May 17, 2017

Ray Co., Ltd.
℅ Rafael Aguila
Responsible Third Party Official
Accelerated Device Approval Services
6800 S.W. 40th Street, Ste. 403
Ludlum, Florida 33155

Re: K211105
Trade/Device Name: Ear-Friendly Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 4, 2021
Received: May 6, 2021

Dear Rafael Aguila:

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,

For Ryan Ortega, Ph.D.
Acting 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)*
K211105

Device Name
Ear-Friendly Mask

Indications for Use *(Describe)*
When properly worn, the Ear-Friendly Masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate material. This device is non sterile and for single use only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K211105 510(k) Summary

1. 510(k) Summary

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

2. Date: May 14, 2021

3. 510(K) Number: K211105

4. Administrative Information

Sponsor Information RAY Co.,Ltd

ADDRESS 38, Simin-daero, Manan-gu, Anyang-si, Gyeonggi-do, 14098, Korea

Manufacturer RAY Co.,Ltd
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5. Device Information

Device Name

Trade/Proprietary Name: Ear-Friendly Mask
Common Name: Surgical Face Mask

Classification

Classification Name: Surgical Face Mask
Regulation Number : 21 CFR 878.4040
Class : II
Product code : FXX
Panel : General and Plastic Surgery

6. Predicate device

Parameter	Predicate Device

Device Name	Avianz® Surgical Face Mask
Manufacturer	MEXPO INTERNATIONAL INC
510(K) Number	K200847
Classification name	Surgical Face Mask
Regulation number	878.4040
Primary product code	FXX

7. Device Description

The Ear-Friendly Masks are non-sterile, single use, 3 layers, flat-pleated style with ear loops and nose piece. The outer layer and inner facing layer of face mask consist of Spunbond Polypropylene, and the middle layer consists of Melt Blown Polypropylene Filter. Each mask contains ear loops to secure the mask over the user's face and mouth with nose piece to firmly fit over the nose. This device is not made from any natural rubber latex.

8. Indication for use

When properly worn, the Ear-Friendly Masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate material. This device is non sterile and for single use only.

9. Comparison of Technological Characteristics with Predicate Device

A summary of the technological characteristics of the subject device as compared to the predicate device is listed below in Table.

Parameter	**Proposed Device**	**Predicate Device**	**Comparison**
Manufacturer	RAY Co., Ltd.	MEXPO INTERNATIONAL INC	-
Device name	Ear-Friendly Mask	Avianz® Surgical Face Mask	-
510(K) Number	K211105	K200847 (Traditional)	-
Common Name	Surgical Apparel	Surgical Apparel	Same
Indications for use	When properly worn, the Ear-Friendly Masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate material. This device is non sterile and for single use only.	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only.	Similar Note1
Materials			

Outer Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Middle Layer	Melt Blown Polypropylene Filter	Melt Blown Polypropylene Filter	Same
Inner Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Nose Piece	Single Galvanize wire, coated By PE	Single Galvanize wire, coated By PE	Same
Ear Loops	Elastic non-woven Fabric (Made With PE&PP mixed)	not made with natural rubber latex	Similar Note2.
Design Features			
Color	White	White	Same
Style	3 Ply, Ear Loops, Flat-Pleated Style	3 Ply, Ear Loops, Flat-Pleated Style	Same
Dimension(Width)	95mm ± 10mm	90 mm ± 5mm	Similar Note3
Dimension(Length)	175mm ± 10mm	175 mm ± 5mm	Similar Note3
Single Use	Yes	Yes	Same
Sterility			
Sterile	Non-Sterile	Non-Sterile	Same
Biocompatibility			
Cytotoxicity	Under the conditions of the studies, the subject device is non-cytotoxic	Under the conditions of the studies, the subject device is non-cytotoxic	Same
Sensitization	Under the conditions of the studies, the subject device is non-sensitizing	Under the conditions of the studies, the subject device is non-sensitizing	Same
Irritation	Under the conditions of the studies, the subject device is non-irritating	Under the conditions of the studies, the subject device is non-irritating	Same
Non-clinical Tests Performed on the device			
ASTM Level	Level 3	Level 2	Different (Note 1)
Bacterial Filtration Efficiency(BFE)	Pass at ≥98%	Pass at ≥98%	Same
Particle Filtration Efficiency(PFE)	Pass at ≥98% @ 0.1 micron	Pass at ≥98% @ 0.1 micron	Same
Synthetic Blood Penetration	Passed at 160mm Hg	Passed at 120mm Hg	Different
Differential Pressure Only	Pass at <6.0 mmH2O/㎠	Pass at <5.0 mmH2O/㎠	Different
Flammability Test	Class 1	Class 1	Same

Comparison in Detail(s):

Note 1. Although the subject device is little difference with predicate device, it meets the requirement of essential performance standard ASTM F2100. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note 2. Although the “Elastic non-woven Fabric” of subject device is little difference with predicate device, it meets the requirement of essential performance standard ISO 10993(cytotoxicity, Sensitization and Irritation). The differences between the predicate device and subject device will not

affect the safety and effectiveness of the subject device.

Note 3. Although the “Dimension” of subject device is little bigger than predicate device, it meets the requirement of essential performance standard ASTM F2100 (Fluid Resistance, PFE, BFE, Differential Pressure and Flammability). The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

10. Summary of Non-clinical Testing

10.1 Biocompatibility Testing

The Ear-Friendly Mask has been subjected to biocompatibility studies to demonstrate the safety of device. The biocompatibility studies are in accordance with ISO 10993 :

- In vitro Cytotoxicity (ISO 10993-5) : under the conditions of the test, the device was non-cytotoxic;
- Sin Sensitization (ISO 10993-10) : under the conditions of the test, the device was non-sensitizing;
- Skin Irritation (ISO 10993-10) : under the conditions of the test, the device was non- irritating.

There is no additional safety risk for the proposed device when compared with the predicate device.

10.2 Performance testing - Bench

The Ear-Friendly Mask have been tested according to ASTM F2100 and standards which comprise ASTM F2100, Standard Specification for Performance of Materials Used in Surgical Face Mask. See the table to blow.

Test Name	Standard	Acceptance Criteria per ASTM F2100-Level 3	Test Result
Fluid Resistance	ASTM F1862	160 mmHg	Pass
Particle Filtration Efficiency(PFE)	ASTM F2299	≥ 98%	Pass
Bacterial Filtration Efficiency(BFE)	ASTM F2101	≥ 98%	Pass
Differential Pressure	MIL-M-36954C	< 6.0 mmH_20/cm^2	Pass
Flammability Test	16 CFR part 1610	Class 1	Pass

All Result of testing met ASTM F2100 Level 3 acceptance Criteria.

11. Summary of Clinical Testing

Not applicable

12. Conclusions

The conclusions drawn from the non-clinical tests demonstrate that the subject Ear-Friendly Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K200847.