May 1, 2023

RIA Tech Co., Ltd.
David Chao
President
5f., No. 25-2, Sec. 4, Ren-ai Rd., Da-an Dist.
Taipei City, 106073
Taiwan

Re: K222416
Trade/Device Name: RIA Safeguard
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: Class II
Product Code: FRF
Dated: March 13, 2023
Received: March 27, 2023

Dear David Chao:

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,

Christopher K. Dugard -S

for Clarence W. Murray, III, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222416

Device Name
RIA SafeGuard

Indications for Use *(Describe)*
The RIA SafeGuard is intended as a room recirculating air cleaner. The system is used for filtering out airborne particles PM2.5 from the air for medical purposes, and is intended for over-the-counter use.

The RIA SafeGuard has wind speed of 1.3 m/s and airflow of 135 CMH (m^3/h). Using the HEPA H13 filter, it provides a 4 log (99.99%) reduction in suspended particulate PM2.5 in 120 minutes within a 29.75 m^3 room.

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.

510(k) SUMMARY

1. Submitter

RIA Tech Co., Ltd.

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Phone:	+886-2-2521-1220
Fax:	+886-2-8773-1130
Contact:	David Chao, President (david@riatechgroup.com)
Date Prepared:	April 27, 2023

2. Identification of the Device

Proprietary/Trade name:	RIA SafeGuard
Model Number:	SG020MS120
Classification Product Code:	FRF
Regulation Number:	880.5045
Regulation Description:	Medical recirculating air cleaner
Review Panel:	General Hospital
Device Class:	II

3. Identification of the Predicate Device

Predicate Device Name:	HEPAir X100
Manufacturer:	Air Innovations, Inc.
Classification Product Code:	FRF
Regulation number:	880.5045
Device Class:	II
510(k) Number:	K112728

4. Identification of the Reference Device

Predicate Device Name:	Novaerus NV1050
Manufacturer:	Novaerus US Inc.
Classification Product Code:	FRF
Regulation number:	880.5045
Device Class:	II
510(k) Number:	K200321

5. Device Description

RIA SafeGuard (SG020MS120) is an air purifier that contains the high-efficiency HEPA technology and Bi-Polar Ionization (BPI) unit to remove 99.99% of particles as small as 2.5 microns from the air stream. SafeGuard addresses suspended particles with a single wind speed of 1.3 m/s, providing a 4 log reduction in PM2.5 particulates within 120 minutes in a 29.75 m^3 space. The airflow is 135 CMH (m^3/h). It is intended to be placed in a room such as medical care institutions and hospitals etc. RIA SafeGuard is a product that is designed as one-touch, easy to use, and no contact with patients. RIA SafeGuard has built in a blue LED as the switch-on indicator. All the maintenance should be done by a trained technician. Changing the HEPA is the only recommended maintenance to do by a non-trained technician, recommended renewing every 12 months.

6. Indications for Use

The RIA SafeGuard is intended as a room recirculating air cleaner. The system is used for filtering out airborne particles PM2.5 from the air for medical purposes, and is intended for over-the-counter use.

The RIA SafeGuard has wind speed of 1.3 m/s and airflow of 135 CMH (m^3/h). Using the HEPA H13 filter, it provides a 4 log (99.99%) reduction in suspended particulate PM2.5 in 120 minutes within a 29.75 m^3 room.

7. Comparison of Technological Characteristics with the Predicate Device

The RIA SafeGuard submitted in this 510(k) file is compared with the predicate device (HEPAir X100, K112728) and reference device (Novaerus NV1050, K200321). A technological comparison evaluating the subject, predicate and reference devices are cited as below.

Item	Subject Device	Predicate Device	Comparison
Manufacturer	RIA Tech Co., Ltd.	Air Innovations, Inc.	
Trade Name	RIA SafeGuard	HEPAir X100	
510(k) No.	K222416	K112728	
Product Code	FRF	FRF	***Same***
Indications for Use	The RIA SafeGuard is intended as a room recirculating air cleaner. The system is used for filtering out airborne particles PM2.5 from the air for medical purposes, and is intended for over-the-counter use. The RIA SafeGuard has wind speed of 1.3 m/s and airflow of 135 CMH (m^3/h). Using the HEPA H13 filter, it provides a 4 log (99.99%) reduction in suspended particulate PM2.5 in 120 minutes within a 29.75 m^3 room.	Filtering out airborne particulates from air for medical purposes. HEPAir X100 is intended for over-the-counter use.	***Similar***
Device Illustration			***Different***
Device Size	42 x 28 x 90 cm	55.9 x 55.9 x 73.7 cm	
Device Weight	30 kg (66 lb)	53.5 kg (118 lb)	
Type of Device	Over the counter use	Over the counter use	***Identical***
Use Location	Medical Facilities	Medical Facilities	

Item	Subject Device	Predicate Device	Comparison
Manufacturer	RIA Tech Co., Ltd.	Air Innovations, Inc.	
Trade Name	RIA SafeGuard	HEPAir X100	
510(k) No.	K222416	K112728	
Filtration of Particles	4 log reduction in PM2.5 in 120 minutes in a 29.75 m^3 sealed room.	HEPA filter with a minimum efficiency of 99.97% DOP tested on 0.3 μm particles.	***Similar***

8. Non-clinical Testing

A series of validation activities were conducted on the subject device, RIA SafeGuard (SG020MS120). All the test results demonstrate RIA SafeGuard meets the requirements of its pre-defined acceptance criteria and indication for use.

Test Name	Purpose	Acceptance Criteria	Result
Filtration of Particles	Demonstration of Device Air Cleaner Efficacy for 4 Log Reduction of PM2.5 Air Particulates in 120 minutes in a 29.75 m^3 room.	Reduction rate > 99.99% (4 log reduction)	Pass
Ozone Emissions UL867	Determine the ozone emissions of the device.	The maximum ozone concentration emitted is below the 0.050 ppm standard.	Pass
Electrical Safety Testing IEC 60601-1:2005, IEC 60601-1:2005+ AMD1:2012, IEC 60601-1:2005+ AMD1:2012+AMD2:2020	Determine the general requirements for basic safety and essential performance of the device.	Meet the test specification according to the standards.	Pass

Test Name	Purpose	Acceptance Criteria	Result
Electromagnetic Compatibility (EMC) Testing IEC 60601-1-2:2014	Determine the electromagnetic compatibility, emissions and immunity of the device.	Meet the test specification according to the standards.	Pass

9. Clinical Testing

No clinical test data was used to support the current 510(k) submission.

10. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K222416, the RIA SafeGuard, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K112728 and reference device cleared under K200321.