March 12, 2021

The Aleen International Corporation
℅ Diana Lam
Regulatory Affairs Consultant
Duocare, LLC
370 W. Grand Blvd, Suite 110
Corona, California 92882

Re: K203775
Trade/Device Name: AIC disposable medical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 28, 2020
Received: December 28, 2020

Dear Diana Lam:

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 and Part 809; 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, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203775

Device Name
AIC Disposable Medical Mask

Indications for Use *(Describe)*
The AIC Disposable Medical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The 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, 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.

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510(k) Summary

K203775

Date Summary Prepared:

March 10, 2021

Applicant:

The Aleen International Corporation

Address: Jiutian Green Science and Technology Industrial Park, Heyuan High-Tech Zone, Heyuan, Guangdong, China 517000

www.aleenic.com

Contact:

Can Huang

The Aleen International Corporation

Email: chuang@aleenic.com

Phone: (+001) 626-620-0184

Correspondent Contact:

Diana Lam,

DuoCare, LLC

info@duocarepro.com

Device Information:

Device Name: AIC Disposable Medical Mask

Trade Name: AIC Disposable Medical Mask

Common Name: Disposable Medical Mask

Device Classification Name: Surgical Apparel

Classification Regulation Number: 21 CFR 878.4040

Device Classification: Class II

Classification Product Code: FXX

Predicate Device

Predicate Device	Disposable Surgical Face Mask	K153496	Xiantao Rayxin Medical Products Co., Ltd.

Description of Device

The AIC Disposable Medical Masks are blue and white color, and Flat Pleated type mask, utilizing Tie-On or Ear Loops way for wearing, and they all has Nose Piece design for fitting the facemask around the nose.

The blue colorant is polypropylene (PP) master batch.

The proposed device(s) are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter.

The model of proposed device, tie-on, is held in place over the users' mouth and nose by four ties welded to the facemask. The tie is made of spun-bond polypropylene.

The model of proposed device, ear loops, is held in place over the users' mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex.

The nose piece contained in the proposed device(s) is in the layers of facemask to allow the user to fit the facemask around their nose, which is made of malleable aluminum wire.

The proposed device(s) are sold non-sterile and are intended to be single use, disposable device

Indications for use

The AIC Disposable Medical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The 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, provided non-sterile.

Technological Characteristics Comparison

Item Name	Subject device	Predicate Device	Comparison
Device name	AIC Disposable Medical Mask	Disposable Surgical Face Mask	-
Manufacturer	The Aleen International Corporation	Xiantao Rayxin Medical Products Co., ltd.	-
510(K) No.	K203775	K153496	-
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Classification Name	Surgical Apparel	Surgical Apparel	Same
Regulatory Class	Class II	Class II	Same
Product Code	FXX	FXX	Same
Indications for use	The AIC Disposable Medical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The 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, provided non-sterile.	The Disposable 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.	Same
Device Description	The AIC Disposable Medical Masks are Blue and white color, and Flat Pleated type mask, utilizing Tie-On or Ear Loops way for wearing, and they all has Nose Piece design for fitting the facemask around the nose. The blue colorant is polypropylene (PP) master batch. The proposed device(s) are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of	The proposed device(s) are Blue color, and Flat Pleated type mask, utilizing Tie-On or Ear Loops way for wearing, and they all has Nose Piece design for fitting the facemask around the nose. The blue colorant is polypropylene (PP) master batch. The proposed device(s) are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter.	Same

		melt blown polypropylene filter. The model of proposed device, tie-on, is held in place over the user's mouth and nose by four ties welded to the facemask. The tie is made of spun-bond polypropylene. The model of proposed device, ear loops, is held in place over the user's mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex. The nose piece contained in the proposed device(s) is in the layers of facemask to allow the user to fit the facemask around their nose, which is made of malleable aluminum wire. The proposed device(s) are sold non-sterile and are intended to be single use, disposable device	The model of proposed device, tie-on, is held in place over the user's mouth and nose by four ties welded to the facemask. The tie is made of spun-bond polypropylene. The model of proposed device, ear loops, is held in place over the user's mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex. The nose piece contained in the proposed device(s) is in the layers of facemask to allow the user to fit the facemask around their nose, which is made of malleable aluminum wire. The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.	
Ear loop model and tie-on model		Ear Loops, Tie-On, Flat Pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	Same
Mater-ial	Outer layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	
	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	
	Ties	Spun-bond polypropylene	Spun-bond polypropylene	
	Nose piece	Malleable aluminum wire	Malleable aluminum wire	
	Ear loops	Polyester	Polyester	
	Mask cover width	9.5 ± 1.0 cm	9.5 ± 1.0 cm	Same
	Mask cover length	17.5 ± 1.0 cm	17.5 cm ± 1.0 cm	Same

Dimen-sion	Single ear loop Length for Ear Loops style	18.0 ± 1.0 cm	17.0 ± 1.0 cm	Similar
	Single tie Length for Tie-On style	38.5 ± 5.0 cm	40 ± 1.0 cm	Similar
	Nose piece length	10.5± 1.0 cm	11.0± 1.0 cm	Similar
Actual perfor mance values (Averag e)	Bacterial filtration efficiency	99.3% (3 lots, 32 samples/lot)	98.7%	Similar
	Differential pressure (Delta-P)	4.40 mmH_2O/cm^2 (3 lots, 32 samples/lot)	4.2 mmH_2O/cm^2	Similar
	Fluid Resistance Performance	96 out of 96 Pass at160 mmHg (3 lots, 32 samples/lot)	32 out of 32 pass at 120 mmHg	Same
	Particulate Filtration Efficiency	99.9% (3 lots, 32 samples/lot)	98.46%	Similar
	Flammability	Class 1 (3 lots, 32 samples/lot)	Class 1	Same
Bioco mpatib ility	Cytotoxicity	Under the conditions of the study, the proposed device extract demonstrated evidence of potential cytotoxicity	Under the conditions of the study, not cytotoxicity effect	Different
	Skin Irritation	Under the conditions of the study, the proposed device extract was determined to be non - irritating	Under the conditions of the study, not an irritant	Same
	Skin Sensitization	Under the conditions of the study, the proposed device extract was determined to be non - sensitizing	Under conditions of the study, not a sensitizer.	Same
	Acute Toxicity	Under the conditions of the study, the proposed device extract was determined to be non-toxic	-	Different, product safety concern was addressed
Color		Blue (outside), White (inside)	Blue	Same
OTC use		Yes	Yes	Same
Single use		Yes	Yes	Same
Sterility		Non-sterile	Non-sterile	Same
ASTM F2100 Level		Level 3	Level 2	Different

Non-Clinical performance Data

Performance Testing summary

Test item (ASTM Level 3)	Test Standard/ method	Pass criteria	Test results	Conclusion
Bacterial filtration efficiency	ASTM F2101-19	≥ 98%	99.3%	Pass
Differential pressure (Delta-P)	ASTM F2100-19	< 6 mm H_2O/cm^2	4.40 mm H_2O/cm^2	Pass
Fluid Resistance Performance	ASTM F1862	Pass at 160 mmHg	96 out of 96 Pass at160 mmHg	Pass
Particulate Filtration Efficiency	ASTM F2299	≥ 98%	99.9%	Pass
Flammability	16 CFR 1610	Class 1 (≥ 3.5 seconds)	Test Article ignited, but extinguished or did not ignite.	Pass

Biocompatibility testing summary

According to ISO 10993-1:2009, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact are A-Limited (≦24h). The following tests for the subject device were conducted. Cytotoxicity testing conducted on the subject device revealed some evidence of potential cytotoxicity. Therefore, acute systemic toxicity was conducted to further assess biocompatibility of the subject device. Acute systemic toxicity testing revealed no evidence of the subject device causing acute systemic toxicity. In light of this finding, it is concluded that the subject device is biocompatible and safe for its intended use

Test Name	Standard followed	Result
Cytotoxicity	ISO10993-5	Under the conditions of the study, the proposed device extract demonstrated evidence of potential cytotoxicity
Skin Irritation	ISO10993-10	Under the conditions of the study, the proposed device extract was determined to be non‐irritating
Skin Sensitization	ISO10993-10	Under the conditions of the study, the proposed device extract was determined to be non‐sensitizing
Acute Toxicity	ISO10993-11	Under the conditions of the study, the proposed device extract was determined to be non-toxic

Clinical performance Data

Clinical data was not included in this submission.

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K203775, the AIC Disposable Medical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K153496