March 9, 2021

Changzhou Combat Protective Equipment Co., Ltd.
Tao Wang
Development Manager
QingSiTang Village, Henglin Town, Wujin District
Changzhou, Jiangsu 213101
China

Re: K210181
Trade/Device Name: Nordiwell Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 22, 2021
Received: March 1, 2021

Dear Tao Wang:

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, Ph.D.
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)*
K210181

Device Name
Nordiwell Surgical 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.

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K210181

510(k) Summary

Date Prepared: 02/20/2021

1. Contact Information

1.1. Applicant

Applicant Name: Changzhou Combat Protective Equipment Co., Ltd.

Address: Qingsitang, Henglin, Changzhou, Jiangsu, 213101 China

Contact Person: Tao Wang

Title: Development Manager

Telephone: +86-519-85190068

E-mail: zhao.huifang@hotmail.com

1.2. Consultant

Company: Sinow Medical AS

Address: Høyteknologisenteret, Thormøhlens gate 55, 5006 Bergen, Norway

Contact Person: Huifang Zhao

Telephone: +86 13961151430

Email: zhao@bergemed.com

2. Device information

Trade Name: Nordiwell Surgical 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

Nordiwell Medical Face Mask (K202615)

4. Indication for 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.

5. Device Description

The Nordiwell Surgical 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 ties (polypropylene spunbond white). The mask contains a malleable nosepiece which is centrally positioned between the opposed side edges along the top edge of the mask. The nosepiece is a stable anchor in the vicinity of the nose and readily bent to conform to contours of a person's face. Thus the nosepiece can 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 with natural rubber latex and Shelf-life of the device is 2 years.

The subject of this submission is a design change to the ear-loop in the Nordiwell Medical Face Mask(K202615). The ear-loop of the Nordiwell Medical Face Mask(K202615) is changed to tie in the subject device.

6. Comparison of Technological Characteristics

Device	**Subject Device (K210181) Nordiwell Surgical Face Mask, Model 952002**	**Predicate Device (K202615) Nordiwell Medical Face Mask, Model 952001**	**Comparison**
Indications for 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 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.	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 by Polypropylene	Single Galvanize Wire, Coated by Polypropylene	Same
Attachment	Tie: Spunbond Polypropylene	Ear-Loop: Spandex and Nylon; Not made with natural rubber.	Different
Design Features			
Colors	Blue	Blue	Same
Style	Flat - Pleated	Flat - Pleated	Same
Multiple Layers	3	3	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	9.5cm ±0.5cm	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
Performance			
ASTM F2100 Level	Level 3	Level 3	Same
Fluid Resistance Performance ASTM F1862	32 of 32 pass at 160 mmHg	32 of 32 pass at 160 mmHg	Same
Particulate Filtration Efficiency ASTM F2299	> 99.9%	99.9%	Same
Bacterial Filtration Efficiency ASTM F2101	> 99.9%	⩾98%	Same
Differential Pressure (Delta P)	5.6 mmH_20/cm^2 (EN 14683:2019, Annex C and ASTM F2100-19)	5.6 mmH_20/cm^2 (EN 14683:2019, Annex C and ASTM F2100-19)	Same

Flammability 16 CFR 1610	Class 1	Class 1	Same

7. Description of the change

The sole modification is the replacement of the ear-loop of the predicate device with a tie attachment. The essential function and performance of the face mask depend on the main body of the mask. The function of ear-loop and tie is to allow the main body of the mask to cover important parts of the face to achieve a protective effect. According to the Instruction for Use, both the ear-loop and tie can achieve the function of fixing the mask. So the modification does not affect the indication for use, essential function and performance of the device.

The labeling will require minor changes in the device name, description and donning/doffing procedures.

8. Performance data

8.1. Non-clinical Performance Testing:

(1) Bench testing was conducted to demonstrate the performance of the subject device. The bench testing includes the following tests:

Fluid Resistance Performance (ASTM F1862-17)

Particulate Filtration Efficiency (ASTM F2299-17)

Bacterial Filtration Efficiency (ASTM F2101-19)

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

Flammability (16 CFR 1610)

(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）

8.2. Clinical Performance Testing

No clinical study is included in this submission.

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210181, the Nordiwell Surgical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202615.