September 13, 2022

R&R Medical Corporation Ltd.
% Chih-Hao Kao
Vice President
Voler Biotech Consulting Co., Ltd.
No. 3-1, Lane 58, Hejiang St., Zhongshan Dist.
Taipei City, 10480
Taiwan

Re: K214035
Trade/Device Name: LAITEST Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 23, 2022
Received: August 31, 2022

Dear Chih-Hao Kao:

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,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K214035

Device Name
LAITEST MEDICAL FACE MASK

Indications for Use *(Describe)*
The LAITEST MEDICAL FACE MASK 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.

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

[As required by 21 CFR 807.92]

1. Submission Information

Preparation date:	August 23th, 2022
Submitter:	R&R Medical Corporation Ltd. No.4, Ln. 38, Zhongxing N. St., Sanchong Dist., New Taipei City 24158, Taiwan (R.O.C.)
Submitter contact:	Wilson Chang Tel: +886-2-2697-6618/Fax: +886-2-2697-6609 E-mail: wcchang@taiwanstanch.com
Official correspondent:	Chih Hao, Kao Tel: + 886-933852972/Fax: + 886-78419003 E-mail: leon.howard01@gmail.com

2. Device Name and Classification

Product Name:	LAITEST Surgical Face Mask
Classification Name:	Mask, Surgical
Common or Usual Name:	Surgical face mask
Regulation medical specialty:	General & Plastic Surgery
Regulation Description:	Surgical apparel.
Review Panel:	General Hospital
Regulation Number:	21 CFR 878.4040
Device Class:	Class 2
Product Code:	FXX

3. Primary Predicate Device(s)

Product Name:	Surgical Face Mask (K182515)
Classification:	Class II
Common or Usual Name:	Surgical face mask
Classification Panel:	Surgical Apparel
Regulation Number:	21 CFR 878.4040
Device Class:	Class 2
Product Code:	FXX

4. Device Description

LAITEST Surgical Face Mask are made of 3-layer non-woven material. The masks have a Bacterial Filtration Efficiency (BFE) and Particle Filtration Efficiency (PFE) Standards of 98%, and Virus Filtration Efficiency (VFE) Standards of 99%, which can effectively protect against sub-micron particles, fine dust, biological agents (bacteria, or viruses), and fluid splashes. The masks have ear loops and nose band which can provide a comfort wear for users.

5. Indications for Use

The LAITEST Surgical 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.

6. Substantial Equivalence

	Proposed Device	Primary predicate device K182515	Differences
Item	LAITEST Surgical Face Mask	Surgical Face Mask	NA
Classification	2 (21CFR878.4040)	2 (21CFR878.4040)	Same Classification
Product Code	FXX	FXX	Same Product Code
Indications for Use	The LAITEST Surgical Face Mask 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.	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.	Both devices are surgical face mask and have same intended use.
Basic design	Ear Loops, Flat Pleated, 3 layers	Ear Loops, Flat Pleated, 3 layers	Same

		Proposed Device	Primary predicate device K182515	Differences
Item		LAITEST Surgical Face Mask	Surgical Face Mask	NA
Material	External layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Filter layer	Melt blown filter	Melt blown polypropylene filter	Same
	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
Nose band		PE coating Aluminum Line	Malleable polyethylene wire	Different
Ear loops		Nylon + Spandex	Spandex	Similar
Color		Blue	Yellow	Different
Dimension-Width		17.5 cm ± 5% cm (0.875 cm)	17.5cm±0.2cm	Similar
Dimension-Length		9.5 cm±5% cm (0.475 cm)	9.5cm±0.2cm	Similar
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level		Level 2	Level 2	Same

Performance Data

Non-clinical Test performed on the proposed device

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 issued on March 5, 2004.

All results of testing met ASTM F2100 **Level 2** acceptance criteria

Item	Purpose	**Proposed device**	**Acceptance Criteria**	**Result**
Fluid Resistance Performance ASTM F1862	Determine synthetic blood penetration resistance	≥29 of 32 pass at 120 mmHg	≥29 of 32 pass at 120 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	Determine the bacterial filtration efficiency	> 98%	≥ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101	Determine submicron particulate filtration efficiency	> 98%	≥ 98%	Pass
Differential Pressure (Delta P) EN 14683	Determine breathing resistance or differential pressure	<6.0mmH_2O/cm^2	<6.0mmH_2O/cm^2	Pass
Flammability 16 CFR Part 1610	Determine flammability or flame spread	Class 1	Class 1	Pass

Biocompatibility Testing

Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the device is noncytotoxic.	Pass
Sensitization	Under the conditions of the study, the device is non sensitizing.	Pass
Irritation	Under the conditions of the study, the device is nonirritating.	Pass

Similarity and differences

The differences between proposed device and the primary predicate device in materials and colors do not raise additional questions for safety and effectiveness.

The proposed device has been tested on safety and performance, and the results were complied with the test requests. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials and color additives.

Therefore, the differences did not raise any safety or effectiveness issue. The proposed device is substantially equivalent to the primary predicate device in intended use, design, safety and performance claims.

Conclusion

After analyzing bench test, device description and indication for use, it can be concluded that LAITEST Surgical Face Mask is as safe and effective as the primary predicate device.