Guangdong Bida Medical Technology Co., Ltd.
% Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road
Huangpu District, Guang
Guangzhou, Guangdong 510700
China

Re: K202387
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: March 23, 2021
Received: March 29, 2021

Dear Cassie Lee:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202387

Device Name
Disposable Surgical Face Mask (Model: MS001)

Indications for Use *(Describe)*
Disposable Surgical Face Mask is intended to be worn to protect both patients and healthcare personnel from transfer of microorganisms, blood and body fluids, and particulates material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The face mask is single use, disposable devices provide 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 of K202387

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Date of the summary: April 20, 2021

2. Submitter's Information

510(k) Owner's Name: Guangdong Bida Medical Technology Co., Ltd.

Establishment Registration Number: Applying

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Application Correspondent:

Contact Person: Ms. Cassie Lee

Share Info (Guangzhou) Medical Consultant Ltd.

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US Consultant Agent:

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Contact Person: Jimmy

Phone: 001-323-5104660

Email: us-agent@glomed-info.com

3. Subject Device Information

Type of 510(k): Traditional

Classification Name: Mask, Surgical

Trade Name: Disposable Surgical Face Mask

Model Name: MS001

Review Panel: General Hospital

Product Code: FXX

Regulation Number: 878.4040

Regulatory Class: II

4. Predicate Device Information

Predicate Device 1:

Sponsor: San-M Package Co. Ltd.

Trade Name: Surgical Face Masks (Ear loops and Tie-on)

Classification Name: Mask, Surgical

510(K) Number: K160269

Review Panel: General Hospital

Product Code: FXX

Regulation Number: 878.4040

Regulatory Class: II

Predicate Device 2:

Sponsor: 3M Health Care

Trade Name: 3M™ Hight Fluid-Resistant Procedure Mask

Classification Name: Mask, Surgical

510(K) Number: K191355

Review Panel: General Hospital

Product Code: FXX

Regulation Number: 878.4040

Regulatory Class: II

5. Intended Use / Indications for Use

Disposable Surgical Face Mask is intended to be worn to protect both patients and healthcare personnel from transfer of microorganisms, blood and body fluids, and particulates material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The face mask is single use, disposable devices provide non-sterile.

6. Device Description

The subject device is a three-layer and flat-pleated mask. The mask materials consist of non-woven/ outer layer (polypropylene spunbond), melt blown/ filter layer (polypropylene melt-blown) and non-woven/ inner layer (polypropylene spunbond). Each mask contains the ear loops to secure the mask over the users' mouth and face and includes a malleable nose piece to provide a firm fit over the nose.

The subject device is a single-use, disposable device, provided non-sterile.

7. Comparison to predicate device and conclusion

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Company	Guangdong Bida Medical Technology Co., Ltd.	SAN-M PACKAGE CO., LTD.	3M Health Care	--
510 (k)	K202387	K160269	K191355	--
Trade Name	Disposable Surgical Face Mask	Surgical Face Masks (Ear loops and Tie-on)	3M™ Hight Fluid-Resistant Procedure Mask	--
Classification Name	Mask, Surgical	Mask, Surgical	Mask, Surgical	Same
Classification	Class II	Class II	Class II	Same
Product Code	FXX	FXX	FXX	Same
Intended use	Disposable Surgical Face Mask is intended to be worn to protect both patients and healthcare personnel from transfer of microorganisms, blood and body fluids, and particulates material. These	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.	3M™ Hight Fluid-Resistant Procedure 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	Same

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
	face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The face mask is single use, disposable devices provide non-sterile.	This is a single-use, disposable device, provided non-sterile.	practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.	
Materials				
Outer facing layer	Polypropylene Spunbond	Polypropylene	Polypropylene Spunbond, green	Similar Note 4
Middle filter layer	Polypropylene Melt blown	- Polypropylene spunbond - Polypropylene meltblown	Polypropylene Meltblown, white	Similar Note 4
Inner facing layer	Polypropylene Spunbond	Polypropylene	Polyethylene Thermal-bonded, white	Similar Note 4
Nose piece	Polyethylene coated iron wire	Polyethylene coated steel wire	Polyethylene Coated Steel Wire	Similar Note 4
Ear loops	Spandex	Polyester, polyurethane	Spandex elastic cord (polyurethane core with polyethylene terephthalate /nylon cover)	Different Note 1
Design features	Color: Blue, Ear loops,	Colors: white or blue Visor option: polyester	Color: Green (Outer) Tie Strings and Ear loops	Different Note 2
Mask Style	Flat-pleated	Flat-pleated	Flat-pleated	Same
Dimensions	17.5 cm x 9.5 cm	- Length: 90 ± 3 mm; Width: 175 ± 5 mm; - Length: 90 ± 3 mm Width: 180 ± 5 mm	-Length: 6.9” ± 0.2” -Width: 3.5” ± 0.3”	Different Note 2
OTC use	Yes	Yes	Yes	Same

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Single Use, Disposable	Same
Performance Testing	Level 3	Level 1; Level 2; Level 3	Level 3	Same
Fluid Resistance Performance	Pass at 160 mm Hg	For Level 3: Pass at 160 mm Hg	Passed at 160mm Hg	Same
Particulate Filtration Efficiency	≥98%	For Level 3: Pass at 99.7%	Passed at ≥98% @ 0.1micron	Same
Bacterial Filtration Efficiency	≥ 98%	For Level 3: Pass at >99%	Passed at ≥98%	Same
Differential Pressure	<6.0 mm H_2O/cm^2	For Level 3: Pass at 2.5 mm H_2O/cm^2	Passed at <5 mm H_2O/cm^2	Different Note 3
Flammability	Class 1	Class 1	Class 1	Same
Biocompatibility				
Cytotoxicity	Under the conditions of the study, the subject device was non-cytotoxic.	Under the conditions of the study, the subject device was non-cytotoxic.	Non-cytotoxic	Same
Irritation	Under the conditions of the study, the subject device was non-irritating.	Under the conditions of the study, the subject device was non-irritating.	Non-irritating	Same
Sensitization	Under the conditions of the study, the subject device was non-sensitizing.	Under the conditions of the study, the subject device was non-sensitizing.	Non-sensitizing	Same

Comparison in Detail(s):

Note 1:

Although the "Nose piece" and "Ear loop" of subject device is a little different from the predicate devices, but they all met the ASTM F2100 and ISO 10993 standards required. So, the differences between the subject device and the predicate devices will not affect the safety and effectiveness.

Note 2:

Although the "Design features" and "Dimensions" of subject device is a little different from predicate devices, but they all met the ASTM F2100 and ISO 10993 standards required. So, the differences between the subject device and predicate devices will not affect the safety and effectiveness.

Note 3:

Although the "Differential Pressure" of subject device is a little different from predicate devices, but they all met the ASTM F2100 standard required. So, the differences between the subject device and predicate devices will not affect the safety and effectiveness.

Note 4:

Although the materials in "Outer facing layer", "Middle filter layer", "Inner facing layer" and "Nose piece" of subject device is a little different from predicate devices, but they all met the ISO 10993 series standard requirements. So, the differences between the subject device and predicate devices will not affect the safety and effectiveness.

8. Summary of Non-Clinical Performance Testing

Performance Testing summary:

Performance Characteristics	Test Method	Acceptance Criteria	Test Results /Verdict
Fluid Resistance Performance (mmHg)	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) according to ASTM F2100: 2019	Fluid resistant claimed at 160 mm Hg	PASS
Particulate Filtration Efficiency Performance (%)	ASTM F2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex	≥ 98%	PASS

	Spheres according to ASTM F2100: 2019		
Bacterial Filtration Efficiency Performance (%)	ASTM F2101-14 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus according to ASTM F2100: 2019	≥ 98%	PASS
Differential Pressure (Delta-P) (mm $H2O/cm^2$)	EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100: 2019	<6.0 mm H_2O/cm^2	PASS
Flammability class Class 1	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100: 2019	Class 1	PASS

Biocompatibility Testing Summary:

According to ISO 10993-1: 2018, the nature of body contact for the subject device is the Surface Device category, Skin Contact, and duration of the contact is Prolonged (>24 h to 30 d). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

Test Item	Test Method	Proposed device	Result
Cytotoxicity	ISO 10993-5: 2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	PASS
Irritation	ISO 10993-10: 2010 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	PASS
Sensitization	ISO 10993-10: 2010 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	PASS

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the proposed device K202387 is as safe, as effective, and performs as well as or better than the legally marketed predicate devices K160269 and K191355.