



January 12, 2026

Beatles Medical Supplies (Xiantao) Co., Ltd.
% Kiwi Xu
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Bldg., 1500# Century Ave.
Shanghai,
China

Re: K252830

Trade/Device Name: Disposable Surgical Face Mask (3P00B, C2900)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 10, 2025
Received: December 10, 2025

Dear Kiwi Xu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

BiFeng Qian, M.D., Ph.D.

Assistant Director

DHT4C: Division of Infection
Control Devices

OHT4: Office of Surgical and
Infection Control Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K252830

Device Name
Disposable Surgical Face Mask (3P00B, C2900)

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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510(K) Summary

K252830

(As requirement by 21 CFR 807.92)

Date prepared: 5th, January,2026

A. Applicant:

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B. Device:

Trade Name: Disposable Surgical Face Mask (3P00B, C2900)

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:

K220597

Disposable Surgical Face Mask

Qingdao Bestex Rubber & Plastic Products 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

Beatles medical supplies (Xiantao) Co., Ltd.
Louhe Industrial Park, Louhe Town, Xiantao City, China

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.

E. Device Description:

The subject Disposable Surgical Face Masks has two models, that is Model: 3P00B, ASTM F2100 Level 2 and Model: C2900, ASTM F2100 Level 3.

The Disposable Surgical Face Masks (Model: 3P00B, 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 blue master batch. The inner layer and outer layer of 3P00B mask are made of spun-bond non-woven fabric, the middle layer is made of Polyethylene Melt-blown non-woven fabric.

The Disposable Surgical Face Masks (Model: C2900, 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 blue master batch.

The inner layer and outer layer of C2900 are made of spun-bonded non-woven fabric, the second layer is made of Polyethylene PE film, the filtration layer is made of Polyethylene Melt-blown non-woven fabric.

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 Polyester and spandex. The aluminum nose piece in the layers of face mask is to allow the user to form the mask around their nose.

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

F. Summary of Technological Characteristics

Table 1 Comparison of Subject and Predicate Devices

Device	Subject Device	Predicate Device	Result
510K #	K252830	K220597	-
Manufacturer	Beatles medical supplies (Xiantao) Co., Ltd.	Qingdao Bestex Rubber & Plastic Products Co., Ltd.	-
Product Name	Disposable Surgical Face Mask (3P00B, C2900)	Disposable Surgical Face Mask	Similar
Level	ASTM F2100-25 Level 2 and Level 3	ASTM F2100-19 Level 2 and Level 3	Similar
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	The Disposable Surgical Face Masks are intended to be worn to protect both the patient and	Same

Beatles medical supplies (Xiantao) Co., Ltd.
Louhe Industrial Park, Louhe Town, Xiantao City, China

	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.	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 nonsterile.	
Design Feature	Level 2 (3P00B): Ear loop Level 3 (C2900): Ear loop	Level 2: Ear loop Level 3: Ear loop	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 98.85% Level 3: average 98.84%	Level 2: average 98.43% Level 3: average 98.56%	Different
Bacterial filtration efficiency	Level 2: average 99.9% Level 3: average 99.9%	Level 2: average 99.9% Level 3: average 99.9%	Same
Differential pressure	Level 2: average 17.92 mmH ₂ O Level 3: average 22.19 mmH ₂ O	Level 2: average 3.45 mmH ₂ O/cm ² Level 3: average 3.65 mmH ₂ O/cm ²	Different
Flammability	Class 1	Class 1	Same
Device	Subject Device	Predicate Device	Result
Fluid resistance	Level 2: Pass at 120mmHg Level 3: Pass at 160mmHg	Level 2: Pass at 120mmHg 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-bonded non-woven fabric	Spun-bond polypropylene	Different
Middle layer	Level 2: Polyethylene Melt-blown non-woven fabric Level 3: Second layer: Polyethylene PE film Filter layer: Polyethylene Melt-blown nonwoven fabric	Level 2: Meltblown Polypropylene Filter Level 3: Second layer: PE film Filter layer: Meltblown Polypropylene Filter	Different
Inner layer	Spun-bond non-woven fabric	Spun-bond polypropylene	Different
Nose wire	Aluminum	Aluminum	Same
Ear loops	Polyester and spandex	Nylon and spandex	Different
Biocompatibility Testing			
Cytotoxicity	Non-cytotoxic under conditions of testing	Non-cytotoxic under conditions of testing	Same

Beatles medical supplies (Xiantao) Co., Ltd.
Louhe Industrial Park, Louhe Town, Xiantao City, China

Skin Irritation	Non-irritating under conditions of testing	Non-irritating under conditions of testing	Same
Skin Sensitization	Non-sensitizing under conditions of testing	Non-sensitizing under conditions of testing	Same
Shelf Life	No shelf life is claimed	No shelf life is claimed	Same

Difference Analysis:

1. The test reports and evaluation use the ASTM F2100-25 performance criteria instead of the currently recognized ASTM F2100-23 criteria. The evaluation is similar, with the exception that the current differential pressure measurement is adjusted by a factor of 4.9 cm², the area of the test sample. Therefore, the F2100-25 criterion of 29.4 mmH₂O is identical to the F2100-23 criterion of 6 mmH₂O/cm². The use of either measure is acceptable.
2. The subject device has different material of nose wire and ear loop to the predicate device. However, biocompatibility test has been performed on the subject device and the results does not show any adverse effect. The subject 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.

G. Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the subject device met all design specification. The test results demonstrated that the subject 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 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation And Skin Sensitization
- ISO 10993-23 Biological evaluation of medical devices Part 23: Tests for irritation
- 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 F3502, 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

Testing	Test method	Acceptance Criteria	Result
Bacterial Filtration Efficiency (BFE)	ASTM F2101	≥ 98%	Pass
Differential Pressure (Delta P)	ASTM F2100	< 29.4 mm H ₂ O (<6.0 mm H ₂ O/cm ²)	Pass

Beatles medical supplies (Xiantao) Co., Ltd.
Louhe Industrial Park, Louhe Town, Xiantao City, China

Sub-Micron Particulate Filtration	ASTM F2100	≥ 98% at 0.1 micron	Pass
Resistance to Penetration by Synthetic Blood	ASTM F1862	3P00B: Resistance at 120 mmHg C2900: Resistance at 160 mmHg	Pass
Flammability	16 CFR Part 1610	Class 1	Pass
Biocompatibility - Cytotoxicity	ISO 10993-5	Non-cytotoxic under the conditions of the testing	Pass
Biocompatibility - Sensitization	ISO 10993-10	Non-sensitizing under the conditions of the testing	Pass
Biocompatibility - Irritation	ISO 10993-10	Non-irritating under the conditions of the testing	Pass

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device, 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 K220597.