August 17, 2022

Cross Protection (M) Sdn Bhd
Grace Tan
Operations Manager
11, JLN Perindustrian5, JLN Meru
Klang, Selangor 41050
Malaysia

Re: K212273
Trade/Device Name: Cross Protection ResQ300 Plus Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 17, 2022
Received: June 17, 2022

Dear Grace Tan:

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,

Bifeng Qian M.D., 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)*
K212273

Device Name
Cross Protection ResQ300 Plus Surgical Face Mask

Indications for Use *(Describe)*
The Cross Protection ResQ300 Plus Surgical Face Masks are intended to be used as isolation face mask, procedure mask and dental face mask.

Cross Protection ResQ300 Plus Surgical Face Masks are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating personnel from transfer of micro-organisms, bodily fluids and particulate material.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY: K212273

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

I. SUBMITTER

Applicant	Cross Protection (M) Sdn Bhd		
Address	11, Jln Perindustrian 5, Batu 5 ½, Off Jln Hj Abdul Manan, 41050 Klang, Selangor, Malaysia		
Phone	603 3392 0000	**Fax**	603 3392 3867
Contact Person	Grace Tan	**Title**	Operations Manager
Date Prepared	August 12, 2022		

II. PROPOSED DEVICE AND PREDICATE DEVICE

	New Device 807.92(a)2)	**Predicate Device 807.92(a)(3)**
Proprietary Names/ 510(k) Number	ResQ300 Plus / K212273	Non-Sterile Surgical Face Mask / K051291
Manufacturer	Cross Protection (M) Sdn Bhd.	A.R. Medicom Inc.
Classification Code	FXX	FXX
Device Classification	2	2
Regulation Number	878.4040	878.4040
Panel	General and Plastic Surgery	General and Plastic Surgery
Device Classification Name	Mask, Surgical	Mask, Surgical
Common Name	Surgical Apparel	Surgical Apparel

III. DEVICE DESCRIPTION

The Cross Protection® ResQ300 Plus Surgical Facemask is a pleated, multi-ply design, which is a non-sterile, single use, disposable device. The mask covers the nose and mouth and is secured to the face using the attached ear loops or attached ties.

The outer layer is made of 100% blue spun-bond polypropylene. The middle layer is filter media composed of 100% white melt-blown polypropylene. The inner (patient contacting) layer is made of either 100% white spun-bond polypropylene or 100% white medical grade tissue paper.

The ear attachments are either Ear Loop style or Tie-On style. Ear Loops are made of elastic and the Tie-On straps are made of 100% white spun-bond polypropylene.

The nosepiece is made of malleable aluminum.

All materials used in the construction of the mask are being used in currently marketed devices.

ResQ300 Plus model numbers:

Description	Product Code
ResQ300 Plus (Tie On)	2-406TO
ResQ300 Plus (Earloop)	2-406EL

IV. INDICATIONS FOR USE

The Cross Protection ResQ300 Plus Surgical Face Mask is intended to be used as an isolation face mask, procedure mask, and dental face mask.

Cross Protection ResQ300 Plus Surgical Face Masks are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating personnel from transfer of micro-organisms, bodily fluids and particulate material.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

	Proposed Device	Predicate Device	Result
510(K) Number	**K212273**	**K051291**	
Device Name	**ResQ300 Plus Surgical Facemask**	**Non-Sterile Surgical Mask**	
Manufacturer	**Cross Protection (M) Sdn Bhd**	**A.R. Medicom Inc.**	
Classification	**Class 2**	**Class 2**	**Same**
Product Code	**FXX**	**FXX**	**Same**
Regulation No.	**878.4040**	**878.4040**	**Same**
Indications for Use	**The Cross Protection® ResQ300 Plus Surgical Facemask is intended to be used as isolation face mask, procedure mask and dental face mask. It is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating personnel from transfer of micro-organisms, body fluids and particulate material.**	**The medical/surgical masks are indicated as a protective nose and mouth covering for health care workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism, body fluid, and particulate aerosol transfer.**	**Similar**

	Proposed Device	Predicate Device	Result
Over-the-Counter Use	Yes	Yes	Same
Sterile	No	No	Same
Single-Use	Yes	Yes	Same
Dimensions			
Body Length	185mm (7.0”)	175mm (6.8”)	Similar
Body Width	90.0mm (3.5”)	90.5mm (3.5”)	Similar
Ear Loop	150mm (5.9“)	165mm (6.5”)	Similar
Ear Tie	900mm (35.4”)	N/A	Different
Nose Piece Length	94mm (3.7”)	105 mm (4.1”)	Similar
Description	Pleated, 3-ply rectangular face masks with a shapeable nosepiece and two earloops (or ties) present, one on each side, in order to hold mask in place.	Shingle pleats rectangular face masks with a shapeable nosepiece and two earloops present, one on each side, in order to hold mask in place.	Similar
Inner Layer (Patient Contacting)	Spun Bond Polypropylene or medical grade tissue paper, white color	Spun Bond Polypropylene or medical grade tissue paper, white color	Same
Middle Layer (Filter Media)	Melt-blown Polypropylene, white color	Melt-blown Polypropylene, white color	Same
Outer Layer	Spun Bond Polypropylene, blue color	Spun Bond Polypropylene, blue color	Same
Nose Piece	Malleable Aluminum	Malleable Aluminum	Same
Ear Attachments			
Ear Loops	100% Flat-type Cotton and Elastic	Flat latex and fiberglass-free elastic	Similar
Ear Ties	Spun-bond Polypropylene	N/A	Different
Biocompatibility Testing			
Cytotoxicity ISO 10993-5	Not cytotoxic	Not cytotoxic	Same
Irritation ISO 10993-10	Non-irritating	Non-irritating	Same
Sensitization ISO 10993-10	Non-sensitizing	Non-sensitizing	Same
ASTM F2100 Level	1	1	Same
Performance Testing - Bench			
ASTM F2101 Bacterial Filtration Efficiency (BFE)	BFE @ 3.0 µm large Bacteria ≥ 95%	BFE @ 3.0 µm large Bacteria ≥ 95%	Same

	Proposed Device	Predicate Device	Result
EN14683 Differential Pressure (Delta P)	**ΔP < 5.0 mm of H2O/cm2**	**ΔP < 5.0 mm of H^2O/cm^2**	**Same**
ASTM F2299 Particulate Filtration Efficiency (PFE)	**PFE @ 0.1 µm large Latex particles ≥ 95%**	**PFE @ 0.1 µm large Latex particles ≥ 95%**	**Same**
ASTM F1862 Fluid Resistance (Synthetic Blood)	**Resistant @ 80mmHg**	**Resistant @ 80mmHg**	**Same**
Textile Flammability 16 CFR 1610	**Class I**	**Class I**	**Same**
Performance Testing – Animal	**None**	**Unknown**	**Unknown**
Performance Testing - Clinical	**None**	**Unknown**	**Unknown**

Substantial Equivalence Discussion:
The above comparison table shows that ResQ300 Plus Surgical Face Masks are similar in design, intended use, and function to the A.R. Medcom Surgical Face Masks. There are a few differences:

1. The ResQ300 Plus Surgical Face masks are slightly longer than the A.R. Medicom Surgical Face Masks in surface area (185mm vs 175mm), which provides better facial coverage for adult-size faces.

2. The ResQ300 Plus ear loops are slightly smaller (150mm vs 160mm) than the A.R. Medicom ear loops and provide a tighter, more secure, hold.

3. The ResQ300 Plus masks have a tie-on option that is not offered in the A.R. Medicom Surgical Face Mask, which provides comfort for people who may be uncomfortable with elastic loops on their ears.

4. The ResQ300 Plus nose piece is smaller (94mm vs 105mm), which makes fitting to the nose area more precise.

All materials used in the ResQ300 Plus Surgical Face masks are used in currently marketed devices. Biocompatibility and performance bench-testing demonstrate that the ResQ300 Plus Surgical Face Masks meet FDA requirements and that there are no new concerns of safety and effectiveness.

VI. SUMMARY OF NON-CLINICAL TESTNG

The ResQ300 Plus Surgical Face Mask was tested for biocompatibility and performance as shown in the below tables.

Biocompatibility Testing

The ResQ300 Plus Surgical Face Mask was tested according to the below ISO 10993 biocompatibility testing standards and test results show that the device presents no new safety risk when compared with the predicate device.

Test Name	Standard	Pass Criteria	Results
Cytotoxicity – MEM Elution Test	ISO 10993-5	0 – None 1 – Slight 2 – Mild	Not cytotoxic – Mild reactivity
Primary Skin Irritation Test	ISO 10993-10	Negligible: 0 to 0.4	Negligible irritant
Maximization Test for Delayed-Type Hypersensitivity in Hartley Guinea Pigs	ISO 10993-10	0 – No visible change	Non-sensitizing

Performance Testing – Bench

The ResQ300 Plus Surgical Face Mask was tested according to the below performance standards and test results show that the device presents no new safety risk when compared with the predicate device.

Test Name	Standard	Pass Criteria	Results
Bacterial Filtration Efficiency (BFE)	ASTM F2100-19 Clause 9.1, ASTM F2101-19	Level 1: ≥ 95% Level 2: ≥98 Level 3: ≥98	Level 1
Differential Pressure (Delta P), mmH20/cm^2	ASTM F2101, EN14683	Level 1: <5.0 Level 2: <6.0 Level 3: <6.0	Level 1
Sub-micron particulate filtration efficiency (PFE)	ASTM F2100-19 Clause 9.3, ASTM F2299/F2299M-03	Level 1: ≥ 95% Level 2: ≥98% Level 3: ≥98%	Level 1
Synthetic Blood Penetration Resistance (mmHg)	ASTM F1862	Level 1: 80 Level 2: 120 Level 3: 160	Level 1
Flammability	ASTM F2100-19 Clause 9.5, 16 CFR 1610	Class 1	Class 1

Animal Testing

Not applicable

VII. SUMMARY OF CLINICAL TESTING

Not applicable

VIII. CONCLUSION

The conclusions drawn from the non-clinical testing demonstrates that the Cross Protection ResQ300 Plus Surgical Face Masks are as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K051291.