December 9, 2020

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: K201893
Trade/Device Name: Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 26, 2020
Received: October 26, 2020

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,

For CAPT Elizabeth Claverie, M.S.
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)*
K201893

Device Name
Disposable Surgical Mask

Indications for Use *(Describe)*
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 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

K201893

Summary prepared Date: 2020-08-13

A. Applicant:

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B. Device:

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

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

C. Predicate device:

K182514
SURGICAL FACE MASK

D. 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 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.

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 non-woven fabric, 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% cm, the length of the ear loop is 16cm, 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 non-sterile and is intended to be single use, disposable devices.

F. Comparison with predicate device

Table 1 General Comparison

Device		**Subject Device**	**Predicate Device**	**Result**
Manufacturer		XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD	Xiantao Zhibo Non-woven Products Co., Ltd	-
510K number		K201893	K182514	-
Product Name		Disposable Surgical Mask	SURGICAL FACE MASK	Similar
Model		MP9017	---	-
Classification		Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same
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 non-sterile.	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 and body fluids. This is a single use, disposable device(s), provided non-sterile.	Same
Material	**Outer layer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown non-woven fabric	Melt blown polypropylene filter	Same

	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clip	Plastic materials and iron wire	Malleable aluminum wire	Different
	Ear loops	Spandex	Polyester	Different
Color		Blue	white	Different
Design Feature		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Flat Pleated, 3 layers	Same
Dimension (Length)		17.5±5%cm	17.5cm±1cm	Similar
Dimension (Width)		9.5cm±5%cm	9.5cm±1cm	Similar
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 level		Level 2	Level 2	Same
Biocompatibility		Meet ISO10993	Meet ISO10993	Same

Table 2 – Comparison of Performance Testing

Item	**Subject device**	**Predicate Device**	**Acceptance Criteria (level 2)**	**Result**
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 120 mmHg	32 out of 32 pass at 120 mmHg	29 out of 32 pass at 120 mmHg	Similar
Particulate Filtration Efficiency ASTM F2299	99.62%	99.88%	≥ 98%	Similar
Bacterial Filtration Efficiency ASTM F2101	99.9%	99.6%	≥ 98%	Similar
Differential Pressure (Delta P) EN 14683 Annex C	5.2mmH_2O/cm^2	3.0mmH2O/cm2	< 6.0mmH_2O/cm^2	Similar
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	Similar

Table 3 Biocompatibility Comparison

Item	**Subject device**	**Predicate Device**	**Result**

Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Under the conditions of the study, the subject device was non-cytotoxic.	Same
Irritation	Under the conditions of the study, the device is non-irritating.	Under the conditions of the study, the subject device was non-irritating.	Same
Sensitization	Under the conditions of the study, the device is non-sensitizing	Under the conditions of the study, the subject device was non-sensitizing.	Same

G. Summary of Technological Characteristic

Non-clinical tests were conducted to verify that the proposed device met all design specifications as same 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, 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;

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, K182514 Xiantao Zhibo Non-woven Products Surgical Face Mask.