April 6, 2021

Anhui Jiabao Protective Equipments Co., Ltd
% Mandy Wu
Consultant
Shanghai Sungo Management Consulting Company Limited
13th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K203801
Trade/Device Name: Disposable Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 28, 2020
Received: December 28, 2020

Dear Mandy Wu:

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 -S

For Ryan Ortega, 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)*
K203801

Device Name
Disposable Surgical Face Mask

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

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510(k) Summary

for K203801

510(K) Summary

K203801

Summary prepared date:2021-03-05

A. Applicant:

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B. Device:

Trade Name: Disposable Surgical Face Mask
Common Name: Surgical Face Mask
Model(s):JB-DM03 (Ear Loops),
JB-DM04 (Tie on)

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

C. Predicate device:

K153496
Disposable Surgical Face Mask
K200923
Single-use Surgical Mask

D. Indications for use of the device:

The Disposable Surgical Face Mask is 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 a single use, disposable device(s), provided non-sterile.

E. Device Description:

The proposed device(s) are Blue color, and Flat Pleated type mask, utilizing Tie-On (model: JB-DM04) or Ear Loops (model: JB-DM03) way for wearing, and they all has Nose Piece design for fitting the facemask around the nose.

The proposed device(s) are manufactured with 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 model JB-DM04 of proposed device, tie-on, is held in place over the user's mouth and nose by four ties welded to the facemask. The tie is made of spun-bond polypropylene.
The model JB-DM03 of proposed device, ear loops, is held in place over the user's mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are made of Nylon and spandex.
The nose chip contained in the proposed device(s) is in the layers of facemask to allow the user to fit the facemask around their nose, which is made of PE and iron.
The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

F. Technological Characteristics Comparison with predicate device

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Comparison
Manufacturer	Anhui Jiabao Protective Equipments Co., Ltd	BYD Precision Manufacturer Co. Ltd	-
510K number	K203801	K200923	-
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Indications for use	The Disposable Surgical Face Mask is 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 a single use,	The Single-use Surgical Masks (Model: FE2311) 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.	Similar

		disposable device(s), provided non-sterile.	This is a single use, disposable device(s), provided non-sterile.	Comparison
Ear loop model and tie-on model		JB-DM03(Ear Loops, Flat Pleated, 3 layers) JB-DM04(Tie-On, Flat Pleated, 3 layers),	Ear Loops, Flat Pleated, 3 layers	Analysis
Material	**Outer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clip	PE and iron	Malleable aluminum wire	Analysis
	Tie-one	Spun-bond polypropylene	/	Analysis
	Ear loops	Nylon and spandex	Polyester	Analysis
Color		Blue	Blue	Same
Dimension		17.5 cm +/- 0.5 cm	17.5 cm +/- 0.4 cm	Analysis
Dimension		9.5 cm +/- 0.5 cm	9.5 cm +/- 0.4 cm	Analysis
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 level		Level 2 and 3	Level 3	Analysis
Biocompatibility		ISO10993	ISO10993	Same

G. Non-Clinical Test Conclusion

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 meets the acceptance criteria 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

Test Methodology	**Proposed device1**(model: JB-DM04)	**Proposed device2** (model: JB-DM03)	**Acceptance Criteria (level 2&3)**	**Result**
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 160 mmHg	32 out of 32 pass at 120 mmHg	29 out of 32 pass at 160 mmHg for level 3 29 out of 32 pass at 120 mmHg for level 2	PASS
Particulate Filtration Efficiency ASTM F2299	99.9%	99.9%	≥ 98%	PASS
Bacterial Filtration Efficiency ASTM F2101	＞99.9%	＞99.9%	≥ 98%	PASS
Differential Pressure (Delta P) EN 14683 Annex C	2.21mmH_2O/cm^2	2.53mmH_2O/cm^2	<6.0mmH_2O/cm^2	PASS
Flammability 16 CFR 1610	Class 1	Class1	Class 1	PASS

Table 3 Biocompatibility Comparison

Item	**Proposed device**	**Acceptance Criteria**	**Result**
Cytotoxicity	Under the conditions of the study, the subject device extract did not show potential toxicity to L929 cells.	No potential cytotoxicity	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 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 or better than the legally marketed predicate device, K200923 BYD Precision Manufacturer Co. Ltd. Single-use Surgical Mask.