September 3, 2021

Altor Safety LLC
% Dallas Thomas
Medical Device Regulatory Consultant
Thomas Regulatory Resolutions, Inc.
1069 Piccadilly St.
Palm Beach Gardens, Florida 33418

Re: K211762
Trade/Device Name: Altor Safety 4-Ply Surgical Mask (Model: 62232)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 2, 2021
Received: June 8, 2021

Dear Dallas Thomas:

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

510(k) Number *(if known)*
K211762

Device Name
Altor Safety 4-Ply Surgical Mask (Model: 62232)

Indications for Use *(Describe)*
The Altor Safety 4-Ply Surgical Mask is intended to be worn to protect both the patient and healthcare professional from transfer of microorganisms, body fluids, and particulate material. The Altor Safety 4-Ply 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, non- sterile, disposable device.

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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510(k) Summary

K211762

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

5.1 General Information

Preparation Date: 2 August 2021

Submitter/Holder

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Primary Submission Contact

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5.2 Regulatory Information

Subject Device

Subject Device Name	Altor Safety 4-Ply Surgical Mask (Model:62232)
Classification Names	Surgical apparel.
Device Classification	II
Common Name	Altor Safety 4-Ply Surgical Mask
FDA Product Code	FXX

CFR References	21 CFR 878.4040
Review Panel	General Hospital

Identification of Predicate Device:

Predicate Device Name	K192374
Classification Names	Surgical apparel.
Device Classification	II
Common Name	Cardinal Health™ Level 3 Surgical Mask
FDA Product Code	FXX
CFR References	21 CFR 878.4040
Review Panel	General Hospital

5.3 Subject Device Description

The Altor Safety 4-Ply Surgical Mask is a flat-pleated mask with ear loops and nose piece for fitting and securing the mask to the to the user's face. The mask outward facing layer is blue in color, using color master batch.
The device is manufactured with 4 layers: 2-Outer Facing Layers: Spunbond nonwoven polypropylene (Blue), Middle Layer: Melt Blown nonwoven polypropylene (White) and Inner Layer: Spunbond nonwoven polypropylene (White). Other Materials used include the Ear loops which are made from Spandex / Nylon. The subject device is provided non-sterile and is a single use, disposable device.

5.4 Subject Device Specification

Design specifications:

- Size/Dimensions:

Mask Dimensions-Width	3.625in (92 mm)

Mask Dimensions-Length	6.75-7.00in (171.45 mm-177.8mm)
Ear Loops Dimensions	Length: 7 inches per each individual ear loop

- ASTM Level 3
- Product model number: 62232
- Materials of subject device are as listed below.

2 Outer Facing Layers (Blue)	Spunbond nonwoven polypropylene
Outer Layer (Blue)	Spunbond nonwoven polypropylene
Middle Layer (White)	Melt blown nonwoven polypropylene
Inner Layer (White)	Spunbond nonwoven polypropylene
Nose Wire	Virgin polyethylene plastic, 24 gauge soft annealed carbon steel, and kraft paper (nominal basis weight of 25 lbs. /ream)
Ear Band / Loop	Spandex / Nylon

5.5 Indications for Use

The Altor Safety 4-Ply Surgical Mask is intended to be worn to protect both the patient and healthcare professional from transfer of microorganisms, body fluids, and particulate material. The Altor Safety 4-Ply 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, non-sterile, disposable device.

5.6 Summary of Technological Characteristics

Table 1. Summary Comparison of Characteristics

Device Characteristic	**Proposed Subject Device**	**Primary Predicate Device**	**Comparison Analysis:**
Product Name	**Altor Safety 4-Ply Surgical Mask**	**Cardinal Health™ Level 3 Surgical Mask With Anti-Fog Foam Strip**	Different
Manufacturer	Altor Safety	Cardinal Health 200, LLC	Different
FDA Product Code	FXX	FXX	Same
CFR Reference	878.4040	878.4040	Same
Device Class	II	II	Same
510(k) reference	k211762	K192374	N/A
			Similar,
Indications for use statement	The Altor Safety 4-Ply Surgical Mask is intended to be worn to protect both the patient and healthcare	The Cardinal Health™ Level 3 surgical masks with Anti-Fog Foam Strip are intended to be worn by operating	Similar, minor wording differences do not impact safety or efficacy.

Device Characteristic	**Proposed Subject Device**	**Primary Predicate Device**	**Comparison Analysis:**
	professional from transfer of microorganisms, body fluids, and particulate material. The Altor Safety 4-Ply 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, non-sterile, disposable device.	room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates. The Cardinal Health™ Level 3 surgical masks are single use, disposable devices provided non-sterile.	
Device Generic Raw Materials	2 Outer Facing Layers: Spunbond nonwoven polypropylene Middle Layer: Melt Blown nonwoven polypropylene filter Inner facing layer: Spunbond nonwoven polypropylene Ear loop: Spandex / Nylon	Spunbond Polypropylene Melt Blown Polypropylene Filter Ear loop: Spandex / Nylon Nose Wire –plastic,	Similar materials based on publicly available details

Device Characteristic	**Proposed Subject Device**	**Primary Predicate Device**	**<u>Comparison Analysis:</u>**
	Nose Wire – Virgin polyethylene plastic, 24 gauge soft annealed carbon steel, and kraft paper (nominal basis weight of 25 lbs. /ream)		
Color (outward facing Layer)	Blue	White	Different -
Patient Anatomical Site for Use of Device	Nose and Mouth	Nose and Mouth	Same
Mode of Operation	Protective Mask	Protective Mask	Same
Reusable or Single Use	Single Use	Single Use	Same
Sold Sterile or Non-Sterile	Non-Sterile	Non-Sterile	Same
Prescription Status	OTC	OTC	Same
Fluid Resistance Performance ASTM F1862-13	32 out of 32 pass at 160mmHg	31 out of 32 pass at 120mmHg	Similar
Particulate Filtration Efficiency ASTM F2299	≥99%	≥98%	Similar

Altor Safety 4-Ply Surgical Mask

Device Characteristic	**Proposed Subject Device**	**Primary Predicate Device**	**Comparison Analysis:**
Bacterial Filtration Efficiency ASTM F2101	99.60%	≥ 98%	Similar-
Differential Pressure (Delta P) EN 14683	3.5mmH 2 O/cm 2 (The average of 3 lots with means of 4.2,3.2 and 3.1))	< 5.0 mm H 2 O/cm 2	Similar
Flammability 16 CFR 1610	Class 1	Class 1	Same
Cytotoxicity	Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Same
Irritation	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-irritating.	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-irritating.	Same
Sensitization	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-sensitizing.	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-sensitizing.	Same

Device Characteristic	Proposed Subject Device	Primary Predicate Device	Comparison Analysis:
Dimensions-Width	3.625in (92 mm)	4in	Similar
Dimensions-Length	6.75-7.00in (171.45 mm-177.8mm)	7 in	Similar -
ASTM F2100 Level	Level 3	Level 3	Same

5.7 Summary of Non-Clinical Performance Testing

Test Method	Purpose	Pass Criteria	Results
ASTM F2101-19Standard Test Method for Evaluating the Bacterial Filtration	The purpose of the test is to evaluate the Bacterial filtration efficiency (BFE) (%)	≥98%	3 lots tested with total 96 samples, 94/96 Passed at ≥98% /Pass
EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019	The purpose of the test is to evaluate the Different pressure (Delta-P)	<6.0 mmH_2O/cm^2	3 lots tested with total 96 samples, 92/96 Passed <6 $mmH2O/cm^2$ / Pass
ASTM F2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres according to ASTMF2100:2019	The purpose of the test is to evaluate the Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	≥98%	3 lots tested with total 96 samples, 96/96 Passed at ≥98% / Pass

ASTM 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) according to ASTMF2100:2019for pass result	The purpose of the test is to evaluate the Resistance to penetration by synthetic blood, Minimum pressure in mmHg	Fluid resistant claimed at 160 mm Hg	3 lots tested with total 96 samples, 95 of 96 test articles passed at 160mmHg /Pass
16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	The purpose of the test is to evaluate the Flame spread	Class 1	3 lots tested with total 96 samples, 96/96 Passed ≥3 seconds burn Time-Class 1 / Pass

- Biocompatibility Testing 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 is A-Limited (≤24h). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use: per ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity,
  1) Skin Sensitization Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization,
  2) Skin Irritation Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization.

5.8 Summary of Clinical Performance Testing

No clinical study is included in this submission

5.9 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K211762, the Altor Safety 4-Ply Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device, cleared under K192374.