December 5, 2023

Supermax Healthcare Canada-Supermax Medical
℅ Alicja Wojewnik
CEO
dicentra, Inc.
7 St Thomas Street, Unit 603
Toronto, Ontario M5S 2B7
Canada

Re: K231005
Trade/Device Name: Aurelia Surgical Mask ASTM Level 1; Aurelia Surgical Mask ASTM Level 2
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 1, 2023
Received: November 1, 2023

Dear Alicja Wojewnik:

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.

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
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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)*
K231005

Device Name
Aurelia Surgical Mask ASTM Level 1; Aurelia Surgical Mask ASTM Level 2

Indications for Use *(Describe)*
The Aurelia Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Aurelia Surgical Mask is 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

Aurelia Surgical Mask

Applicant

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Summary Date	October 20, 2023
Proprietary Name	Aurelia Surgical Mask ASTM Level 1; Aurelia Surgical Mask ASTM Level 2
Common Name	Surgical Mask
Classification Regulation	21 CFR 878.4040.
Product Codes	FXX
Device Classification	Class II
Predicate Device	a. Crosstex® Isofluid® Earloop Face Mask **(K082258) Primary Predicate** b. Crosstex® Procedural Earloop Face Mask **(K082258)**

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Indications for Use

The Aurelia Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Aurelia Surgical Mask is 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.

Device Description

The proposed device, Aurelia Surgical Masks are three-layer masks constructed of nonwoven polypropylene. The inner and outer layers are made of spun-bonded polypropylene. The middle layer consists of 25gsm melt-blown polypyrene. The mask contains an ear loop to secure the mask over the users' mouth and face and includes a nosepiece to provide a firm fit over the nose. Ear loops are made of polyurethane and nylon. The nose clip which is made of 3mm aluminum flat wire. The disposable surgical face mask is available in two different specifications: ASTM Level 1 and ASTM Level 2.
The masks meet the following ASTM 1 and ASTM 2 Technical standards.

Table 1: ASTM Standards

Test	ASTM 1	ASTM 2
Fluid Resistance	80mmHg	120mmHg
Bacterial Filtration Efficiency	≥95%	≥98%
Particulate Filtration Efficiency	≥95%	≥98%
Differential Pressure	<5.0 mm H2O/cm²	<6.0 mm 2O/cm²
Flammability	Class 1	Class 1

The device is single use and provided non-sterile. Both masks are blue in color and have the following dimensions: Length: 17.5 cm, Height: 9.5 cm, Ear loop Length: 15.2 cm, Nosepiece: 11.5 cm

Table 2: Material Information

Raw Material	Product Details	Supplier	Chemical Composition	Colorant
Inner Layer	White 25 gsm Spunbonded non-woven fabric	Anhui Medysen Import & Export Co., LTD	Polypropylene CAS:9003-07-0	N/A
Middle Layer	White 25 gsm Melt-Blown non-woven fabric	Anhui Medysen Import & Export Co., LTD	Polypropylene CAS:9003-07-0 Irganox CAS:6683-19-8	N/A
Outer Layer	Blue 25 gsm Spun-bonded nonwoven fabric	Anhui Medysen Import & Export Co., LTD	Polypropylene CAS:9003-07-0	Phthalocyanine blue CAS:147-14-8
Nose Piece	3mm Aluminum Flat Wire Nose Strip	Anhui Medysen Import & Export Co., LTD	Aluminum CAS:7429-90-5	N/A
Ear Loops	White 4MM Elastic Ear Loop	Anhui Medysen Import & Export Co., LTD	Nylon CAS:32131-17-2 Polyurethane CAS:51852-81-4	N/A

Table 3: Comparison to Predicate Device (LV1)

Comparison to Predicate Device	Predicate Device: Crosstex® Isofluid® Earloop Face Mask (K082258)	Candidate Device: Aurelia Surgical Mask Lv. 1	Conclusion
Product Code	FXX	FXX	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Fluid Resistance	80mmHg	80mmHg	Same
Particulate Filtration Efficiency	95%	99.5%	Different
Bacterial Filtration Efficiency	95%	99.7%	Different

Differential Pressure	<4.0 mm H2O/cm²	4.5 mm H2O/cm²	Different
Flammability	Class 1	Class 1	Same
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No Sensitization	No Sensitization	Same
Irritation	No Irritation	No Irritation	Same

Table 4: Comparison to Predicate Device (LV2)

Comparison to Predicate Device	Predicate Device: Crosstex® Procedural Earloop Face Mask (K082258)	Candidate Device: Aurelia Surgical Mask Lv. 2	Conclusion
Product Code	FXX	FXX	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Fluid Resistance	120mmHg	120mmHg	Same
Particulate Filtration Efficiency	98%	99.6%	Different
Bacterial Filtration Efficiency	98%	99.8%	Different
Differential Pressure	<5.0 mm H2O/cm²	4.1 mm H2O/cm²	Different
Flammability	Class 1	Class 1	Same
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No Sensitization	No Sensitization	Same
Irritation	No Irritation	No Irritation	Same

Performance Testing Summary

Non-clinical performance tests and Biocompatibility were conducted to verify that the Aurelia Surgical Masks met or exceeded all the design specifications as the predicate device K082258.The results were indicated in the Predicate Comparison Section above and restated below.

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Table 5: Summary of Performance Testing

Test	Purpose	Acceptance Criteria per ASTM F2100-19	Results
Fluid Resistance (ASTM F1862)	FXX This test is performed to Evaluate Personal Protective Equipment against fluid penetration. An arterial spray is simulated to test the PPE.	Level1: 80mmHg	Aurelia Mask Level 1: 80mmHg
		Level 2: 120mmHg	Aurelia Mask Level 2: 120 mmHg
Differential Pressure (Delta-P) (ASTM F2100-19 EN 14683:2019)	The purpose of this test is to ensure the drop in pressure is not too great so the user may breathe through the subject device.	Level1: < 5.0 mm H2O/cm	Aurelia Mask Level 1: < 4.5 mm H2O/cm²
		Level 2: < 6.0 mm H2O/cm²	Aurelia Mask Level 2: < 4.1 mm H2O/cm²
Bacterial Filtration Efficiency (BFE) (ASTM F2101)	The BFE test is performed to determine the bacterial filtration efficiency of test articles.	Level1: ≥ 95%	Aurelia Mask Level 1: ≥ 99.7%
		Level 2: ≥ 98%	Aurelia Mask Level 2: ≥ 99.7%
Particulate Filtration Efficiency (PFE) (ASTM F2299)	The PFE test is performed to evaluate the non-viable particle filtration efficiency of the test article.	Level1: ≥ 95%	Aurelia Mask Level 1: ≥ 99.5%
		Level 2: ≥ 98%	Aurelia Mask Level 2: ≥ 99.6%
Flammability (16 CFR 1610)	The purpose of this test is to ensure the subject device does not ignite when exposed to flame.	Level1: Class 1	Aurelia Mask Level 1: Class 1
		Level 2: Class 1	Aurelia Mask Level 2: Class 1
Biocompatibility	**Test Method/ Standard**	**Accaptance Criteria**	**Results**
Cytotoxicity	ISO 10993-5	Non- Cytotoxicity	Pass
Sensitization	ISO 10993-10	Non- Sensitization	Pass
Irritation	ISO 10993-10	Non- Irritating	Pass

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Shelf-Life

The proposed shelf life for the Aurelia Surgical masks is 5 years. An accelerated aging test was performed to support this claim and a real time aging study has been underway since December 2021.

The Accelerated Aging Test was initiated on 10th January 2022 and completed on 16th September 2022. The test was conducted in compliance with USFDA regulations (21 CFR Parts 58, 210, 211, and 820). 60 boxes/samples were subjected to an incubation temperature of 50°C ± 20°C for 229 days (5 years simulated shelf life)
The test report does not specify any failures of the packaging or loss of sterile integrity after the accelerated aging. Therefore, the results indicate the packaging, maintained integrity and sterile barrier properties up to 5 years of simulated shelf life under the test conditions.

Conclusion

The Aurelia Surgical masks are substantially equivalent to the predicate device [K082258]. The design and technological characteristics of the devices are the same and the proposed device meets or exceeds the efficacy and safety tests results of the predicate device.