April 2, 2024

R&G Seguridad e Higiene Industrial S.A.C.
℅ Juan Tezak
Consultant
Compliance 4 Devices
118 W Prive Cr.
Delray Beach, Florida 33445

Re: K232112
Trade/Device Name: R&G Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 6, 2024
Received: March 6, 2024

Dear Juan Tezak:

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,

Bifeng Qian -S

Bifeng Qian, M.D., 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232112

Device Name

R&G Surgical Mask

Indications for Use *(Describe)*

The R&G Surgical 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 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.

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510(k) Summary
K232112

Prepared April 1, 2024

I) Applicant

Submitter	R&G Seguridad e Higiene Industrial S.A.C.
Address	Mz. V Lt. 11-15 Urb. Los Carrizales Ventanilla Callao Lima 07046 Peru
Contact	Mrs. Pola Guanilo
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II) Device

Trade Name	R&G Surgical Mask
Common Name	Surgical apparel
Classification Name	Mask, Surgical
Regulation Number	21 CFR 878.4040
Product Code	FXX

III) Predicate Device

510(k) Number	K202745
Applicant	Ningbo Jingeao Electronics Inc.
Trade Name	Disposable medical face mask
Classification Name	Mask, Surgical
Regulation Number	878.4040

IV) Indication For Use

The R&G Surgical 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 the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

V) Device Description

The R&G surgical mask is a single-use, three-layer, flat-pleated surgical mask with ear loops and nosepiece. The mask is made of three layers, the inner layer is made of white polypropylene nonwoven fabric, the outer layer is made of white polypropylene nonwoven fabrics, and the middle layer is made of meltblown fabrics. The mask is held in place over the wearer's mouth and nose by two elastic ear loops welded to the mask. The elastic ear loops are made of 80% polypropylene + 20% spandex. The nose piece on the mask is to allow the user to adjust the mask around their nose and is made of 75% plastic + 25% wire. The R&G surgical mask will be supplied in white. The mask is sold unsterilized and is intended to be a single-use disposable device.

VI) Comparison of Technological Characteristics

	K232112	K202745	Comparison
Product Trade Name	R&G Surgical Mask	Disposable medical face mask	Similar
Regulation	21 CFR 878.4040	21 CFR 878.4040	Same
Indications For Use	The R&G Surgical 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 the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	The 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. The face mask is 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.	Similar
OTC/Rx	OTC	OTC	Same
Composite	3 pleated non-woven polypropylene layers	Flat Pleated, 3 layers	Similar
Internal layer material	White spunbond polypropylene non-woven fabric	Spunbond polypropylene	Similar
Middle Layer Material	Melt blown filter	Melt blown polypropylene	Similar
External Layer Material	White spunbond polypropylene non-woven fabric	Spunbond polypropylene	Similar
Nose Piece	Plastic-coated aluminum wire	Galvanized iron wire	Different
Ear Loop Material	80% polypropylene / 20% spandex	Polyester / spandex	Different
Color	White	Blue	Different
Mask Length	17.5cm ± 0.5cm	17.5cm ± 0.5cm	Same
Mask Width	9.5cm ± 0.5cm	9.5cm ± 0.5cm	Same
Sterility	Non-sterile	Non-sterile	Same
ASTM F2100	ASTM F2100-23 Level 2	ASTM F2100 Level 2	Similar
Cytotoxicity	Under the conditions of the study, not	Under the conditions of the study, not	Same

	cytotoxic	cytotoxic	
Sensitization	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
Irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same

The differences in material and color on safety and performance do not prevent the subject device from achieving similar acceptable biocompatibility and compliance with ASTM F2100 Level 2 performance requirements.

VII) Summary of Non-Clinical Testing

Test	Purpose	Criteria	Result
ASTM F2101-2023	To demonstrate adequate bacterial filtration efficiency	Under the conditions of the study, at least 98% efficiency	Pass
EN 14683:2019+AC Annex C	To demonstrate acceptable breathability	Under the conditions of the study, at most 6.0 mm H_2O/cm^2	Pass
ASTM F3050	To demonstrate adequate particulate filtration efficiency	Under the conditions of the study, at least 85% efficiency	Pass
ASTM F1862	To demonstrate adequate resistance to liquids	Under the conditions of the study, passing at 120 mmHg conditions	Pass
16 CFR 1610	To evaluate flame spread resistance	Class 1 under the conditions of the testing	Pass
ASTM F2100-23	To evaluate mask performance	Level 2 under the conditions of the evaluation	Pass
ISO 10993-5	To evaluate the cytotoxic potential of the mask	Under the conditions of the study, non-cytotoxic	Pass
ISO 10993-10 Sensitization	To evaluate the sensitization potential of the mask	Under the conditions of the study, not a sensitizer	Pass
ISO 10993-10 Irritation	To evaluate the irritation potential of the mask	Under the conditions of the study, not an irritant	Pass

VIII) Summary of Clinical Testing

No clinical testing was performed in support of this submission.

IX) Conclusion

The conclusions drawn from the non-clinical testing demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K202745.