June 6, 2024

Golden Grande Corp.
% Tyra Chiu
Regulatory Consultant
VOLER Biotech Consulting Co., Ltd.
1F., No. 3-1, Ln. 58, Hejiang St., Zhongshan Dist.
Taipei City, 104
Taiwan

Re: K232968
Trade/Device Name: Grande Medical Masks, Model SF-600
Regulatory Class: Not Classified
Product Code: FXX
Dated: July 8, 2023
Received: September 21, 2023

Dear Tyra Chiu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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)*
K232968

Device Name
Grande Medical Masks, Model SF-600

Indications for Use *(Describe)*
Grande Medical Masks is intended to be worn to protect both the patient and healthcare personnel from the 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. The Grande Medical Masks are 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 (K232968)

(As required by 21 CFR 807.92)

Date June 4, 2024

Manufacturer/ 510(k) Owner Golden Grande Corp.
NO. 622-6, GUANGHUA LI, XUEJIA DIST., TAINAN CITY, 72651, TAIWAN

Contact Person Hsin Hui Tseng
Phone:
E-mail: cindytseng@grande.com.tw

Device Trade Name Grande Medical Masks
Common Name Surgical Masks
Classification Name Masks, Surgical
Device Class II
Medical Specialty General & Plastic Surgery
Regulation Number 878.4040
Product Code FXX

Device Description and Technology Characteristics Grande Medical Masks are 4-layer surgical masks that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. This device is non-sterile and for single use only.
The mask is constructed of nonwoven fabric, including the bottom layer, surface layer 1, surface layer 2 and middle layer, and is provided with ear loops and nose clip.

Models SF-600

Indications for Use Grande Medical Masks is intended to be worn to protect both the patient and healthcare personnel from the 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. The Grande Medical Masks are single use, disposable device, provided non-sterile.

Predicate Device(s) K160269 Surgical Face Masks, SAN-M PACKAGE CO., LTD.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Proposed Device	**Predicate Device**	**Comparison**
Device Name	**Grande Medical Masks**	Surgical Face Masks	Different
510(k) #	K232968	K160269	Different
Applicant	Golden Grande Corp.	SAN-M PACKAGE CO., LTD.	Different
Product code	FXX (21 CFR 878.4040)	FXX (21 CFR 878.4040)	Same

Classification	II	II	Same
OTC use	YES	YES	Same
Intended Use	Grande Medical Masks is intended to be worn to protect both the patient and healthcare personnel from the 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. The Grande Medical Masks are single use, disposable device, 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, provided non-sterile.	Same
Dimensions	175±3 mm x 95±3 mm	90mm±3*175±5mm, 90mm±3*180±5mm	Similar
Layers	4	4	Same
Mask Style	Flat-pleated	Flat-pleated	Same
Design Feature	Ear loops	Ear loops	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use	Single Use	Same
Material:	Surface Layer 1: Polypropylene spunbond Surface Layer 2: Polypropylene spunbond Middle Layer: Polypropylene Meltblown Bottom Layer: Polypropylene Spunbond Nose Clip: malleable aluminum wire covered with polyethylene Ear Loops: Polyamide	Outer Layer: Polypropylene. Filter Layer 1: Polypropylene spunbond Filter Layer 2: Polypropylene meltblown Inner Layer: polypropylene. Earloops: Polyester, polyurethane Side tapes: Polyester spunbond (ear loops mask only) Tie tapes: Polypropylene spunbond or polyester spunbond Nose clamp: Polyethylene coated steel wire	Similar
ASTM Level	2	1,2,3	Similar
Fluid Resistance ASTM F1862	120 mmHg	80 mmHg ,120 mmHg or 160 mmHg	Similar
Bacterial Filtration Efficiency ASTM F2101	Pass at 99 %	Pass at 98% (Level 1) Pass at 98% (Level 2) Pass at 99% (Level 3)	Similar
Differential Pressure Mil-M-36954C	Less than 4.5 mmH_2O/cm^2	Less than 2.0 mmH2O/cm2 (Level 1) Less than 1.6 mmH2O/cm2 (Level 2) Less than 2.5 mmH2O/cm2 (Level 3)	Similar
Particle Filtration Efficiency ASTM F2299	Pass at 99%	Pass at 99.6% (Level 1) Pass at 99.6% (Level 2) Pass at 99.7% (Level 3)	Similar
Flammability 16 CFR 1610	Class I	Class I	Same

Biocompatibility	non- cytotoxic, non-irritating, non-sensitizing (ISO 10993-5, ISO 10993-10)	non- cytotoxic, non-irritating, non-sensitizing (ISO 10993-5, ISO 10993-10)	Same

Discussion on Performance Data Non-Clinical Tests

The proposed devices were tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission.

Non-Clinical Testing Summary

Test Methodology	Purpose of the test	F2100-19 Level 2 Criteria	**Result**
Bacteria Filtration Efficiency	Determine the bacterial filtration efficiency as directed in Test Method ASTM F2101.	≥ 98 %	Pass
Particle Filtration Efficiency	Determine particulate filtration efficiency as directed in Test Method F2299.	≥ 98 %	Pass
Differential Pressure (Delta-P)	Determine breathing resistance or differential pressure as directed in EN 14683:2019, Annex C.	<6.0 mmH_2O/cm^2	Pass
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	Determine synthetic blood penetration resistance as specified in Test Method F1862	120 mmHg (≥ 29/32 show passing results per lot)	Pass
Flammability	Determine flammability as specified in 16 CFR Part 1610	Class I (Burn time ≥3.5 s, IBE, or DNI)	Pass

Biocompatibility Testing Summary:

Test Methodology	Purpose of the test	Criteria	Results
In vitro Cytotoxicity test	Determine the effects on cells following ISO 10993-5	Under the conditions of the test, non-cytotoxic	Pass
Skin sensitization Test	Estimate the potential for contact sensitization following ISO 10993-10	Under the conditions of the test, not a sensitizer	Pass
Skin Irritation Test	Estimate the irritation potential of medical device following ISO 10993-10	Under the conditions of the test, not an irritant	Pass

A shelf-life evaluation was conducted, and the test results demonstrate that the device maintains its performance in its claimed 3-year shelf life.

Discussion on Clinical Test Performed

No clinical testing was performed in support of this submission.

Conclusion

The conclusions drawn from the non-clinical tests demonstrate

that the subject device, Grande Medical Masks is as safe, as effective, and performs as well as or better than the legally marketed predicate device K160269.