February 2, 2021

Tianjin Teda Jinshan Easy Packing Manufacture Co., LTD
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K202323
Trade/Device Name: Disposable Medical Surgical Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 12, 2020
Received: August 17, 2020

Dear Ray 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)*

K202323

Device Name

Disposable Medical Surgical Masks

Indications for Use *(Describe)*

The Disposable Medical Surgical Masks is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Single-Use Surgical Mask with Ear Loop 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K202323

1. Date of Preparation:2021/02/02

2. Sponsor Identification

Tianjin Teda Jinshan Easy Packing Manufacture Co., Ltd.
No.3 Wuhai Road, Jinhai Economic Development Area, Tianjin, China 301600

Contact Person: Hui Liu
Position: International Trading Manager
Tel: +86-22-68228888
Fax: +86-22-68225555
Email: jinshan@tedajinshan-bag.com

3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, 102401, China

Tel: +86-18910677558
Fax: +86-10-56335780
Email: Ray.Wang@believe-med.com

4. Identification of Proposed Device

Trade Name: Disposable Medical Surgical Masks
Common Name: Surgical Face Mask

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

Indication for use Statement:
The Disposable Medical Surgical Masks is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Single-Use Surgical Mask with Ear Loop 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.

Device Description
The Disposable Medical Surgical Masks is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Disposable Medical Surgical Masks 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.

The proposed device(s) are ***Blue color***, and ***Flat Pleated*** type mask, utilizing ***Ear Loops'*** way for wearing, and they all have ***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 non-woven, and the middle layer is made of Melt-blown non-woven fabric.

The Disposable Medical Surgical Masks 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 not made with Polyurethane fiber and Nylon.

The nose piece contained in the proposed device(s) is in the layers of the facemask to allow the user to fit the facemask around their nose, which is made of PE and iron wire.

The proposed device(s) are sold non-sterile and are intended to be single-use, disposable devices.

The proposed device(s) are meet the Level 3 Barrier requirements per ASTM F2100-19.

5. Identification of Predicate Device(s)

Predicate Device
K153496
Disposable Surgical Face Mask
Xiantao Rayxin Medical Products Co., ltd.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- 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 F2100-19, Standard Specification For Performance Of Materials Used In Medical Face Masks.
- ASTM F1862-17, Standard Test Method For Resistance Of Medical Face Masks To Penetration By Synthetic Blood (Horizontal Projection Of Fixed Volume At A Known Velocity)
- MIL-M-36945C, Method 1 Military Specifications: Surgical Mask disposable;
- ASTM F2101-19, Standard Test Method For Evaluating The Bacterial Filtration Efficiency (Bfe) Of Medical Face Mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus;
- ASTM F2299-03, 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;
- Bench Testing for the performance of Dimensions.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of the Technological Characteristics of the Device

Table 1 General Comparison

ITEM		Proposed Device K202323	Predicate Device K153496	Remark
Intended Use		The Disposable Medical Surgical Masks is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Single-Use Surgical Mask with Ear Loop 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.	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 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
Basic Design		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	SAME
Materials	Outer Facing Layer	Spun-bond non-woven fabric	Spun-bond polypropylene	Analysis
	Middle Layer	Melt blown non-woven fabric	Melt blown polypropylene filter	
	Inner Facing Layer	Spun-bond non-woven fabric	Spun-bond polypropylene	
	Nose Piece	PE + iron wire	Malleable aluminum wire	
	Ear Loops	Polyurethane fibre + Nylon	Polyester	
Color		Blue	Blue	SAME
Dimension (Length)		17.5 cm +/- 5%	17.5 cm +/- 1cm	Similar
Dimension (Width)		10 cm +/- 5%	9.5 cm +/- 1cm	
OTC use		Yes	Yes	SAME
Single Use		Yes	Yes	SAME
Sterile		No	No	SAME
ASTM F2100 Level		Level 3	Level 2	Analysis

Table 2 Performance Characteristic Comparison

ITEM	Proposed Device K202323	Predicate Device K153496	ASTM F2100 Requirements for Level 3 Classification	Remark
Fluid Resistance Performance ASTM F1862	160 mmHg	120 mmHg	160 mmHg	Analysis
Particulate Filtration Efficiency ASTM F2299	98.02 – 98.80%	98.46%	≥ 98%	
Bacterial Filtration Efficiency ASTM F2101	99.6 – 99.7%	98.7%	≥ 98%	
Differential Pressure	3.20 - 4.18 mmH2O/cm^2	4.2 mmH2O/cm^2	< 6.0 mmH2O/cm^2	

(Delta P) MIL-M-36954C				
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	SAME

Table 3 Biocompatibility Comparison

ITEM	Proposed Device K202323	Predicate Device K153496	Remark
Cytotoxicity	Under the conditions of the study, not cytotoxicity effect	Comply with ISO 10993-5	SAME
Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	SAME
Sensitization	Under conditions of the study, not a sensitizer.		SAME

Analysis:

a. The proposed device has different materials with the predicate device, the different material may cause biocompatibility risk, so the proposed device has conducted the biocompatibility testing as ISO 10993-5 and ISO 10993-10 for cytotoxicity, irritation and sensitization, the test results shown that the materials used in the proposed device could not raise biocompatibility risk. This difference between the proposed and predicate device will not affect the effectiveness and safety of the proposed device.

b. The proposed device has different barrier level as ASTM F2100 with the predicate device, Level 3 vs. Level 2, so the proposed device has conducted the performance testing as ASTM F2100, the test results shown that the proposed device meet the requirements of Level 3. This difference between the proposed and predicate device will not affect the effectiveness and safety of the proposed device.

c. The proposed device has different Dimension with the predicate device, Level 3 vs. Level 2, so the proposed device has conducted the dimension testing, the test results shown that the proposed device meet the design specification. This difference between the proposed and predicate device will not affect the effectiveness and safety of the proposed device.

d. The proposed device has different Performance Characteristic as ASTM F2100 with the predicate device, so the proposed device has conducted the performance testing as ASTM F2100, the test results shown that the proposed device meet the requirements of ASTM F2100. This difference between the proposed and predicate device will not affect the effectiveness and safety of the proposed device.

9. 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, Disposable Surgical Face Mask cleared under K153496.