April 16, 2021
Jiangsu Guangda Medical Material Group Co., Ltd.
℅ W. Victoria Rogers
Regulatory Affairs Consultant
Rogers Consulting
11110 Arranmore Cove
Roanoke, Indiana 46783

Re: K201718
Trade/Device Name: GD Disposable Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 6, 2021
Received: April 12, 2021

Dear W. Victoria Rogers:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 15, 2021. Specifically, FDA is updating this SE Letter as an administrative correction due to omission of the signature in the original SE letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Dr. Clarence W. Murray III, OHT4: Office of Surgical and Infection Control Devices, at: 301-796-0270 or Clarence.Murray@fda.hhs.gov.

Sincerely,

Bifeng Qian -S

For Clarence W. Murray III, Ph.D.
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

April 15, 2021

Jiangsu Guangda Medical Material Group Co., Ltd.
℅ W. Victoria Rogers
Regulatory Affairs Consultant
Rogers Consulting
11110 Arranmore Cove
Roanoke, Indiana 46783

Re: K201718
Trade/Device Name: GD Disposable Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 6, 2021
Received: April 12, 2021

Dear W. Victoria Rogers:

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.
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)*

K201718

Device Name
GD Disposable Medical Face Mask

Indications for Use *(Describe)*

The GD Disposable Medical 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 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the GD Disposable Medical Face Mask 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

510(k) Number: K201718

Sponsor: Jiangsu Guangda Medical Material Group Co., Ltd.
No. 18 Baochang Road North Libao Town, Haian County,
Jiangsu Province, China

Contact Person: George Zhang
President
Telephone: 86-513-88219002

Designated Submission Correspondent: W. Victoria Rogers
Rogers Consulting
11110 Arranmore Cove
Roanoke, Indiana 46783
574-265-8356

Date: 6 April 2021

Subject Device: **Trade Name:** GD Disposable Medical Face Mask
Common Name: Surgical Facemask

Classification Name:
- FXX– Surgical Apparel (21 CFR 878.4040)

Predicate Device(s):

K160269	Surgical Face Masks (Ear Loops and Tie-on)	SAN-M Package Co., LTD.

Purpose and Device Description:

The GD Disposable Medical Face Mask is a single use multi-layer Level 2 surgical mask. It houses a meltblown polypropylene filter between an outer and inner layer of spunbond polypropylene that covers the nose and mouth of the end user and held in place by a pliable nose piece and ear loops. Contact duration is less than 24 hours.

Intended Use and Indications for Use:

The GD Disposable Medical 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 is a single use, disposable device, provided non-sterile.

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

	GD Level 2 Mask K201718	**Surgical Face Masks (Ear Loops and Tie-on), K160269**	**Remark**
Intended Use/ Indications for Use	The GD Disposable Medical 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 is a single use, disposable device(s), provided non-sterile.	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. This is a single use, disposable device(s), provided non-sterile.	Same
Materials			
Outer Materials	Polypropylene spunbond	Polypropylene	Similar
Filter Media	Polypropylene meltdown	1. Polypropylene spunbond	Similar

		2. Polypropylene meltdown	
Inner Material	Polypropylene spunbond	Polypropylene	Similar
Nose Piece	Malleable aluminum wire	Polyethylene coated steel wire	Similar
Ear Loops	Polyester	Polyester	Similar
Specifications	Length: 175mm Width: 95mm	Length: 175 ± 5mm Width: 90 ± 3mm	Similar
Mask Style	Flat-pleated	Flat-pleated	Same
Design Features	White	White or Blue Visor option: Polyester	Similar
Sterility	Non-sterile	Non-sterile	Same
Performance Testing			
ASTM F2100 – Level 2			
	GD Level 2 Mask	**Surgical Face Masks (Ear Loops and Tie-on), K160269**	**Remarks**
Fluid resistance ASTM F1862	Pass at 120 mmHg	Pass at 120 mmHg	Same
Particle Filtration Efficiency ASM F2299	Pass at 99.4%	Pass at 99.6%	Similar
Bacterial Filtration Efficiency ASTM F2101	Pass at >99.9%	Pass at >98%	Similar
Flammability Class 16 CFR 1610	Class I	Class I	Same
Delta-P	Pass at 4.3 mmH_2O/cm^2	Pass at 1.6 mmH_2O/cm^2	Similar

Biocompatibility Testing			
	GD Level 2 Mask	**Surgical Face Masks (Ear Loops and Tie-on), K160269**	**Results**
Cytotoxicity ISO 10993-5	Comply with ISO 10993-5. Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic	Comply with ISO 10993-5. Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic	Non-cytotoxic
Irritation ISO 10993-10	Comply with ISO 10993-10. Under the conditions of the study, the proposed device extract was determined to be non-irritating	Comply with ISO 10993-10. Under the conditions of the study, the proposed device extract was determined to be non-irritating	Non-irritating

Sensitization ISO 10993-10	Comply with ISO 10993-10. Under the conditions of the study, the proposed device extract was determined to be non-sensitizing	Comply with ISO 10993-10. Under the conditions of the study, the proposed device extract was determined to be non-sensitizing	Non-sensitizing

Summary of Performance Data
(Nonclinical and/or Clinical)

Name of the Test Methodology	Purpose	Acceptance Criteria	Results
ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity	Safety Testing	Non-Cytotoxic	Pass
ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	Safety Testing	Non-Irritating and Non-Sensitizing	Pass
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)	Barrier Testing	Pass at 120mm Hg	Pass
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;	Barrier Testing	≧98%	Pass
ASTM F2299-03, Stand test method for determining the initial	Barrier Testing	≧98%	Pass

efficiency of materials used in medical face masks to penetration by particulates using latex spheres;			
EN 14683: European standard for face masks	Physical Testing	<6.0 mm H_2O /cm^2	Pass
16 CFR 1610, Standard for the Flammability of clothing textiles.	Safety Testing	Class 1 (≧ 3.5 seconds)	Pass

- **Clinical Tests:**
  - No clinical tests were performed.

Substantial Equivalence 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.