June 14, 2021

Shandong Haidike Medical Products Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K210518
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 10, 2021
Received: May 13, 2021

Dear Diana Hong:

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 Clarence W. Murray, III, Ph.D.
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)*
K210518

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
The Surgical Face Mask is intended for single use by operation room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K210518

1. Date of Preparation: 05/10/2021

2. Sponsor Identification

Shandong haidike Medical Products Co.,Ltd.
Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Surgical Face Mask

Common Name: Surgical Face Mask

Regulatory Information

Classification Name: Mask, Surgical

Classification: II;

Product Code: FXX;

Regulation Number: 21CFR 878.4040

Review Panel: General Hospital

Indication for use

The Surgical Face Mask is intended for single use by operation room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

Device Description:

The proposed device, Surgical Face Mask is a three-layer, single-use, flat-pleated mask. The mask body is made of 25g/m^2 PP non-woven cloth. The mask contains tie strings or ear loops to secure the mask over the users' mouth and face and includes a nosepiece to provide a firm fit over the nose. Ear loops are made of Nylon and Spandex, and tie strings are made of 25g/m^2 PP non-woven cloth. The nose clip which is made of high-density polyethylene and Galvanized wire. The device is provided in sterile.

5. Identification of Predicate Device

510(k) Number: K202029

Product Name: Medical Surgical Mask

6. Non-Clinical Test Conclusion

Non clinical tests, including biological tests and performance tests, has been performed on the proposed device according to the following standards:

- ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials;
- ISO 10993-7:2008 Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);

- ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres;
- ASTM F2101-2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus;
- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- EN 14683:2019 Medical face mask- Requirements and test methods- Annex C Method for determination of breathability (differential pressure)

And all the test results of non-clinical tests are summarized in the following table:

Table 1 Summary of Biocompatibility Test Results

Test/Purpose	Test Method/ Standard	Acceptance Criteria	Result
In Vitro Cytotoxicity Test	ISO 10993-5: 2009	Reduction of cell viability shall be not more than 30%.	Passed: No Cytotoxicity Observed
Skin Sensitization Test	ISO 10993-10: 2010	The skin reactions grades shall be less than 1.	Passed: No Skin Sensitization Observed
Skin irritation Test	ISO 10993-10: 2010	The irritation response category shall be slight or less.	Passed: No Skin irritation Observed

Table 2 Summary of Performance Testing

Performance Test/ Purpose	Test Method/ Standard	Acceptance Criteria	Test Results		
			Lot #1	Lot #2	Lot #3
Bacterial Filtration	ASTM F2101-2019	Level 2: >98%	MIN: 98.99% AVG: 99.53%	MIN: 98.46% AVG: 99.10%	MIN: 98.36% AVG: 99.2%
Differential Pressure	EN 14683 Annex C	Level 2: <6.0 mm H2O/cm2	MAX: 4.05 AVG: 3.79	MAX: 4.18 AVG: 3.83	MAX: 4.12 AVG:3.75
Flammability	16 CFR Part 1610	Level 2: Class I	Class I	Class I	Class I
Particulate	ASTM		MIN:	MIN:	MIN:

Filtration	F2299/F2299M-03 (2017)	Level 2: >98%	98.99% AVG: 99.58%	98.30% AVG: 99.25%	98.45% AVG: 99.11%
Resistance to Penetration	ASTM F1862/F1862M-17	Level 2: 120 mmHg	Pass at 120 mmHg	Pass at 120 mmHg	Pass at 120 mmHg
Seal strength of immediate package	ASTM F88/F88M-15	Seal strength ⩾ 2N/15mm	MIN: 2.2 AVG: 3.04	MIN: 3.2 AVG: 3.54	MIN: 2.2 AVG: 2.9
Seal leak of immediate package	ASTM F1929-15	No apparent solution channel through the whole seal edge in the whole seal area	No	No	No
EO ECH Residue	ISO 10993-7:2008	EO residue ≤4mg/device ECH residue ≤9mg/device	EO Residue: 0.01 mg/device ECH Residue: 0.0053 mg/device	EO Residue: 0.0053 mg/device ECH Residue: 0.0027 mg/device	EO Residue: 0.006 mg/device ECH Residue: 0.01 mg/device

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device K202029	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	The Surgical Face Mask is intended for single use by operation room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms,	The medical surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms,	Same

	blood and body fluids, and particulate materials.	blood and body fluids, and particulate materials.	
Mask style	Flat pleated	Flat pleated	Same
Mask Color	Blue	Blue	Same
Design feature	Ear loops or tie-on	Ear loops or tie-on	Same
Dimensions (mm)	Mask body: 175mm*95mm Ear loops: 180mm Ear strings: 380mm Nose clip: 101mm Tolerance: ±5%	Mask body: 175mm×95mm (Tolerance: ±1mm) Ear loops: (2.5-3)mm×200mm Ear strings: 90mm×9mm Nose clip: 100mm×(2.5-3.5)mm Mask body: 145mm×90mm (Tolerance: ±1mm) Ear loops: (2.5-3)mm×160mm Ear strings: 80mm×9mm Nose clip: 80mm×(2.5-3.5)mm Mask body: 120mm×70mm (Tolerance: ±1mm) Ear loops: (2.5-3)mm×140mm Ear strings: 70mm×9mm Nose clip: 70mm×(2.5-3.5)mm Tolerance: ±1mm	Similar 1
ASTM F2100 Level	Level 2	Level 2	Same
Performance			
Fluid resistance	Pass at 120mmHg	Pass at 120mmHg	Same
Particulate efficiency level	Average 99.19%	Average 98.87%	Similar 2
Bacterial filtration level	Average 99.23%	Average 99.46%	Similar 3
Differential pressure	Average 3.81 mmH_2O/cm^2	Average 3.72mmH_2O/cm^2	Similar 4
Flammability	Class 1	Class 1	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Patient Contacting Material			
Ear Loops	Spandex, nylon	Nylon and PU	Similar 5
Nose clip	Polyethylene, galvanized wire	Iron strip covered by polypropylene covering	Similar 6
Mask body	25g/m^2 PP non-woven cloth	25g/m^2 PP non-woven cloth	Same
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same

Sensitization	No Sensitization	No Sensitization	Same
Irritation	No Irritation	No Irritation	Same
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	Same

Similar 1-Dimensions

The dimensions of proposed device are different from the predicate device. However, the dimensions of the proposed device are similar with the largest specification of the predicate device, and performance test result of the propose device can meet the requirements of level 2 mask according to the ASTM F2100-19. This difference does not affect intended use and will not raise any safety issues. Thus, this difference does not affect substantially equivalence between the proposed device and predicate device.

Similar 2-Particulate efficiency level

The particulate efficiency level of the proposed device is different from predicate device. However, the test result of the propose device can meet the requirements of level 2 mask according to the ASTM F2100-19. Therefore, this difference does not affect substantially equivalence between the proposed device and predicate device.

Similar 3-Bacterial filtration level

The bacterial filtration level for the proposed device is different from predicate device. However the test result of the proposed device can meet the requirements of level 2 mask according to the ASTM F2100-19. Therefore, this difference does not affect substantially equivalence between the proposed device and predicate device.

Similar 4-Differential pressure

The differential pressure of the proposed device is different from predicate device. However, the test result for the proposed device can meet the requirements of level 2 mask according to the ASTM F2100-19. Therefore, this difference does not affect substantially equivalence between the proposed device and predicate device.

Similar 5-Ear loops

The material of ear loops for the proposed device is partly different from predicate device. However, the biocompatibility test has been conducted on the proposed device and the test result does not show any adverse effect. Therefore, this difference does not affect substantially equivalence between the proposed

device and predicate device.

Similar 6- Nose clip

The material of the Nose clip for proposed device is different from the predicate device. However, the biocompatibility test has been conducted on the proposed device and the test result does not show any adverse effect. Therefore, this difference does not affect substantially equivalence between the proposed device and predicate device.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device K202029.