June 29, 2021

Changzhou Combat Protective Equipment Co., Ltd.
Xiaoqing Xue
Quality Manager
QingSiTang Village, Henglin Town, Wujin District
Changzhou, Jiangsu 213101
China

Re: K210445
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: March 31, 2021
Received: March 31, 2021

Dear Xiaoqing Xue:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210445

Device Name
Nordiwell Medical Face Mask

Indications for Use *(Describe)*
The Nordiwell Medical Face Mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate matters. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device(s) and 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.

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

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510(k) Summary
K210445

1. Contact Information

1.1. Applicant

Applicant Name: Changzhou Combat Protective Equipment Co., Ltd.
Address: Qingsitang, Henglin, Changzhou, Jiangsu, 213101 China
Contact Person: Xiaoqing Xue
Title: Quality Manager
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E-mail: xqxue2003@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
Date of the 510(k) Summary Prepared: June 25, 2021

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: 3M™ High Performance Surgical Mask
510(k) Number: K180874
Product Code: FXX
Manufacture: 3M Health Care

4. Indication for use

The Nordiwell Medical Face Mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate matters. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device(s) and provided non-sterile.

5. Device Description

The Nordiwell Medical Face Mask has a flat-folded design consisting of three layers that are comprised of an (polypropylene spunbond) inner and outer cover web and (polypropylene melt blown) filter web. The mask has earloops or tie strings to secure the mask over the users' mouth and face and includes a malleable nosepiece to provide a firm fit over the nose. This is a single use, disposable device, provided non-sterile.

6. Technological Characteristic Comparison

Device	**Subject Device K210445 Nordiwell Medical Face Mask**	**Predicate Device K180874 3M™ High Performance Surgical Mask 1838R**	**Comparison**
Intend use/Indications for Use	The Nordiwell Medical Face Mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate matters. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device(s) and provided non-sterile.	3M™ High Performance Surgical Mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face mask(s) are intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device(s) and provided non-sterile.	same

Material			
Outer Cover Web	Polypropylene Spunbond	Polypropylene Spunbond, (w Print) – Upper Top Half Polypropylene Spunbond, White – Lower Bottom Half	same
Middle Web/Filter	Polypropylene Melt Blown	Polypropylene Melt Blown	same
Inner Cover Web	Polypropylene Spunbond	Polypropylene Spunbond	same
Earloops or tie strings	Spandex and Nylon	Polypropylene Spunbond or Polyethylene Terephthalate	Different[1]
Nose Piece	Polyethylene coated steel wire	Polyethylene coated steel wire	same
Design Features			
Colors	White	Blue - Outer Cover Web (Upper) White – Outer Cover Web (Lower)	silimar
Mask Design			
Style	Flat folded	Duckbill	Different[2]
Single Use	Yes	Yes	same
Sterility			
Sterile	Non-Sterile	Non-Sterile	same
Dimension			
Length	160 mm ± 5 mm	187 mm ± 4 mm	Different[2]
Width	106 mm ± 5mm	107 mm ± 6 mm	similar

Technological Characteristics: Product Performance Specifications Per ASTM F2100 - Meets ASTM Level 2			
Fluid Resistance	31 of 32 pass at 120 mmHg	Meet ASTM F2100 level 2 and ASTM F1862 requirement	same
Particulate Filtration Efficiency	99.9%, 32 of 32 pass	Meet ASTM F2100 level 2 and ASTM F2299 requirement	same
Bacterial Filtration Efficiency	99.9%, 32 of 32 pass	Meet ASTM F2100 level 2 and ASTM F2101 requirement	same
Differential pressure	4.6 mmH_20/cm^2 32 of 32 pass	Meet ASTM F2100 level 2 and MIL-M36954C requirement	same
Flammability	Class 1, 32 of 32 pass	Meet ASTM F2100 level 2 and 16 CFR 1610 requirement	same
Shelf life	2 years	Unknown	
Biocompatibility			
Results	Biocompatible, Non-Cytotoxic, Non-Irritating, Non-Sensitizing	Biocompatible, Non-Cytotoxic, Non- Irritating, Non-Sensitizing	same

Different[1]: The patient contacting material for the proposed device is different from predicate device. However, biocompatibility test has been performed on the proposed device and the results does not show any adverse effect.

Different[2]:The design style and dimension for proposed device is different from predicate device, but the differences of design and size don't affect the indication for use.

7. Non-Clinical Test

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

(1) Performance test:

Bench test was conducted on 3 nonconsecutive lots of Medical Face Mask for proposed device to determine if the subject device met the specifications in the standard. The bench tests include the following tests:

Item	Proposed Device	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862-17	31 of 32 pass at 120 mmHg	≥29 of 32 pass at 120 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299-17	99.9%, 32 of 32 pass	≥ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101-19	99.9%, 32 of 32 pass	≥ 98%	Pass
Differential Pressure (Delta P) EN 14683:2019, Annex C and ASTM F2100-19.	4.6 mmH_20/cm^2 32 of 32 pass	<6.0 mmH_20/cm^2	Pass
Flammability 16 CFR 1610	Class 1, 32 of 32 pass	Class 1	Pass

(2) Biocompatibility evaluation and test

Biocompatibility evaluation conducted in accordance with FDA's 2020 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. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrate that the subject device in 510(k) submission K210445 is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K180874.