February 24, 2022

ROKI Co., Ltd.
% Mr. Fumiaki Kanai
President & CEO
MIC International Corp.
4-32-16 Ryogoku
Sumida-ku, Tokyo
Japan

Re: K214094
Trade/Device Name: ROKI Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 10, 2021
Received: December 28, 2021

Dear Mr. Kanai:

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 L. 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)*

K214094

Device Name
ROKI Surgical Mask

Indications for Use *(Describe)*

The ROKI Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The ROKI Surgical 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, provided non-sterile.
Model: L and M, white color, and Level 3 barrier level per ASTM F2100-19.

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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ROKI Surgical Mask
Traditional 510(k) Submission

510(k) Summary

This summary of 510(k) is prepared in accordance with 21 CFR 807.92.

Date of Preparation: December 10, 2021

I. SUBMITTER

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II. DEVICE

Trade name: ROKI Surgical Mask
Regulation: 21 CFR 878.4040 - Surgical Apparel
Classification Name: Mask, Surgical
Regulatory Class: Class II
Product Code: FXX

III. PRIMARY PREDICATE DEVICE

Qiqihar Hengxin Medical Supplies, Ltd. Single-Use Surgical Mask (K201924)
No reference devices were used in this submission.

ROKI Surgical Mask
Traditional 510(k) Submission

IV. DEVICE DESCRIPTION

The subject device is white color, and flat pleated type mask, utilizing ear loops' way for wearing, and has nose fitter design for fitting the facemask around the nose.

The subject device is consisted of three layers, the inner and outer layers are made with spun-bond polypropylene, and the middle layer is made with melt blown polypropylene.

The subject device is held in place over the user's mouth and nose by two elastic ear loops welded to the mask. The elastic ear loops are made with polyester and polyurethane. The nose fitter contained in the subject device is in the layers of the mask to allow the user to fit the mask around their nose, which is made of malleable aluminum wire.

There are two models of the subject device, Model L and Model M. They differ only in the width. Model L is wider than Model M. However, the material type, material formulation, chemical composition, and material 's processing methods are the same. The subject device is a single-use, disposable device, provided non-sterile.

The performance of the subject device meets Level 3 requirements per ASTM F2100-19.

V. INDICATIONS for USE

The ROKI Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The ROKI Surgical 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, provided non-sterile.

Model: L and M, white color, and Level 3 barrier level as ASTM F2100-19.

ROKI Surgical Mask
Traditional 510(k) Submission

VI. COMPARISON of TECHNOLOGICAL CHARACTERISTICS with THE PREDICATE DEVICE

a. Substantially Equivalent Comparison

Table 6.1. Comparison of Technological Characteristics

Item	Subject Device	Predicate Device	Remark
510K number		K201924	
Manufacturer	ROKI Co., Ltd.	Qiqihar Hengxin Medical Supplies, Ltd.	
Trade Name	ROKI Surgical Mask	Single-Use Surgical Mask	Similar
Product Code	FXX	FXX	Same
Classification	Class II 21 CFR 878.4040 Surgical apparel.	Class II 21 CFR 878.4040 Surgical apparel.	Same
Intended Use/ Indications for Use	The ROKI 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 Surgical 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, provided non-sterile. Model: L and M, white color, and Level 3 barrier level as ASTM F2100.	The Single-Use Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The Single-Use Surgical Mask 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. Model: M and L, blue color, and Level 3 barrier level as ASTM F2100.	Same
Model	L, M	L, M	Same
Basic Design	Ear Loops, Flat Pleated, 3 layers	Ear Loops, Flat Pleated, 3 layers	Same
Materials			
Outer Layer	Spun-bond polypropylene	Spun-bond non-woven fabric	Same[1)]
Middle Layer	Melt blown polypropylene	Melt blown non-woven fabric	
Inner Layer	Spun-bond polypropylene	Spun-bond non-woven fabric	
Nose Fitter	Malleable aluminum wire	Malleable aluminum wire	
Ear Loops	Polyester/ polyurethane	Polyester	Different

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Table 6.1. Comparison of Technological Characteristics (continued)

Item	Subject Device	Predicate Device	Remark
Design Features			
Color	White	Blue	Different
Dimension (Width)	Model L : 17.5cm ± 1cm Model M: 16cm ± 1cm	Model L : 18cm ± 1cm Model M: 14cm ± 1cm	Similar
Dimension (Length)	9.5cm ±1 cm	9cm ±1cm	
OTC use	Yes	Yes	Same
Single Use	Yes	Yes	Same
Sterile	No	No	Same

[1)] The material of each layer of the predicate device is all made of polypropylene, which is also the same as the material of each layer of the corresponding subject device.

The differences in the materials of the ear loop and color do not raise additional questions for safety and effectiveness as a result of performance and biocompatibility testing on the final finished product, including all component materials.

Table 6.2. Performance Characteristic Comparison

Item & Standard (Testing Method)	Subject Device		Predicate Device	Remark
	Model L	Model M		
Fluid Resistance Performance ASTM 1862/F1862M: 2017	160mmHg	160mmHg	160mmHg	Same
Particulate Filtration Efficiency ASTM 2299/F2299M-3:2017	≥ 98.09%	≥ 98.07%	≥ 99.03%	Similar
Bacterial Filtration Efficiency ASTM F2101-19	≥ 98.1%	≥ 98.1%	≥ 99.50%	Similar
Differential Pressure (Delta-P) EN14683:2019+AC:2019	< 4.4 mmH_2O/cm^2	< 3.7 mmH_2O/cm^2	< 5.1 mmH_2O/cm^2	Similar
Flammability 16 CFR Part 1610-08	Class 1	Class 1	Class 1	Same
ASTM F2100-19	Level 3	Level 3	Level 3	Same

Although the test results are not identical to each other, but they are similar and they both meet the requirement of Level 3 medical face mask according to the ASTM F2100-19 recognized by FDA as a consensus standard.

ROKI Surgical Mask
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Table 6.3. Biocompatibility Comparison

Item & Standard (Testing Method)	Subject device	Predicate device	Remark
Cytotoxicity ISO 10993-5-09	Under the conditions of the study, the subject device is non-cytotoxic.	Under the conditions of the study, not cytotoxicity effect as ISO 10993-5	Same
Irritation ISO 10993-10-10	Under the conditions of the study, the subject device is non-irritating.	Under conditions of the study, not an irritant as ISO 10993-10	Same
Sensitization ISO 10993-10-10	Under the conditions of the study, the subject device is non-sensitizing.	Under the conditions of the study, not a sensitizer as ISO 10993-10	Same

The subject device complies with the same standards as those used in the predicate device. Those three standards are FDA recognized consensus standards.

VII. NON‐CLINICAL TETING DATA

a. Performance testing

The performance evaluation for the subject device was conducted in accordance with the FDA guidance "Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission" March 5, 2004 and ASTM F2100 "Standard Specification for Performance of Materials Used in Medical Face Masks" as recognized by FDA. Performance evaluation included the following tests:

- Fluid Resistance Performance
- Particulate Filtration Efficiency
- Bacterial Filtration Efficiency
- Differential Pressure (Delta-P)
- Flammability

Both models L and M were used as test samples. Sample size was determined according to a 4% acceptance quality limit (AQL) on the production lot size. A total of 96 samples, 32 samples per lot from three non-consecutive lots, were used under the condition of 4% AQL according to ASTM F2100-19.

Table 6.4 and Table 6.5 shows the results of the testing for model L and M, respectively. All testing results met ASTM F2100-19 Level 3 acceptance criteria as well as the predicate device.
Performance comparison between the subject device and the predicate device are summarized in the Table 6.2.

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Table 6.4. Results and verdict of the performance testing for model L

Item & Testing method (Standard)	Model L Results			Pass/Fail Acceptance criteria: ASTM F2100-19 Level 3
	Number of Passes out of 32	Minimum or Maximum	Result	
Fluid Resistance Performance ASTM F1862: 2017	Lot 1: 32	at 160mmHg	96 out of 96 no penetration	Pass ≧29 out of 32 pass/ lot
	Lot 2: 32	at 160mmHg		
	Lot 3: 32	at 160mmHg		
Particulate Filtration Efficiency ASTM F2299/ F2299M-03: 2017	Lot 1: 32	≥ 98.13%	≥ 98.09%	Pass ≧98%
	Lot 2: 32	≥ 98.09%		
	Lot 3: 32	≥ 98.13%		
Bacterial Filtration Efficiency ASTM F2101-2019	Lot 1: 32	≥ 98.7%	≥ 98.1%	Pass ≧98%
	Lot 2: 32	≥ 98.1%		
	Lot 3: 32	≥ 98.2%		
Differential Pressure (Delta-P) EN14683:2019+AC:2019	Lot 1: 32	≤ 4.4mmH_2O/cm^2	≤ 4.4 mmH_2O/cm^2	Pass <6.0 mmH_2O/cm^2
	Lot 2: 32	≤ 4.1mmH_2O/cm^2		
	Lot 3: 32	≤ 4.1mmH_2O/cm^2		
Flammability class 16 CFR 1610:2008	Lot 1: 32	No ignition	96 out of 96 no ignition	Class 1 ≥3.5 sec.
	Lot 2: 32	No ignition		
	Lot 3: 32	No ignition		

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Table 6.5. Results and verdict of the performance testing for model M

Item & Testing method (Standard)	Model M Results			Pass/Fail Acceptance criteria: ASTM F2100-19 Level 3
	Number of Passes out of 32	Minimum or Maximum	Result	
Fluid Resistance Performance ASTM F1862:2017	Lot 1: 32	at 160mmHg	96 out of 96 no penetration	Pass ≧29 out of 32 pass/ lot
	Lot 2: 32	at 160mmHg		
	Lot 3: 32	at 160mmHg		
Particulate Filtration Efficiency ASTM F2299/ F2299M-03:2017	Lot 1: 32	≥ 98.07%	≥ 98.07%	Pass ≧98%
	Lot 2: 32	≥ 98.10%		
	Lot 3: 32	≥ 98.11%		
Bacterial Filtration Efficiency ASTM F2101-2019	Lot 1: 32	≥ 98.5%	≥ 98.1%	Pass ≧98%
	Lot 2: 32	≥ 98.3%		
	Lot 3: 32	≥ 98.1%		
Differential Pressure (Delta-P) EN14683:2019+AC: 2019	Lot 1: 32	≤ 3.5mmH_2O/cm^2	≤ 3.7 mmH_2O/cm^2	Pass ＜6.0 mmH_2O/cm^2
	Lot 2: 32	≤ 3.5mmH_2O/cm^2		
	Lot 3: 32	≤ 3.7mmH_2O/cm^2		
Flammability class 16 CFR 1610:2008	Lot 1: 32	No ignition	96 out of 96 no ignition	Class 1 ≥3.5 sec.
	Lot 2: 32	No ignition		
	Lot 3: 32	No ignition		

The testing results demonstrated that the subject device complies with the following standards:

- ASTMF2100-2019, Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862/F1862M:2017, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2299/F2299M-03:2017, Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- ASTM F2101-2019, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- EN14683:2019+AC:2019, Appendix C, Medical face masks- Requirements and test methods
- 16 CFR 1610-08, Standard for the Flammability of clothing textiles

ROKI Surgical Mask
Traditional 510(k) Submission

b. Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process' Guidance for Industry and Food and Drug Administration Staff'" September 4, 2020 and ISO 10993-1 as recognized by FDA. Biocompatibility evaluation included the following tests:

- In vitro Cytotoxicity
- Irritation
- Skin Sensitization

Table 6.5 shows the testing results of the subject device. Under the condition of this study, the subject device is non-cytotoxic, non-irritating and non-sensitizing as well as the predicate device. Biocompatibility comparison between the subject and predicate device are summarized in the Table 6.3.

Table 6.6. Biocompatibility Testing Results

Item	Standard (Testing Method)	Results
in vitro Cytotoxicity	ISO 10993-5-09 MEM elution using L-929 mouse fibroblast cell	Pass Under the conditions of the study, no in vitro cytotoxicity observed.
Irritation	ISO 10993-10-10 Animal irritation test	Pass Under the conditions of the study, no irritation observed.
Skin Sensitization	ISO 10993-10-10 Guinea pig maximization test	Pass Under the conditions of the study, no skin sensitization observed.

The test results demonstrated that the subject device complies with the following FDA recognized consensus standards:

- ISO 10993-5-09: Biological Evaluation of Medical Devices - Part *5:* Tests For In Vitro Cytotoxicity
- ISO 10993-10-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-12-21: Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

ROKI Surgical Mask
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c. Summary

The subject device has the same or similar performance characteristics and conform to the same or similar standards as for the predicate device.

VIII. CLINICAL TEST CONCLUSION

No clinical study is included in this submission.

IX. CONCLUSION

Intended use and indications for use, basic design, materials, design features, and non-clinical testing result of the subject device are same as or similar to the predicate device. The difference between the subject device and the predicate device does not raise any question to safety and effectiveness. Accordingly, it is concluded that the subject device is substantially equivalent to the predicate device K201924.