May 26, 2022

Qingdao Bestex Rubber & Plastic Products Co.,Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Century Avenue
Shanghai, 200122
China

Re: K220597
Trade/Device Name: Disposable Surgical Face Mask (FM-34EE, FM-44EE)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 1, 2022
Received: March 1, 2022

Dear Ms. 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
Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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.*

Submission Number *(if known)*

K220597

Device Name

Disposable Surgical Face Mask (FM-34EE, FM-44EE)

Indications for Use *(Describe)*

The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transferring of microorganisms, body fluids and particulate material. These surgical 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.

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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# K220597

# 510(K) Summary

*Date prepared: 22nd, February, 2022*

**A. Applicant:**

Name: Qingdao Bestex Rubber & Plastic Products Co., Ltd.
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**B. Device:**

Trade Name: Disposable Surgical Face Mask (FM-34EE, FM-44EE)
Common Name: Surgical Mask

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 21 CFR 878.4040
Review Panel: Surgical Apparel

**C. Predicate device:**

K210030
Medical surgical mask
Tianjin Aoshang Outdoor Equipment Co., Ltd.

**D. Indications for use of the device:**

The Disposable 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 surgical masks are intended for use in infection control practices toreduce the potential exposure to blood and body fluids. This a single use, disposable device(s), provided non-sterile.

**E. Device Description:**

The subject Disposable Surgical Face Masks have two models, that is Model: FM-34EE, Level 2 and Model: FM-44EE, Level 3.

The Disposable Surgical Face Masks (Model: FM-34EE, Level 2) are three-layer, flat-pleaded masks with nose piece and ear loops, which are composed of inner layer, middle layer and outer layer. The colorant is polypropylene (PP) master batch.
The inner layer and outer layer of FM-34EE mask are made of spun-bond polypropylene, the middle layer is made of melt-blown polypropylene.

The Disposable Surgical Face Masks (Model: FM-44EE, Level 3) are four-layer, flat-pleaded masks with nose piece and ear loops, which are composed of inner layer, second layer, filtration layer and outer layer. The colorant is polypropylene (PP) master batch.
The inner layer and outer layer of FM-44EE are made of spun-bonded polypropylene, the second layer is made of PE film, the filtration layer is made of melt-blown polypropylene.

The ear loops of both models are held in place over the users' mouth and nose by two ear loops welded to the face mask. The ear loops are made with nylon and spandex. The nose piece in the layers of face mask is to allow the user to fit the mask around their nose, which is made of aluminum.

The Disposable Surgical Face Masks of both models are sold non-sterile and are intended to be single use, disposable devices.

The masks are designed and manufactured in accordance with ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks.

**F. Non-clinical Test Conclusion**

The Disposable Surgical Face Mask was tested in accordance with the tests recommended in the FDA guidance document, Guidance for Industry and FDA Staff Surgical Masks – Premarket Notification [510(k)] Submission issued March of 2004. Based upon the guidance document the following testing has been performed.

| **Performance Testing** | | | | |
|---|---|---|---|---|
| Test Methodology | Purpose | Acceptance Criteria for Level 2 Barrier | Acceptance Criteria for Level 3 Barrier | Result |
| Bacterial Filtration Efficiency | Measure bacterial filtration efficiency | ≥98% | ≥98% | Passed |

| | | | | |
|---|---|---|---|---|
| ASTM F2101 | | | | |
| Differential Pressure ($mmH_2O/cm^2$) EN 14683:2019 Annex C | Determine breathability of the mask | <6.0 $mmH_2O/cm^2$ | <6.0 $mmH_2O/cm^2$ | Passed |
| Sub-micron Particulate Filtration Efficiency ASTM F2299-17 | Measure initial particle filtration efficiency | ≥98% | ≥98% | Passed |
| Resistance to Penetration by Synthetic Blood ASTM F1862-17 | Evaluate the resistance to penetration by impact of small volume of synthetic blood | 120 mmHg | 160 mmHg | Passed |
| Flammability 16 CFR Part 1610-2008 | Response of materials to heat and flame | Class I | Class I | Passed |

**Biocompatibility Testing**

The biocompatibility evaluation for the Disposable Surgical Face Mask was conducted in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process, as recognized by FDA. The Medical Surgical Mask is classified as a surface contacting device. Specific biocompatibility tests were selected under the guidance of ISO 10993-1:2018 Annex A.

| **Biocompatibility Evaluation** | | | | |
|---|---|---|---|---|
| **Biological Effect** | | **Standard** | **Result** | |
| 1 | Cytotoxicity | ISO 10993-5 | Non-cytotoxic | Passed |
| 2 | Sensitization | ISO 10993-10 | Non-sensitizing | Passed |
| 3 | Irritation | ISO 10993-10 | Negligibly irritating | Passed |

## G. Summary of Technological Characteristics

**Table 1 Comparison of Proposed and Predicate Devices**

| **Device** | **Proposed Device** | **Predicate Device** | **Result** |
|---|---|---|---|
| **510K #** | - | K210030 | **-** |
| **Manufacturer** | Qingdao Bestex Rubber & Plastic Products Co., Ltd. | Tianjin Aoshang Outdoor Equipment Co., Ltd. | - |

| | | | |
|---|---|---|---|
| **Product Name** | Disposable Surgical Face Mask | Medical surgical mask | Similar |
| **Level** | Level 2 and Level 3 | Level 2 and Level 3 | Same |
| **Product Code** | FXX | FXX | Same |
| **Regulation Number** | 21 CFR 878.4040 | 21 CFR 878.4040 | Same |
| **Indications for use** | The Disposable 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 surgical masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This a single use, disposable device(s), provided non-sterile. | The Disposable 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 surgical masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This a single use, disposable device(s), provided non-sterile. | Same |
| **Design Feature** | Level 2: Ear loop<br>Level 3: Ear loop | Level 2: Ear loop<br>Level 3: Ear loop and tie-on | Similar |
| **Color** | Blue | Blue | Same |
| **Dimension** | 17.5cm×9.5cm | 17.5cm×9.5cm | Same |
| **Sterility** | Non-sterile | Non-sterile | Same |
| **Use** | Single Use, Disposable | Single Use, Disposable | Same |
| **Particulate filtration efficiency** | Level 2: average 98.43%<br>Level 3: average 98.56% | Level 2: average 99.71%<br>Level 3: average 99.93% | Different |
| **Bacterial filtration efficiency** | Level 2: average 99.9%<br>Level 3: average 99.9% | Level 2: average 99.7%<br>Level 3: average 99.9% | Different |
| **Differential pressure** | Level 2: average 3.45 $mmH_2O/cm^2$<br>Level 3: average 3.65 $mmH_2O/cm^2$ | Level 2: average 2.8 $mmH_2O/cm^2$<br>Level 3: average 4.0 $mmH_2O/cm^2$ | Different |
| **Flammability** | Class 1 | Class 1 | Same |
| **Fluid resistance** | Level 2: Pass at 120mmHg<br>Level 3: Pass at 160mmHg | Level 2: Pass at 120mmHg<br>Level 3: Pass at 160mmHg | Same |
| **Label/Labeling** | Complied with 21 CFR part 801 | Complied with 21 CFR part 801 | Same |
| **Material** | | | |
| **Outer layer** | Spun-bond polypropylene | Spunbond Polypropylene | Same |
| **Middle layer** | Level 2: Meltblown Polypropylene Filter<br><br>Level 3: | Meltblown Polypropylene Filter | Different |

| | | | |
|---|---|---|---|
| | Second layer: PE film<br>Filter layer: Meltblown Polypropylene Filter | | |
| **Inner layer** | Spun-bond polypropylene | Spunbond Polypropylene | Same |
| **Nose wire** | Aluminum | PE+iron | Different |
| **Ear loops** | Nylon and spandex | Spandex | Different |
| **Biocompatibility Testing** | | | |
| **Cytotoxicity** | Non-cytotoxic | Non-cytotoxic | Same |
| **Skin Irritation** | Non-irritating | Non-irritating | Same |
| **Skin Sensitization** | Non-sensitizing | Non-sensitizing | Same |

**Difference Analysis:**

**1.** The test results for particulate filtration efficiency, bacterial filtration efficiency and differential pressure for the proposed device are different from the predicate device. However, the test result for the proposed device can meet the requirements of level 2 mask and Level 3 mask. Thus, these differences will not affect the safety and effectiveness between the proposed and predicate devices.

**2.** The proposed device has different material of nose wire and ear loop to the predicate device. However, biocompatibility test has been performed on the proposed device and the results does not show any adverse effect. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

**3.** The proposed device has different layers and material of the mask body to the predicate device, but the masks has been tested and the test results shown that the mask meet the requirements of the medical mask. This difference do not affect the safety and effectiveness of the proposed device.

## H. Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specification. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Mask - Premarket Notification [510(K)] Submission issued on March 5, 2004:

- ISO 10993-05:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation And Skin Sensitization
- ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- EN 14683, Medical Face Masks - Requirements and Test Methods
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus Aureus
- ASTM F2299, Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- 16 CFR 1610, Standard for the Flammability of Clothing Textiles

## I. Clinical Test Conclusion

No clinical study is included in this submission.

**J. Conclusion**

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Disposable Surgical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K210030.