April 21, 2021

Chongqing COE Display Technology Co., Ltd.
℅ James Tsai
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K202759
Trade/Device Name: Disposable medical surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 12, 2020
Received: September 21, 2020

Dear James Tsai:

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 and Part 809); 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 Clarence W. Murray III, 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)*
K202759

Device Name
Disposable medical surgical mask

Indications for Use *(Describe)*
The disposable medical surgical 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, provided as sterile and non-sterile.

Level 3, surgical mask model, sterile: CCSM-SC
Level 3, surgical mask model, non-sterile: CCSM-NC

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**

K202759

## 1. Administrative Information

| | |
|---|---|
| **Date of Summary prepared** | April 17, 2021 |
| **Applicant information** | Company: Chongqing COE Display Technology Co., Ltd.<br>Company address:<br>No. 3, Tonggui Avenue, Yufengshan Town, Yubei District, Chongqing, China<br>Contact person: Liu Qingjun<br>Phone: 86-023-67849398<br>Fax: 86-023-67843279<br>E-mail: liuqj@szcoe.com |
| **Submission Correspondent** | Shenzhen Joyantech Consulting Co., Ltd.<br>Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen<br>Contact person: James Tsai<br>E-Mail: james_tsai@cefda.com; field@cefda.com |

## 2. Device Information

| | |
|---|---|
| **Type of 510(k) submission:** | Traditional |
| **Trade Name:** | Disposable medical surgical mask |
| **Classification name:** | Surgical Face Mask, Apparel |
| **Review Panel:** | General and plastic surgery devices |
| **Product Code:** | FXX |
| **Common name** | Surgical mask |
| **Device Class:** | II |
| **Regulation Number:** | 878.4040 |

## 3. Predicate Device Information

| | |
|---|---|
| **Sponsor:** | SAN-M PACKAGE CO., LTD. |
| **Device trade name:** | Surgical face mask (Ear loops and Tie-on) |
| **Device Class:** | II |
| **510(K) Number:** | K160269 |
| **Regulation name** | Masks, Surgical |

| | |
|---|---|
| **Production regulation:** | 21 CFR §878.4040 |
| **Product code:** | FXX |
| **Review Panel:** | General and plastic surgery devices |

**4. Device Descriptions**

The surgical mask consists of a mask body, a nose piece, and ear loops. The mask body is divided into three layers, the inner and outer layers are made of polypropylene fabrics; the middle layer is composed of Melt-blown cloth (polypropylene); the nose piece is made of polypropylene & iron (Fe), and the ear loops are made of nylon & spandex.

**5. Indications for Use**

The disposable medical surgical 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, provided as sterile and non-sterile.

**6. Summary of Technological Characteristics**

**6.1 Comparisons for non-sterile mask**

| Comparison item | Proposed Device | Predicate Device | Remark |
|---|---|---|---|
| Manufacturer | Chongqing COE Display Technology Co., Ltd. | SAN-M PACKAGE CO., LTD. | Different |
| 510k number | K202759 | K160269 | Different |
| Product name | Disposable medical surgical mask | Surgical face mask | Similar |
| Product model | CCSM-NC | EL 20000 | Different |
| Product Code | FXX | FXX | Same |
| Classification | Class II (21 CFR 878.4040) | Class II (21 CFR 878.4040) | Same |
| Intended use & Indications for Use | The disposable medical surgical 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 | The 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 | Similar |

| | | | |
|---|---|---|---|
| | potential exposure to blood and body fluids. This is a single-use, disposable device, provided as sterile and non-sterile | and body fluids. This is a single-use, disposable device, provided non-sterile. | |
| Mask features | Ear Loops, flat Pleated | Ear Loops, flat Pleated | Same |
| Layers | 3 layers | 4 layers | Different |
| Outer layer | Polypropylene | Polypropylene | Same |
| Filter media | Melt-blown cloth (polypropylene) | Polypropylene spunbond Polypropylene meltblown | Similar |
| Inner layer | Polypropylene | Polypropylene | Same |
| Ear loops | Nylon & Spandex | Ear loops: Polyester, polyurethane | Similar |
| Nose piece | Polypropylene & Iron (Fe) | Polyethylene coated steel wire | Similar |
| Color | Blue | White or Blue | Same |
| Dimension (Length*Width) | Mask body: 17.5cm*9.5cm<br>Nosepiece:<br>length: 8cm-12cm; width: 3cm<br>Ear loop: 18cm±0.9cm | 17.5cm*9.5cm | Same |
| OTC use | Yes | Yes | Same |
| Sterility | Non-sterile | Non-sterile | Same |
| Use | Single-use, disposable | Single-use, disposable | Same |
| Performance level | Level 3 | Level 3 | Same |
| Fluid Resistance Performance ASTM F1862 | 32 Out of 32 Pass at 160mmHg | 32 Out of 32 Pass at 160mmHg | Same |
| Particulate Filtration Efficiency ASTM F2299 | Pass at ≥ 98.0% | Pass at 99.72% | Similar |
| Bacterial Filtration Efficiency ASTM F2101 | Pass at ≥98% | Pass at 99% | Similar |
| Differential Pressure ASTM F2100-19 | Pass at 4.6 mm $H_2O/cm^2$ | Pass at 2.5 $mmH_2O/cm_2$ | Similar |
| Flammability 16 CFR 1610 | Class I | Class I | Same |

| | | | |
|---|---|---|---|
| Cytotoxicity ISO 10993-5 | Under the conditions of the study, the subject device was non-cytotoxic | Under the conditions of the study, the subject device was non-cytotoxic | Same |
| Sensitization ISO 10993-10 | Under the conditions of the study, the subject device was non-sensitizing | Under the conditions of the study, the subject device was non-sensitizing | Same |
| Irritation ISO 10993-10 | Under the conditions of the study, the subject device was non-irritating | Under the conditions of the study, the subject device was non-irritating | Same |

The subject device only includes level 3 and ear loops type, it was covered by the scopes of predicate device, which includes level 1, level 2 and level 3, as well as types of ear loop.

Both proposed device and predicate device conform to ASTM F2100, the difference is the versions of the standard, the proposed device was tested by the latest version, and this difference will not raise any new issue of safety and effectiveness of the proposed device.

Although the materials, and layers of subject device are a little different from the predicate device, the performance and biocompatibility testing of the subject device meet all the requirements of standards of ASTM F2100 and ISO 10993-5 &-10. So, the differences between the predicate device and subject device will not raise any new issue of safety and effectiveness of the subject device.

**6.2 Comparisons for sterile mask**

| Comparison item | Proposed Device | Predicate Device | Remark |
|---|---|---|---|
| Manufacturer | Chongqing COE Display Technology Co., Ltd. | SAN-M PACKAGE CO., LTD. | Different |
| 510k number | K202759 | K160269 | Different |
| Product name | Disposable medical surgical mask | Surgical face mask | Similar |
| Product model | CCSM-SC | EL 20000 | Different |
| Product Code | FXX | FXX | Same |
| Classification | Class II (21 CFR 878.4040) | Class II (21 CFR 878.4040) | Same |
| Intended use & Indications for Use | The disposable medical surgical 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 | The 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 | Similar |

| | | | |
|---|---|---|---|
| | practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device, provided as sterile and non-sterile | potential exposure to blood and body fluids. This is a single-use, disposable device, provided non-sterile. | |
| Mask features | Ear Loops, flat Pleated | Ear Loops, flat Pleated | Same |
| Layers | 3 layers | 4 layers | Different |
| Outer layer | Polypropylene | Polypropylene | Same |
| Filter media | Melt-blown cloth (polypropylene) | Polypropylene spunbond Polypropylene meltblown | Similar |
| Inner layer | Polypropylene | Polypropylene | Same |
| Ear loops | Nylon & Spandex | Ear loops: Polyester, polyurethane | Similar |
| Nose piece | Polypropylene & Iron (Fe) | Polyethylene coated steel wire | Similar |
| Color | Blue | White or Blue | Same |
| Dimension (Length*Width) | Mask body: 17.5cm*9.5cm<br>Nosepiece:<br>length: 8cm-12cm; width: 3cm<br>Ear loop: 18cm±0.9cm | 17.5cm*9.5cm | Same |
| OTC use | Yes | Yes | Same |
| Sterility | Sterile | Non-sterile | Different |
| Packaging material | Paper plastic bag | Not publicly available | Different |
| Sterilization method and S.A.L. | Sterilized by ethylene oxide gas, SAL=$10^{-6}$ | Not applied | Different |
| Residues | $M_{EO} \leq 4mg/d$; $M_{ECH} \leq 9mg/d$ | Not applied | Different |
| Shelf life | No shelf life claim | No shelf life claim | Same |
| Use | Single-use, disposable | Single-use, disposable | Same |
| Performance level | Level 3 | Level 3 | Same |
| Fluid Resistance Performance ASTM F1862 | 32 Out of 32 Pass at 160mmHg | 32 Out of 32 Pass at 160mmHg | Same |
| Particulate Filtration Efficiency ASTM F2299 | Pass at ≥ 98.0% | Pass at 99.72% | Similar |

| | | | |
|---|---|---|---|
| Bacterial Filtration Efficiency ASTM F2101 | Pass at ≥98% | Pass at 99% | Similar |
| Differential Pressure ASTM F2100-19 | Pass at 4.8 mm $H_2O/cm^2$ | Pass at 2.5 $mmH_2O/cm_2$ | Similar |
| Flammability 16 CFR 1610 | Class I | Class I | Same |
| Cytotoxicity ISO 10993-5 | Under the conditions of the study, the subject device was non-cytotoxic | Under the conditions of the study, the subject device was non-cytotoxic | Same |
| Sensitization ISO 10993-10 | Under the conditions of the study, the subject device was non-sensitizing | Under the conditions of the study, the subject device was non-sensitizing | Same |
| Irritation ISO 10993-10 | Under the conditions of the study, the subject device was non-irritating | Under the conditions of the study, the subject device was non-irritating | Same |

The subject device only includes level 3 and ear loops type, it was covered by the scopes of predicate device, which includes level 1, level 2 and level 3, as well as types of ear loop.

Both proposed device and predicate device conform to ASTM F2100, the difference is the versions of the standard, the proposed device was tested by the latest version, and this difference will not raise any new safety and effectiveness of the proposed device.

Although the materials, layers and sterility status of subject device are a little different from the predicate device, the performance, biocompatibility and EO sterilization of the subject device meet all the requirements of standards of ASTM F2100, ISO 10993-5 &-10 and ISO 11135. So, the differences between the predicate device and subject device will not raise any new issue of safety and effectiveness of the subject device.

## 7. Brief discussion of Non-Clinical Testing

Surgical Face Mask conforms to the following standards:
ASTM F 2100-19, Standard Specification for Performance of Materials Use in Medical Face Masks.
ISO 10993-1:2018, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process.

**Bench testing**
The bench testing of Surgical Face Mask includes the following tests:
*Fluid Resistance Performance
*Particulate Filtration Efficiency
*Bacterial Filtration Efficiency
*Differential Pressure

*Flammability

**Biocompatibility testing**

The biocompatibility evaluation for the proposed device was conducted in accordance with the International Standard ISO 10993-1: 2018 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. Biocompatibility evaluation included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

**Ethylene oxide Sterilization Validation**

The proposed device is also provided for sterility, sterilization validation is performed, and the results show that the proposed device complies with the following standards:

- ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ASTM F88-2015 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-2015 Standard test method for detecting seal leaks in porous medical packaging by dye penetration.

**Summary**

Based on the non-clinical performance data as documented above in the device development, the proposed device has a safety and effectiveness profile that is similar to the predicate device, the testing results are summarized in the following table:

| Name of Test Methodology (standard) | Purpose | Acceptance Criteria | Results | |
|---|---|---|---|---|
| | | | Sterile mask | Non-sterile mask |
| ASTM F 1862-17 | Fluid Resistance Performance | 29 out of 32 pass at 160 mmHg | Lot 1# pass at 160mmHg;<br>Lot 2# pass at 160mmHg;<br>Lot 3# pass at 160mmHg | Lot 1# pass at 160mmHg;<br>Lot 2# pass at 160mmHg;<br>Lot 3# pass at 160mmHg; |
| ASTM F2101-19 | Bacterial Filtration Efficiency | ⩾ 98% | Lot 1# 99.6%-99.9%;<br>Lot 2# 99.7%-99.9%;<br>Lot 3# 99.6%-99.9% | Lot 1# 99.6%-99.9%;<br>Lot 2# 99.6%-99.8%;<br>Lot 3# 99.7%-99.9% |

| | | | | |
|---|---|---|---|---|
| | Performance | | | |
| EN 14683: 2019 | Differential Pressure (Delta-P) | < 6.0mm $H_2O/cm^2$ | Lot 1# 4.0-5.2;<br>Lot 2# 4.4-5.4;<br>Lot 3# 3.6-5.2 | Lot 1# 4.0-5.1;<br>Lot 2# 4.1-5.0;<br>Lot 3# 4.3-5.0 |
| ASTM F2299-2007 | Particulate Filtration Efficiency Performance | ⩾ 98% | Lot 1# 98.0%-98.9%;<br>Lot 2# 98.3%-98.9%;<br>Lot 3# 98.3%-98.9% | Lot 1# 98.2%-98.9%;<br>Lot 2# 98.5%-99.1%;<br>Lot 3# 98.6%-99.0% |
| 16 CFR Part 1610 | Flammability | Class I | Lot 1# Class I;<br>Lot 2# Class I;<br>Lot 3# Class I | Lot 1# Class I;<br>Lot 2# Class I;<br>Lot 3# Class I |
| ISO 10993-5 | Cytotoxicity | Non-cytotoxic | Under the conditions of the study, the subject device was non-cytotoxic | |
| ISO 10993-10 | Sensitization | Non-sensitizing | Under the conditions of the study, the subject device was non-sensitizing | |
| ISO 10993-10 | Irritation | Non-irritating | Under the conditions of the study, the subject device was non-irritating | |

**8. Brief discussion of clinical tests**

No clinical tests were performed.

**9. Conclusions**

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202759, the Disposable medical surgical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K160269.