November 12, 2024

Supermax Healthcare Canada - Supermax Medical
% Sajeev Joseph
Senior Director- QA, RA
Maxter Healthcare Inc
14559 County Road 48
Rosharon, Texas 77583

Re: K242502
Trade/Device Name: Aurelia Surgical Mask ASTM Level-3 (2130)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 5, 2024
Received: August 22, 2024

Dear Sajeev Joseph:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D, Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242502

Device Name
Aurelia Surgical Mask ASTM Level-3 (2130)

Indications for Use *(Describe)*
Aurelia Surgical Masks ASTM Level-3 (2130) is intended for use to minimize contamination caused by inhaled and exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids. This is a single use, disposable device and 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.

510(k) Summary

K242502

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

1.0 Submitter Information

- Company Name: **Supermax Healthcare Canada - Supermax Medical**
- Address: 1001 rue Jean-Talon bureau 100
  Saint-Bruno-de-Montarville
  Quebec, J3V 0N3, Canada
- Phone Number: +1 (866) 428 9188
- Contact: **Chiew Yi Tay**
  VP Operations, Supermax Healthcare Canada-Supermax Medical
  Cell: +1 (647) 835-3882
  Email: cytay@supermaxcanada.com

2.0 Designated Submission Correspondent

- Company Name: **Sajeev Joseph**
- Address: Maxter Healthcare Inc.14559 County Rd 48, Rosharon, Texas 77583
- Phone Number: +1 (832) 598-3858
- Contact: +1 (713) 282-1136
- Email: sajeev.joseph@maxtergloves.com

3.0 Date of Preparation: 10/28/2024

4.0 Device Information

- Trade/Device Name: Aurelia Surgical Mask ASTM Level 3
- Model(s): 2130
- Common Name: Surgical Mask
- 510(k) Number: K242502

5.0 Classification

- Device: Surgical Face Mask
- Regulation Description: 21 CFR878.4040
- Review Panel: General Hospital
- Product Code: FXX
- Submission Type: Traditional 510(k)
- Regulation Number: 21 CFR §878.4040
- Device Class: Class II

6.0 Predicate Device Information

- Device Name: Crosstex® Surgical Masks
- 510(k) Number: K082258
- Manufacturer: Crosstex International Inc.

7.0 Device Description

The Aurelia Surgical Masks ASTM Level 3 are constructed with three layers of nonwoven polypropylene. The direct body contact materials include polypropylene, polyurethane, and nylon. The indirect body contacting materials include polypropylene and aluminum wire coated with melt-blown polypropylene embedded within the three layers.

8.0 Indications for Use

Aurelia Surgical Masks ASTM Level 3 are intended to minimize contamination caused by inhaled and exhaled microorganisms and reduce the wearer's potential exposure to blood and body fluids. This is a single- use, disposable device that is provided non-sterile.

9.0 Comparison of Characteristics of Proposed and Predicate Devices

General Comparison			
Particulars	**Proposed Device-K242502**	**Predicate K082258**	**Conclusion**
Material: Ear loops	A mixture of Nylon & Polyurethane	Not available	Unknown
Material: Nose clip	3mm Aluminum Flat Wire	Aluminum	Same
Material: Mask body (inner & outer)	Spunbonded Polypropylene	Spunbonded Polypropylene	Same
Material: Middle layer	Melt-blown Polypropylene	Melt-blown Polypropylene	Same
Color	White for the contact surface	White and various colors	Similar
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single-Use	Single-Use	Same
R_x Only or OTC	OTC	OTC	Same

Technological Comparison			
Particulars	**Proposed Device K242502**	**Predicate K082258**	**Conclusion**
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication For Use	Aurelia Surgical Masks ASTM Level 3 are intended for use to minimize contamination caused by inhaled and exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids. This is a single-use, disposable device and is provided non-sterile.	Crosstex® Surgical Masks are intended for use in infection control practices to minimize contamination caused by inhaled and exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids.	Same
Design Feature	Ear Loop	Ear Loop	Same
Dimensions	17.5 cm x 9.5 cm	Not Available	Unknown
Level	III	III	Same
Fluid Resistance, minimum	160mmHg	160mmHg	Same
Particulate Filtration Efficiency (PFE)	99%	98%	Similar
Bacterial Filtration Efficiency (BFE)	99%	98%	Similar
Differential pressure (Delta P)	5.5 mm H_2O/cm^2	<6.0 mm H2O/cm^2	Similar
Flammability	Class 1	Class 1	Same
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Biocompatibility Comparison			
Particulars	**Proposed Device K242502**	**Predicate K082258**	**Conclusion**
Cytotoxicity **ISO 10993-5**	Under the condition of this study, the device non cytotoxic	Details not available	Proposed device is found safe to use
Irritation **ISO 10993-10**	Under the condition of this study, the device non Irritant	Details not available	Proposed device is found safe to use
Skin Sensitization **ISO 10993-10**	Under the condition of this study, the device non Sensitizer	Details not available	Proposed device is found safe to use

10.0 Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- **ASTM F2100-23** Standard Specification for Performance of Materials Used in Medical Face Masks.
- **ASTM F2101-19** Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.
- **ASTM F2299/F2299M-03(2017)** Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres.
- **ASTM F1862/F1862M-17** Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity).
- **EN 14683:2019**, **Annex C** Method for determination of breathability (differential pressure).
- **16 CFR Part 1610** Standard for Flammability of Clothing Textiles.
- **ISO 10993-5:2009** Biological evaluation of medical devices - **Part 5:** Tests for in vitro cytotoxicity.
- **ISO 10993-10:2010** Biological Evaluation of Medical Devices - **Part 10:** Tests for Irritation and Skin Sensitization.

Summary of non-clinical performance testing			
Test Method	**Purpose**	**Acceptance Criteria**	**Results**
ASTM F2101-19	Bacterial Filtration Efficiency	≥ 98%	99% Pass
ASTM F2299/F2299 M-03(2017)	Sub-micron Particulate Filtration Efficiency	≥ 98%	99% Pass
EN 14683:2019, Annex C	Differential Pressure, H_2O/cm^2	<6 H_2O/cm^2	5.5 H_2O/cm^2, Pass
ASTM F1862/F1862M-17	Resistance to penetration by synthetic blood, min pressure in mm Hg for pass	160 mmHg	160 mmHg, Pass
16 CFR Part 1610	Flame Spread	Class 1	Class 1, Pass
ISO 10993-5	Cytotoxicity	Non-toxic	Under the conditions of the study, the device extract is non-cytotoxic/ Pass
ISO 10993-10	Irritation	Non-irritating	Under the conditions of the study, not an irritant. / Pass
ISO 10993-10	Sensitization	Non-sensitizing	Under the conditions of the study, not a sensitizer. / Pass

11.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

12.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device **Aurelia Surgical Masks ASTM Level 3** is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K082258.