September 28, 2021

Shenzhen RealTone Medical Appliance Co., Ltd.
% Tracy Che
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K210878
Trade/Device Name: Surgical Face Mask (Model: CM2006, CM2008, A88)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 19, 2021
Received: March 24, 2021

Dear Tracy Che:

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

510(k) Number *(if known)*
K210878

Device Name
Surgical Face Mask (Model: CM2006, CM2008, A88)

Indications for Use *(Describe)*
Surgical Face Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, body fluids, and particulate materials.

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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K210878 510 (k) Summary

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information

510 (k) owner's name:	Shenzhen RealTone Medical Appliance Co., Ltd.
Address:	Flat B, 5 Floor, Yaoxiang Industrial Building, No.92 Fukang Road, Henggang Street, Longgang District, Shenzhen, China
Contact person:	Wei Zhou
Phone number:	86-755-28266631
Fax number:	/
Email:	akoszhou@163.com
Date of summary prepared:	2021-9-7

(2) Reason for the submission

New device, there were no prior submissions for the device.

(3) Proprietary name of the device

Trade name:	Surgical Face Mask (Model: CM2006, CM2008, A88)
Regulation Name:	Surgical apparel
Regulation number:	21 CFR 878.4040
Product code	FXX
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(4) Predicate device

Sponsor	Mexpo International Inc.
Device Name	Avianz® Surgical Face Mask
510(k) Number	K200847
Product Code	FXX
Regulation Number	21 CFR 878.4040
Regulation Class	II

(5) Description/ Design of device

Surgical Face Mask is a non-sterile, single use multi-layer mask with outer layer and inner layer (spun-bond polypropylene) that sandwich a meltblown polypropylene filter material. There are 2

options for the Surgical Face Mask to be secured on user via earloops (model CM2006 and A88) or ties (model CM2008). Earloops are of Chinlon+Spandex Elastic Fiber (model CM2006) and polyester fibre (model A88) and not made with natural rubber latex; and ties are of spun-bond polypropylene and also not made with natural rubber latex. The nose piece is a single galvanize wire, coated by Polyethylene (model CM2006 and CM2008) and aluminum (model A88). All of the materials used in the construction of the surgical face mask are being used in currently marketed devices.

(6) Indications for use

Surgical Face Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, body fluids, and particulate materials.

(7) Materials

Component of Device Requiring Biocompatibility	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Surgical Face Mask (Model:CM2006)	Spun-bond polypropylene; melt-blown polypropylene; Single Galvanize Wire, Coated By Polyethylene; Chinlon+Spandex Elastic Fiber.	Surface-contacting device: skin	< 24hours
Surgical Face Mask (Model:CM2008)	Spun-bond polypropylene; melt-blown polypropylene; Single Galvanize Wire, Coated By Polyethylene.	Surface-contacting device: skin	< 24hours
Surgical Face Mask (Model:A88)	Spun-bond polypropylene; melt-blown polypropylene; aluminum; polyester fibre.	Surface-contacting device: skin	< 24hours

The body-contacting material used in the Surgical Face Mask have all passed biocompatibility test. Details can be seen in "Biocompatibility Discussion".

Note:

Dyes used in this product: Blue colorant is used for model CM2006 and CM2008, and no colorant is used for model A88. No printing ink has been used in the three models. The Blue colorant information is as follows.

Name: Blue masterbatch Supplier: Shantou Kecai New Materials Co., Ltd.	
Component	CAS number

Polypropylene	9003-07-0
Titanium dioxide	1317-80-2
Pigment blue 15:3	147-14-8
Pe wax	9002-88-4

(8) Comparison to Predicate Device

Item		Proposed device	Predicate device	Remark
Trade name		Surgical Face Mask	Avianz® Surgical Face Mask	/
510 (k) number		K210878	K200847	/
Regulation number		21 CFR 878.4040	21 CFR 878.4040	Same
Regulation description		Surgical apparel	Surgical apparel	Same
Product code		FXX	FXX	Same
Class		II	II	Same
Indications for use/ Intended use		Surgical Face Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, body fluids, and particulate materials.	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, only wording difference
Materials	Inner layer	Spun-bond Polypropylene	Spunbond Polypropylene	Same
	Middle layer	Melt-blown Polypropylene	Melt Blown Polypropylene Filter	Same
	Outer layer	Spun-bond Polypropylene	Spunbond Polypropylene	Same
	Nosepiece	Model CM2006 and CM2008: Single Galvanize Wire, Coated By Polyethylene; Model A88: Aluminum.	Single Galvanize Wire, Coated By PE	Differences resolved by biocompatibility testing
	Headband	Model CM2006: Chinlon+Spandex Elastic Fiber; Model CM2008: Spun-bond Polypropylene ; Model A88: Polyester Fibre.	Not made with natural rubber latex	Differences resolved by biocompatibility testing
	Dyes	Blue Masterbatch which is composed of	/	Differences resolved by

		polypropylene (CAS No.: 9003-07-0), titanium dioxide (CAS No.: 1317-80-2), pigment blue 15:3 (CAS No.: 147-14-8), pe wax (CAS No.: 9002-88-4)		biocompatibility testing
Mask style		Flat pleated	Flat pleated	Same
Design feature		Earloop or tie-on	Earloop	Similar
Dimensions		Model CM2006 and CM2008: 17.5cm×9.5cm; Model A88: 19.5cm×8cm.	(17.5cm±0.5cm)×(9.0cm± 0.5cm)	Similar
Latex		Not made with natural rubber latex	Not made with natural rubber latex	Same
Color		Model CM2006 and CM2008: Blue&White; Model A88: White	White	Differences resolved by biocompatibility testing
Sterility		Non-sterile	Non-sterile	Same
Use		Single use	Single use	Same
Prescription or OTC		OTC	OTC	Same
ASTM F2100 Level		Level 3	Level 2	Proposed device demonstrated higher resistance to fluid penetration
Performance test result				
Fluid resistance		No penetration pass at 160 mmHg	30 out of 32 pass at 120 mmHg	Proposed device demonstrated higher resistance to fluid penetration
Particle Filtration Efficiency		CM2006 and CM2008: Average 99.88% A88: Average 99.56%	99.9%	Similar
Bacterial Filtration Efficiency		CM2006 and CM2008: Average 99.88% A88: Average 99.9%	> 99.9%	Similar
Flammability Class		Class 1	Class 1	Same

Delta – P	CM2006 and CM2008: Average 3.69 mmH_2O/cm^2 A88: Average 3.55 mmH_2O/cm^2	3.0 mmH_2O/cm^2	Similar, both masks met requirements of <6.0 mmH_2O/cm^2
Biocompatibility	No cytotoxicity (ISO 10993- 5) No sensitization (ISO 10993- 10) No irritation (ISO 10993-10)	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Same

(9) Non-clinical studies and tests performed

The following performance tests of Surgical Face Mask were conducted:

Test Methodology	Purpose	Acceptance criteria	Results
Fluid Resistance Performance ASTM F1862-17	To evaluate the effectiveness of the test article in protecting the user from possible exposure to body fluids.	No penetration pass at 160mmHg	Pass, no penetration pass at 160mmHg.
Particulate Filtration Efficiency ASTM F2299-17	To evaluate the effectiveness of the test article in protecting the user from possible exposure to particulates.	⩾98%	Pass, CM2006 and CM2008: Average 99.88% A88: Average 99.56%
Bacterial Filtration Efficiency ASTM F2101-19	To evaluate the bacterial filtration efficiency (BFE) of mask.	⩾98%	Pass, CM2006 and CM2008: Average 99.88% A88: Average 99.9%
Differential Pressure (Delta P) EN 14683:2019, Annex C and ASTM F2100-19	To measure the differential pressure of mask which is related to breathability.	<6.0 mmH_20/cm^2	Pass, CM2006 and CM2008: Average 3.69 mmH_2O/cm^2 A88: Average 3.55 mmH_2O/cm^2

Flammability 16 CFR 1610	To evaluate the flammability of mask.	Class 1	Pass, Class 1
In vitro cytotoxicity ISO 10993-5	To evaluate the biological safety of the product which has direct contact with intact skin.	The test article should not have potential toxicity to L-929 in the MTT method.	Pass, the test article Surgical face mask has no potential toxicity to L-929 in the MTT method.
Skin sensitization ISO 10993-10	To evaluate the biological safety of the product which has direct contact with intact skin.	The test article should not cause delayed dermal contact sensitization in the guinea pig.	Pass, the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article Surgical face mask has no potential skin sensitization on guinea pigs in the extraction method.
Skin irritation ISO 10993-10	To evaluate the biological safety of the product which has direct contact with intact skin.	The irritation response category in the rabbit should be negligible.	Pass, the response of the test article extract was categorized as negligible under the test condition. The test article Surgical Face Mask has no potential skin irritation on rabbit in the extraction method.

(9) Conclusion

Based on the nonclinical tests performed, the subject device, K210878, is as safe, as effective, and performs as well as the legally marketed predicate device, K200847, Avianz® Surgical Face Mask.