May 13, 2021

Biobase Scientific (Shandong) Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box. 120-119
Shanghai, 200120
China

Re: K210815
Trade/Device Name: Disposable Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 15, 2021
Received: March 18, 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,

Clarence w. Murray, III, Ph.D.
Acting Assistant Director
Sterility Device Team
DHT4A: Division of General 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)*

K210815

Device Name
Disposable Face Mask

Indications for Use *(Describe)*

The Disposable 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, 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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92. The assigned 510(k) Number: K210815

1. Date of Preparation: 05/06/2021

2. Sponsor Identification

Biobase Scientific (Shandong) Co., Ltd.
NO.1777 Dazheng Road, High-Tech District, Jinan City, Shandong Province, China. Establishment

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3. Designated Submission Correspondent

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

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Disposable Face Mask
Common Name: Surgical Face Mask
Model: BK-DSFM
Size: 175mm×95mm

Regulatory Information Classification
Name: Mask, Surgical Classification: II;
Product Code: FXX;
Regulation Number: 21CFR 878.4040
Review Panel: General Hospital

Indication for use:
The Disposable 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, provided non-sterile.

Device Description:
The Disposable Face Mask is single use, three-layer, flat-pleated mask with ear loops and nose clip. The inner and outer layers of the mask are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene. The ear loops are held in place over the users' mouth and nose by two elastic ear straps. The ear loops are made of spandex and nylon. The nose clip is a malleable iron wire covered by polyethylene. Users can adjust the nose clip according to the shape of the bridge of the nose and fix the mask on the bridge of the nose to prevent the mask from falling off. The Disposable Face Mask is blue and provided non-sterile.

5. Identification of Predicate Device

510(k) Number: K202211
Product Name: Disposable Medical Surgical Face Masks

6. Summary of Technological Characteristics

Provided below is the technological characteristic comparison table comparing the subject device and the predicate device.

Table 1 Comparison of Disposable Face Mask

ITEM	Subject Device K210815	Predicate Device K202211	Comparison
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	The Disposable Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The face mask is intended for use in infection control practices to reduce potential exposure to blood and body fluids. The face mask is a single use, disposable device, provided non-sterile.	The Disposable Medical 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
Design feature	Ear loop	Ear loop	Same
Color	Blue	Blue	Same
Dimension	175mm×95mm	175mm×95mm	Same
Level	Level 2	Level 2	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Fluid resistance	32 out of 32 per lot pass at 120 mmHg, 3 non-consecutive lots tested	32 out of 32 per lot pass at 120 mmHg, 3 non-consecutive lots tested	Same
Particulate Filtration Efficiency	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 99.30% Lot 2: 99.46% Lot 3: 99.47%	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1:99.68% Lot 2:99.56% Lot 3:99.81%	Different

Bacterial Filtration Efficiency	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 99.40% Lot 2: 99.45% Lot 3: 99.46%	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1:99.9% Lot 2:99.9% Lot 3:99.9%	Different
Differential Pressure	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 2.05 mm H_2O/cm^2 Lot 2: 1.95 mm H_2O/cm^2 Lot 3: 2.03 mm H_2O/cm^2	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 3.6 mm H_2O/cm^2 Lot 2: 3.6 mm H_2O/cm^2 Lot 3: 3.7 mm H_2O/cm^2	Different
Flammability	Class 1, 3 non-consecutive lots tested, using a sample size of 32/lot.	Class 1, 3 non-consecutive lots tested, using a sample size of 32/lot.	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Patient Contacting Material			
Outer facing layer	Spun-bond polypropylene	Spun-bond nonwoven fabric	Different
Middle layer	Melt blown polypropylene filter	Melt blown non-woven fabric	
Inner facing layer	Spun-bond polypropylene	Spun-bond nonwoven fabric	
Nose clip	Malleable polyethylene wire and iron	PE and iron wire	
Ear loop	Spandex and nylon	Spandex and nylon	
Biocompatibility			
Cytotoxicity	ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	Same
Sensitization			
Irritation			

7. 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:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- 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 F2100-2019 Standard Specification for Performance of Materials Used in Medical Face Masks
- EN 14683: 2019 Medical face masks- Requirements and test methods
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritation and skin sensitization

Table 1: Summary of Performance Testing

No.	**Performance Test**	**Sample Size**	**Test Meth**	**Acceptance Criteria**	**Test Result**			**Evidence Reports:** 041 to 043; Passed
					Lot #1: 20070721	Lot #2: 20071021	Lot #3: 20072221	
1	Bacterial Filtration	32	ASTM F2100-19	Level 2: >98%	Min: 99.03% Avg: 99.40%	Min: 99.22% Avg: 99.45%	Min: 99.27% Avg: 99.46%	
2	Differential Pressure		Annex C, EN 14683: 2019	Level 2: <6.0 mm H_2O/cm^2	Max: 2.55 Avg: 2.05	Max: 2.75 Avg: 1.95	Max: 2.86 Avg: 2.03	044 to 046; Passed

3	Flammability		16 CFR Part 1610	Level 2: Class I	Class I	Class I	Class I	047 to 049; Passed
4	Particulate Filtration		F2299/F2299M-03	Level 2: >98%	Min: 99.24% Avg: 99.50%	Min: 99.25% Avg: 99.46%	Min: 99.33% Avg: 99.47%	050 to 052; Passed
5	Resistance to Penetration		ASTM F1862/F1826M-17	Level 2: 120 mmHg	Pass at 120 mmHg	Pass at 120 mmHg	Pass at 120 mmHg	053 to 055; Passed

Table 2: Biocompatibility Test Results

Test	**Standard**	**Report**	**Result**
In Vitro Cytotoxicity Test	ISO 10993-5-2009	2020-0451-001	Passed: No Cytotoxicity Observed
Skin Sensitization Test	ISO 10993-10:2010	2020-0451-002	Passed: No Skin Sensitization Observed
Skin irritation Test	ISO 10993-10:2010	2020-0451-003	Passed: No Skin irritation Observed

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202211.