February 19, 2022

Taiwan Comfort Champ Manufacturing Co., Ltd.
℅ Jen Ke-Min
Contact Person
Chinese-European Industrial Research Society
No. 58, Fu-Chiun St
Hsin-Chu City, Taiwan 30067
Taiwan

Re: K212863
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 8, 2022
Received: February 14, 2022

Dear Jen Ke-Min:

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, PhD
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)*
K212863

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
The Surgical Face Mask is 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 potential exposure to blood and body fluids. The face mask is single use, disposable device, 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Taiwan Comfort Champ Manufacturing Co., Ltd.
No.55, Aly. 51, Ln. 50, Daren Rd., Taoyuan Dist., Taoyuan City, TAIWAN
Tel: +886-3-363-7999, Fax: +886-3-366-0999
Website：https://taiwan-champ.com/

510(k) Summary *(Per 21 CFR 807.92)*

510(k) number: ***K212863***

- **Submitter's information**

Name	Taiwan Comfort Champ Manufacturing Co., Ltd.
Address	No.55, Aly. 51, Ln. 50, Daren Rd., Taoyuan Dist., Taoyuan City, TAIWAN
Telephone	Tel:+886-3-363-7999
Fax	Fax: +886-3-366-0999
Contact Person	Dr. Jen, Ke-Min No. 58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan TEL: +886-3-5208829 FAX: +886-3-5209783 Email: ceirs.jen@msa.hinet.net
Date the Summary was prepared	February 11, 2022

- **Name of the Subject Device**

Trade or Proprietary name	Surgical Face Mask
Common or Usual name	Surgical Mask
Classification name	Surgical Apparel (21 CFR 878.4040)

- **Predicate Device**

Owner	Modern Healthcare Corp.
Product name	Motex Anti-Fog Surgical Face Mask, type: Tie-on, Ear-loop
510(k) number	K201549

- **Device descriptions**

  - **General description**

    The Surgical Face Mask is 4 ply Flat Pleated type mask, utilizing ear loops for wearing, and it has nose band design for fitting the face mask around the nose.

The Surgical Face Mask is manufactured with four layers. The first and second layers are made of polypropylene (PP) non-woven fabric with green coloration. The third layer has filtration function and is made of polypropylene (PP) melt-blown non-woven fabric. The fourth layer (inner layer) contacting with face is made of polypropylene (PP) non-woven fabric without color. The functions of the four layers are as follows,

1st Layer：Water-repelling, non-woven fabric. Prevents droplet and spray penetration.
2nd Layer：Water-repelling, non-woven fabric. Prevents droplet and spray penetration.
3rd Layer：Electrostatic-induced melt-blown polypropylene, blocks dust and microbes.
4th Layer：PP non-woven fabric, provides soft feel and reinforces spray and droplet protection.

The Surgical Face Mask is held in place over the user's mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are made of Nylon.
The nose band, made of steel wire coated with Polyethylene resin, contained in the subject device is in the layers of face mask to allow the user to fit the face mask around their nose.

The Surgical Face Masks are sold non-sterile and are intended to be single-use. The size of the face mask is 175 mm * 95 mm.

- **Device components and materials**

NO.	Device Components	Materials	Specification Material
1.	Face masks (First layer)	Polypropylene nonwoven	40g/m^2, Green non-woven fabric
2.	Face masks (Second layer)	Polypropylene nonwoven	30g/m^2 Green non-woven fabric

3.	Face masks (Third layer)	Polypropylene melt-blown non-woven fabric	20g/m^2 melt-blown non-woven fabric
4.	Face masks (Fourth layer)	Polypropylene nonwoven	20g/m^2 white non-woven fabric
5.	Elastic ear loops	Nylon	white round elastic string
6.	Nose band	PE	white

- **Indications for Use**

  The Surgical Face Mask is 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 potential exposure to blood and body fluids. The face mask is single use, disposable device, provided non-sterile.

- **Comparison Table**

Description	**Subject Device**	**Predicate Device**	**Comparison**
Manufacturer	Taiwan Comfort Champ Manufacturing Co., Ltd.	Modern Healthcare Corp.	--
Product trade name	Taiwan Comfort Champ Surgical Face Mask	Motex Anti-Fog Surgical Face Mask, type: Tie-on, Ear-loop	--
510(k) number	K212863	K201549	--
Classification name	Apparel, Surgical	Apparel, Surgical	Same
Product Code	FXX	FXX	Same
Device Class	2	2	Same
Regulation number	878.4040	878.4040	Same
Material composition	Inner (Fourth) layer: Polypropylene non-woven fabric Third (filter) layer: Polypropylene melt-blown non-woven fabric **Second layer**: Polypropylene non-woven fabric **First layer**: Polypropylene non-woven fabric (green color) Nose band: Polyethylene resin **Ear loop: Nylon**	Inner layer: Bicomponent thermal-bonded nonwoven (PP/PE) Filter layer: Polypropylene Melt-blown **Outer layer**: Polypropylene Spunbond (blue, green, white, pink color) Anti-Fog film: EP coated Polyethylene Nose band: Steel wire coated with Polyethylene resin **Ear loop: Spandex** Tie strip: Polypropylene Spunbond	**Different**

Anti-Fog function	**No**	**Yes**	**Different**
Dimensions	Length: 175±5 mm Width: 95 ±5 mm	Length: 165±5 mm Width: 95 ±2 mm	Similar
Mask style	Flat pleated	Flat pleated	Same
Design features	Ear-loop	Ear-loop & Tie-on	Similar
Differential Pressure (Delta-P) Test (mm H_2O/cm^2), complying with EN 14683:2019+ AC:2019 (E), Annex C	< 5 mmH_2O/cm^2 Per ASTM F2100-20, Section 9.2, criteria: < 6 mmH_2O/cm^2	≤ 2.8 mmH_2O/cm^2 Per ASTM F2100-20, Section 9.2, criteria: < 6 mmH_2O/cm^2	Same
Resistance to penetration by synthetic blood (mm Hg), complying with ASTM F1862/F1862M-17	No penetration at 160 mmHg Per ASTM F2100-20, Section 9.4, criteria: no penetration at 160 mmHg	No penetration at 160 mmHg Per ASTM F2100-20, Section 9.4, criteria: no penetration at 160 mmHg	Same
Particulate Filtration Efficiency at 0.1 micron (%), complying with ASTM **F**2299/F2299M-03(2017)	≥ 99.8% Per ASTM F2100-20, section 9.3, criteria: ≥ 98%	≥ 99.72% Per ASTM F2100-20, section 9.3, criteria: ≥ 98%	Same
Flammability test, **c**omplying with 16 CFR Part 1610	Class I (Did Not Ignite) Per ASTM F2100-20, Section 9.5, criteria: Class 1	Class 1 (Ignited but Extinguished) Per 16 CFR Part 1610, criteria: Class 1	Similar
Bacterial Filtration Efficiency (%), complying with ASTM F2101-19	≥ 99.8% Per ASTM F2100-20, Section 9.1, criteria: ≥ 98%	≥ 99.5 % Per ASTM F2100-20, Section 9.1, criteria: ≥ 98%	Same

- **Nonclinical performance testing**

Provided below is a summary of the nonclinical testing that was performed with the subject devices to demonstrate that the device met the acceptance criteria of the standard and test methodology listed below. Each test was performed using 3 nonconsecutive lots of 32 for a total of 96 samples.

Item	Test method (Performance Level 3)	Purpose	Acceptance criteria	Test results / Verdict
1	EN 14683:2019+AC: 2019(E), Annex C	Evaluate the mask's resistance to airflow across the face mask Differential pressure (Delta-P)	ASTM F2100-20, Section 9.2: < 6 mm H_2O/cm^2	< 5 mm H_2O/cm^2 / Pass
2	ASTM F1862/F1862M-17	Evaluate the mask's resistance to penetration by synthetic blood	ASTM F2100-20, Section 9.4, No penetration at 160 mmHg	No penetration at 160 mmHg / Pass
3	ASTM F2299/F2299M-03 (2017)	Evaluate the efficiency of material used in medical face masks to penetration by particulates using latex spheres	ASTM F2100-20, Section 9.3, ≥ 98%	≥ 99.8 % / Pass
4	16 CFR Part 1610 (as amended in 2008)	Evaluate the mask's flammability when exposed to a direct source of ignition	ASTM F2100-20, Section 9.5, Class 1	Class 1 / Pass
5	ASTM F2101-19 Bacterial filtration efficiency (BFE)	Evaluate the efficiency of material used in medical face masks to penetration by bacterial organisms	ASTM F2100-20, Section 9.1, ≥ 98%	≧99.8 % / Pass

- **Biocompatibility Testing**

According to ISO 10993-1:2018, Table A.1, the nature of body contact for the subject device is **Surface Device** category, **Skin Intact Contact**, and duration of contact is **A-Limited** duration (less than 24 hours). Under these categorizations, it is necessary to conduct the following testing to address the Cytotoxicity, Sensitization and Irritation effects. Thus, we provide the following test reports for the subject device to demonstrate that it is biocompatible with human body and safe for its intended use,

1) **In vitro Cytotoxicity Test** per ISO 10993-5:2009 Biological evaluation of

medical devices- Part 5: Tests for *in vitro* cytotoxicity,

2) **Irritation Test** per ISO 10993-10:2010 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization,
3) **Skin Sensitization Test** per ISO 10993-10:2010 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization,

- **Conclusions**

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Taiwan Comfort Champ Surgical Face Mask (K212863), is as safe, as effective, and performs as well as or better than the legally marketed (predicate) device, Modern Healthcare Corp Motex Anti-Fog Surgical Face Mask, (K201549)