July 2, 2021

Xiamen Probtain Medical Techology Co., Ltd
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
13th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K202954
Trade/Device Name: Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 19, 2021
Received: May 19, 2021

Dear Ivy 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,

Clarence W. Murray, III, PhD
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)*
K202954

Device Name
Disposable Surgical Mask

Indications for Use *(Describe)*
The Disposable Surgical Mask 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 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.**

# 510(K) Summary

K202954

Summary prepared date: 2021-05-14

## A. Applicant:

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD
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Submission Correspondent:
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## B. Device:

Trade Name: Disposable Surgical Mask
Common Name: Disposable Surgical Mask
Model(s): MP9017

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

## C. Predicate device:

K100846
IMC Surgical Face Mask (non-sterile and sterile, yellow)
International Medsurg Connection

## D. Indications for use of the device:

The Disposable Surgical Mask 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 sterile.

## E. Device Description:

The Disposable Surgical Mask is composed of mask body, nose clip and ear loop. The body of the mask is composed of three layers: the inner and outer layers are made of Spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter, the nose clip is made of plastic materials and iron wire, ear loop is made of spandex.

The size of the disposable surgical mask is 17.5*9.5cm with tolerance +-5%, the length of the ear loop is 16cm with tolerance +-5%, and the length of the nose clip should no less than 8.0cm.

The outer layer of disposable surgical mask will be provided in blue, the inner layer of the disposable surgical mask will be provided in white, and it will be provided with sterile and is intended to be single use, disposable devices.

## F. Comparison of technological characteristics with the predicate device.

Table 1 General Comparison

| **Device** | **Subject Device** | **Predicate Device** | **Comparison** |
|---|---|---|---|
| **Manufacturer** | XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD | INTERNATIONAL MEDSURG CONNECTION | - |
| **510K number** | K202954 | K100846 | - |
| **Model Name** | Disposable Surgical Mask | IMC Surgical Face Mask (non-sterile and sterile, yellow) | - |
| **Classification** | Class II Device, FXX (21 CFR878.4040) | Class II Device, FXX (21 CFR878.4040) | Same |
| **Intended/Indications for use** | The Disposable 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 to use in infection control practices to reduce the potential exposure to blood and body fluids. This is a disposable device(s), provided sterile. | This device is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. | Similar |
| **Model** | MP9017 | / | - |
| **Design feature** | Ear Loops, Flat Pleated, 3 layers | Ear Loops, Tie-On, Flat Pleated, 3 layers | Similar |

| | | | | |
|---|---|---|---|---|
| **Material** | **Outer layer** | Spun-bond polypropylene | Spun-bond polypropylene | Same |
| | **Middle layer** | Melt blown polypropylene filter | Melt blown polypropylene filter | Same |
| | **Inner layer** | Spun-bond polypropylene | Spun-bond polypropylene | Same |
| | **Nose clip** | Plastic materials and iron wire | NA | Different |
| | **Ear loops** | Spandex | NA | Different |
| **Color** | | Blue | Yellow | Different |
| **Dimension (Length)** | | 17.5±5%cm | 17.8cm (7 inches) | Different |
| **Dimension (Width)** | | 9.5cm±5%cm | 8.9cm (3.5inches) | Different |
| **OTC use** | | Yes | Yes | Same |
| **Sterility** | | Sterile | Sterile | Same |
| **Use** | | Single Use, Disposable | Single Use, Disposable | Same |
| **ASTM F2100 level** | | Level 2 | Level 2 | Same |
| **Fluid Resistance** | | Per ASTM F1862, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥ 29 of 32 test articles show passing results. | The surgical face mask were tested in accordance with ASTM F1862-07 test methods and meets its acceptance Criteria of Low =80, Moderate =120,High = 160. | Similar |
| **Particulate Filtration Efficiency** | | The test results in average of 98.6% are in accordance with the requirements under ASTM F2299 | The surgical face mask were tested in accordance with ASTM F2299 test methods and meets its acceptance Criteria of ≥98% | Similar |
| **Bacterial Filtration Efficiency** | | The test results in average of 99.6% are in accordance with the requirement under ASTM F2101-19 | The surgical face mask were tested in accordance with ASTM F2101-07 test methods and meets its acceptance criteria of Low≥95%, Moderate =≥98%,,High ≥98%,. | Similar |
| **Differential Pressure** | | The test results in average of 5.0mm$H_2O/cm^2$ are in accordance with the requirement < 6.0mm$H_2O/cm^2$ under EN 14683 Annex C | The surgical face mask were tested in accordance with MIL-M36945C 4.4.1.1.1 test methods and meets its acceptance criteria of < 4 mm$H_2O/cm^2$ | Similar |
| **Flammability** | | The test results is Class I under test method of 16 CFR Part 1610 | The surgical face mask were tested in accordance with 16 CFR Part 1610 test methods and meets its acceptance criteria of Class I | Similar |
| **In Vitro Cytotoxicity test** | | Under the conditions of the study, the device is non-cytotoxic. | The materials of the surgical face mask were tested in accordance with ISO10993-5 test methods and were found to be acceptable for the | Similar |

| | | | |
|---|---|---|---|
| | | intended use. | |
| **Skin Irritation** | Under the conditions of the study, the device is non-irritating. | The materials of the surgical face mask were tested in accordance with ISO10993-10 test methods and were found to be acceptable for the intended use. | Similar |
| **Skin Sensitization** | Under the conditions of the study, the device is non-sensitizing | The materials of the surgical face mask were tested in accordance with ISO10993-10 test methods and were found to be acceptable for the intended use. | Similar |

From the comparison we found the material of the current nose clip, the ear loop and the color were different from the predicate device. The biocompatibility tests were conducted to ensure their compliance to the ISO10993-5 and ISO10993-10. There is no new risk generated from the difference of the material.
Also, the size of the mask was different from the predicate device. The performance testing was conducted and although the test results are not identical to each other, they are similar and they both meet the requirement of Level 2 medical mask according to the ASTM F2100.

## G. Summary of Non-clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was similar to the predicate device. 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 Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004:

- ISO 10993-5: 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, Stand 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;

Table 2 - Performance Testing

| **Item** | **Proposed device** | **Acceptance Criteria (level 2)** | **Result** |
|---|---|---|---|
| **Fluid Resistance Performance ASTM** | 32 out of 32 pass at 120 mmHg | 29 out of 32 pass at 120 mmHg | PASS |

| | | | |
|---|---|---|---|
| **F1862** | | | |
| **Particulate Filtration Efficiency ASTM F2299** | 99.77% | ≥ 98% | PASS |
| **Bacterial Filtration Efficiency ASTM F2101** | 99.7% | ≥ 98% | PASS |
| **Differential Pressure (Delta P) EN 14683 Annex C** | 4.26mm$H_2O/cm^2$ | < 6.0mm$H_2O/cm^2$ | PASS |
| **Flammability 16 CFR 1610** | Class 1 | Class 1 | PASS |

**Table 3 Biocompatibility Comparison**

| Item | Proposed device | Acceptance Criteria | Result |
|---|---|---|---|
| **Cytotoxicity** | Under the conditions of the study, the device is non-cytotoxic. | Non-Cytotoxic | PASS |
| **Irritation** | Under the conditions of the study, the device is non-irritating. | Non-Irritating | PASS |
| **Sensitization** | Under the conditions of the study, the device is non-sensitizing | Non-Sensitizing | PASS |

## H. Clinical Tests

No clinical study is included in this submission.

### I. Conclusion

The conclusions drawn from the nonclinical tests that demonstrate that the subject is as safe, as effective, and performs as well as the legally marketed predicate device, IMC Surgical Face Mask (non-sterile and sterile, yellow) cleared under K100846.