> 99.9%	≥ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101-19	> 99.9%	≥ 98%	Pass
Differential Pressure (Delta P) EN 14683:2019, Annex C and ASTM F2100-19.	5.6 mmH_20/cm^2	<6.0 mmH_20/cm^2	Pass
Flammability 16 CFR 1610	Class 1	Class 1	Pass

(2) 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（ISO 10993-5: 2009）

Skin Irritation Test（ISO 10993-10:2010）

Skin Sensitization Test（ISO 10993-10:2010）

(3) Shelf-life accelerated aging test

The accelerated aging tests were conducted with 3 non-consecutive lots. The following performances were tested both for before and after aged products:

Fluid Resistance Performance according to ASTM F1862-17.

Particulate Filtration Efficiency according to ASTM F2299-17.

Bacterial Filtration Efficiency according to ASTM F2101-19.

Differential Pressure (Delta P) according to EN 14683:2019, Annex C and ASTM F2100-19.

Flammability according to 16 CFR 1610.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The summary includes the conclusions drawn from the nonclinical and clinical tests (discussed above) that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device.