August 19, 2022

HuiZhou TianChang Industrial Co., Ltd
% Viky Verna
CEO
Mhetra LLC
848 Brickell Ave. PH 5
Miami, Florida 33131

Re: K203078
Trade/Device Name: CAREWE Surgical Face Mask Models N001-AW, N002-AW, and N003-AW
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 8, 2022
Received: August 10, 2022

Dear Viky Verna:

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,

Bifeng Qian, M.D., 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)*
K203078

Device Name
CAREWE Surgical Face Mask Models N001-AW, N002-AW, and N003-AW

Indications for Use *(Describe)*
The CAREWE Surgical Face Masks Models N001-AW, N002-AW, and N003-AW are intended to be worn to protect both the adult patient and healthcare personnel from transfer of microorganisms, body fluids and material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The masks are single-use and disposable.

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 K203078

1. Applicant/ Device Information

Submitter Name:	Hui Zhou Tian Chang Industrial Co. Ltd
Responsible person:	Johnny Chan
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Official Correspondent:

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Date prepared:	August 18, 2022

Device Name	CAREWE Surgical Face Mask Models N001-AW, N002-AW, and N003-AW
510(k) Number	K203078
Common Name	Surgical Face Mask
Classification Name:	Surgical apparel
Classification Regulation:	21CFR 878.4040
Product Code:	FXX

2. Predicate Device Information

Manufacturer	GUANGDONG KAIDI GARMENTS CO., LTD
Device Name	Disposable Medical Surgical Face Masks
510(k) Number	K202211
Classification Name:	Surgical apparel
Classification Regulation:	21CFR 878.4040
Product Code:	FXX

3. Device Description

The CAREWE Surgical Face Masks Models N001-AW, N002-AW, and N003-AW are flat-folded, single-use, disposable face masks which cover the user's nose and mouth. The mask is held in place by two elastic nylon ear loops ultrasonically bound to the mask, which attach to the user's ears. The color of the mask is white.

The CAREWE Surgical Face Mask consists of 4 ultrasonically bound layers:
1) an outer layer made of hydrophobic non-woven polypropylene;
2) a middle-layer made of polyester fiber;
3) a medium composed of melt-blown polypropylene; and
4) an inner-layer made of hydrophilic non-woven polypropylene.

The mask also features a polyurethane (PU) nose pad which is attached to the mask's interior (on the hydrophilic layer). The mask meets ASTM F2100 Level 2 standards.

The design, configuration, materials, and production process are all the same for all three proposed models N001-AW, N002-AW, N003-AW. They are all manufactured with the same technical specifications. The models are labeled differently strictly for marketing, sales and logistic reasons only.

4. Indications For Use

The CAREWE Surgical Face Masks Models N001-AW, N002-AW, and N003-AW are intended to be worn to protect both the adult patient and healthcare personnel from transfer of microorganisms, body fluids and material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The masks are single-use and disposable.

5. Comparison of Technological Characteristics

Table 5.1 provides a comparison of the predominant technical characteristics of the subject device and the legally marketed predicate device.

Table 5.1: Comparison of Technological Characteristics

Description	Predicate Device	Subject Device	Comparison
Device Name	Disposable Medical Surgical Face Masks	CAREWE Surgical Face Mask Models N001-AW, N002-AW, and N003-AW	N/A
510(k) Number	K202211	K203078	N/A
Manufacturer	Guangdong Kaidi Garments Co., Ltd	Hui Zhou Tian Chang Industrial Co. Ltd	N/A
Classification, Product Code and Regulation	Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same
Classification name/ panel	Surgical apparel/ General Hospital	Surgical apparel/ General Hospital	Same
Indications For Use	The Disposable Medical 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.	The CAREWE Surgical Face Masks Models N001-AW, N002-AW, and N003-AW are intended to be worn to protect both the adult patient and healthcare personnel from transfer of microorganisms, body fluids and material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The masks are single-use and disposable.	Similar
Design	Flat pleated	Butterfly flat-fold	Different
Outer Facing layer	Spunbound non-woven fabric	Non-woven PP hydrophobic	Similar
Inner Facing layer	Spunbound non-woven fabric	Non-woven PP hydrophilic	Similar
Filter Media	N/A	Meltblown PP charged	Different
Middle	Melt-blown non-woven fabric	Polyester Fiber	Different
Nose Piece	Polyethylene (PE) & iron wire	Polyvinylchloride (PVC) & annealed iron wire	Similar
Layers	3ply	4ply	Different

Description	Predicate Device	Subject Device	Comparison
Ear Loop/ Strap	Ear Loop (Nylon & Spandex)	Ear Loop (Nylon)	Similar
Nose Foam	N/A	Polyurethane (PU)	N/A
Use	Single Use, Disposable	Single Use, Disposable	Same
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
ASTM F2100	Level 2	Level 2	Same

6. Summary of Non-clinical Performance Tests:

The following tests were performed to verify appropriate safety and effectiveness.

Table 5.2 Summary of Performance Testing Performed

Description	Purpose	Acceptance Criteria (Level 2)	Results
Fluid Resistance ASTM F1862	Demonstrate adequate resistance to fluid penetration	29 out of 32 Pass at 120 mmHg	Pass
Particulate Filtration Efficiency (PFE) ASTM F2100	Demonstrate adequate particulate barrier properties	≥ 98%	Pass
Bacterial Filtration Efficiency (BFE) ASTM F2101	Demonstrate adequate bacterial barrier properties	≥ 98%	Pass
Differential Pressure (Delta P) ASTM F2100	Demonstrate adequate air penetration properties	< 6.0mmH_2O/cm^2	Pass
Flammability 16CFR 1610	Demonstrate adequate flammability resistance	Class I	Pass
Cytotoxicity ISO 10993-5	Determine the cytotoxicity of the test article	Under the conditions of the study, the device is non-cytotoxic in accordance with ISO 10993-5:2010 standard	Pass
Skin Irritation ISO 10993-10	Evaluate potential of the test article to cause skin irritation	Under the conditions of the study, the device is non-irritating in accordance with ISO 10993-10:2010 standard	Pass
Skin Sensitization ISO 10993-10	Evaluate potential of the test article to cause delayed dermal contact sensitization	Under the conditions of the study, the device is non-sensitizing in accordance with ISO 10993-10:2010 standard	Pass

The nonclinical test results demonstrate compliance with ASTM F2100 Level 2 requirements for face masks.

7. Clinical testing

No clinical testing was included in this submission.

8. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the CAREWE Surgical Face Mask Models N001-AW, N002-AW and N003-AW, the subject device, is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K202211).