July 23, 2021

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

Re: K211249
Trade/Device Name: Altor Safety 3-Ply Surgical Mask (Model:62222)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX,
Dated: April 21, 2021
Received: April 26, 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); 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,

Clarence W. Murray, III, PhD
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)*
K211249

Device Name
Altor Safety 3-Ply Surgical Mask (Model:62222)

Indications for Use *(Describe)*
The Altor Safety 3-Ply Surgical Mask (Model:62222) 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 3-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
# K211249

## 5.1 General Information

Preparation Date: 23 July 2021

**Submitter/Holder**

Jared Scott

Altor Safety LLC

711 Executive Boulevard Suite C, Valley Cottage, NY, USA 10989

Contact Phone#: +1 845-422-8320

Contact Email:jared.scott@altorsafety.com

**Primary Submission Contact**

**Dallas L. Thomas, RAC, MHA, MPA, SSYB**
**Medical Device Regulatory Consultant**
Thomas Regulatory Resolutions, Inc.
**1069 Piccadilly St. Palm Beach Gardens, FL 33418**
**Mobile** +1 801 556 6809
**Email: dallas@thomasregulatory.com**

## 5.2 Regulatory Information

| | |
|---|---|
| Subject Device Name | Altor Safety 3-Ply Surgical Mask (Model:62222) |
| Classification Names | Surgical apparel. |
| Device Classification | II |
| Common Name | Altor Safety 3-Ply Surgical Mask |
| FDA Product Code | FXX |
| CFR References | 21 CFR 878.4040 |
| Review Panel | General Hospital |

### 5.3 Identification of Predicate Device

The predicate device for this submission has been identified as the Disposable Surgical Mask K202463.

### 5.4 Subject Device Description

The Altor Safety 3-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 product model number of the subject device is : **62222**

The ASTM Level of the subject device is **ASTM Level 2**

The subject device is manufactured with three layers:

Outer Layer: Spunbond nonwoven polypropylene

Middle Layer: Melt Blown nonwoven polypropylene

Inner Layer: Spunbond nonwoven polypropylene

The subject device is provided non-sterile and is a single use, disposable device.

A visual representation of the device can be found in the following figure.

**Figure 1: Altor Safety 3-Ply Surgical Mask Product Image**


### 5.5 Subject Device Specification

Design specifications:

- Size/Dimensions:

| | |
|---|---|
| Dimensions-Width | 3.625in (92 mm) |
| Dimensions-Length | 6.75-7.00in (171.45 mm-177.8mm ) |

- Materials of subject device are as listed below.

| | |
|---|---|
| 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 | Spandex |

### 5.6 Indications for Use

Per the current proposed product labeling, the indications for use for the Altor Safety 3-Ply Surgical Mask (Model:62222) are quoted as follows:

***The Altor Safety 3-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 3-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.***

Please note that the above indication is slightly reworded compared to the already cleared indications for the predicate Disposable Surgical Mask K202463 and updated accordingly per current FDA Guidance. The indications for use statement also provides further clarification that is complementary to the cleared predicate indications for use.

### 5.7 Technological Characteristics Comparison

Below is a summary table of the technological characteristics comparison between the subject and predicate devices.

**Table 1.Technological Characteristics Comparison Table**

| **Device Characteristic** | **Proposed Subject Device** | **Primary Predicate Device** | **Comparison Analysis:** *Identical / Same / Similar /* |
|---|---|---|---|
| Product Name | **Altor Safety 3 Ply Surgical Mask** | **Disposable Surgical Mask** | Different |
| Manufacturer | Altor Safety | Unisources Group LLC | Different |
| FDA Product Code | FXX | FXX | Identical |
| CFR Reference | 878.4040 | 878.4040 | Identical |
| Device Class | II | II | Identical |
| 510(k) reference | K211249 | K202463 | Different |
| Implanted Device | No | No | Identical |
| Intended Use | The Altor Safety 3-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 3-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. | The Disposable Surgical Mask, FILTECH M201 is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material.<br><br>The Disposable 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(s), provided non-sterile. | Same |

| **Device Characteristic** | **Proposed Subject Device** | **Primary Predicate Device** | **Comparison Analysis:** *Identical / Same / Similar /* |
|---|---|---|---|
| Indications for use statement | The Altor Safety 3-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 3-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. | The Disposable Surgical Mask, FILTECH M201 is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. The disposable 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(s), provided non-sterile. | Same |
| Device Generic Raw Materials | Outer Facing Layer: Spunbond nonwoven polypropylene<br>Middle Layer: Melt Blown nonwoven polypropylene filter<br>Inner facing layer: Spunbond nonwoven polypropylene<br>Ear loop: Spandex | Outer Facing Layer: Spunbond polypropylene<br>Middle Layer: Melt Blown polypropylene filter<br>Inner facing layer: Spunbond polypropylene<br>Ear loop: Spandex | Similar |
| ASTM Level | Level 2 | Level 2 | Same |
| Color (outward facing Layer) | Blue | Blue | Similar |
| Color (middle Layer) | White | Not-publicly Available | Different |
| Color (inward facing Layer) | White | Not-publicly Available | Different |

| **Device Characteristic** | **Proposed Subject Device** | **Primary Predicate Device** | **Comparison Analysis:** *Identical / Same / Similar /* |
|---|---|---|---|
| Colorant(s) | Submitted Independently to FDA by supplier as this was considered proprietary information. | Not-publicly Available | Different |
| Patient Anatomical Site for Use of Device | Nose and Mouth | Nose and Mouth | Identical |
| Mode of Operation | Protective Mask | Protective Mask | Identical |
| Reusable or Single Use | Single Use | Single Use | Identical |
| Sold Sterile or Non-Sterile | Non-Sterile | Non-Sterile | Identical |
| Prescription Status | OTC | OTC | Identical |
| Fluid Resistance Performance ASTM F1862-13 | Lot 1:31 out of 32 pass at 120mmHg<br><br>Lot 2:32 out of 32 pass at 120mmHg<br><br>Lot 3: 32 out of 32 pass at 120mmHg | 32 out of 32 pass at 120mmHg | Similar |
| Particulate Filtration Efficiency ASTM F2299 | Lot 1 : ≥99%<br><br>Lot 2: ≥99%<br><br>Lot 3: ≥99% | ≥98% | Similar |
| Bacterial Filtration Efficiency ASTM F2101 | Lot 1: 99.60%<br><br>Lot 2: 99.80%<br><br>Lot 3: 99.75% | 99.60% | Similar |
| Differential Pressure (Delta P) EN 14683 | 2.6mmH 2 O/cm 2 (2 lots have an average of 2.7) | 5.5mmH 2 O/cm 2 | Similar |

| | | | |
|---|---|---|---|
| Flammability 16 CFR 1610 | Class 1 | Class 1 | Identical |
| Cytotoxicity | Under the conditions of the study, the proposed device extract was | Under the conditions of the study, the proposed device extract was | Similar |

| **Device Characteristic** | **Proposed Subject Device** | **Primary Predicate Device** | **Comparison Analysis:** *Identical / Same / Similar /* |
|---|---|---|---|
| | determined to be non-cytotoxic. | determined to be non-cytotoxic. | |
| 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. | Similar |
| 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. | Similar |
| Dimensions-Width | 3.625in (92 mm) | 95mm±5mm | Similar |
| Dimensions-Length | 6.75-7.00in (171.45 mm-177.8mm ) | 175mm±5mm | Similar |
| ASTM F2100 Level | Level 2 | Level 2 | Identical |

### 5.8 Sterilization and Shelf Life

Sterilization and Shelf Life are not applicable to the Altor Safety 3-Ply Surgical Mask subject device. The device is provided non-sterile and there is no claimed shelf life.

### 5.9 Biocompatibility

Biocompatibility tests of Altor Safety 3-Ply Surgical Mask have been performed on

representative finished, sterilized devices as outlined in **Table 2**.

**Table 2. Biocompatibility Summary & Standards Applied**

| Test Method/ Standard | Purpose | Acceptance Criteria | Results |
|---|---|---|---|
| ISO 10993-5:2009 | Cytotoxicity | For the test to be valid, the reagent control and the negative control must have had a reactivity of none (grade 0) and the positive control must have been a grade 3 or 4. Percent rounding and percent cells without intracytoplasmic granules are not evaluated in the event of 100% lysis. The test article met the requirements of the test if the biological response was less than or equal to grade 2 (mild). The test would have been repeated if the controls did not perform as anticipated. | No cytotoxicity or cell lysis was noted in any of the test wells. No pH shift was observed at 48 hours. The reagent control, negative control and the positive control performed as anticipated. |
| ISO 10993-10:2010 | Sensitization | The responses from the challenge phase were compared within the test animal group and between test and control conditions. In the final analysis of data, consideration was given to the overall pattern, intensity, duration and character of reactions of the test as compared to the control conditions. The control conditions are (1) the control vehicle on the test animals, (2) the test on the control animals, and (3) the control vehicle on the control animals. Statistical manipulation of data was not applicable to this study. Grades of 1 or greater observed in the test group generally indicated sensitization, provided that grades of less than 1 were observed on the control animals. If grades of 1 or greater were noted on control animals, then the reactions of test animals that exceeded the most severe control reaction were considered to be due to sensitization. | Unless otherwise indicated, all animals were observed with the expected dermal reactions associated with intradermal injection of FCA and were clinically normal throughout the study.<br><br>No evidence of sensitization was observed. |
| ISO 10993-10:2010 | Sensitization | The responses from the challenge phase were compared within the test animal group and between test and control conditions. In the final analysis of data, consideration was given to the overall pattern, intensity, duration and character of reactions of the test as compared to the control conditions. The control conditions are (1) the control vehicle on the test animals, (2) the test on the control animals, and (3) the control vehicle on the control animals. Statistical manipulation of data was not applicable to this study. Grades of 1 or greater observed in the test group generally indicated sensitization, provided that grades of less than 1 were observed on the control animals. If grades of 1 or greater were noted on control animals, then the reactions of test animals that exceeded | Unless otherwise indicated, all animals were observed with the expected dermal reactions associated with intradermal injection of FCA and were clinically normal throughout the study.<br><br>No evidence of sensitization was observed. |

| Test Method/ Standard | Purpose | Acceptance Criteria | Results |
|---|---|---|---|
| | | the most severe control reaction were considered to be due to sensitization. | |
| ISO 10993-10:2010 | Irritation | The erythema and edema site scores for the test article and control extracts for each animal at each scoring interval were calculated by adding the erythema and edema scores together. The mean score of each individual animal (test and control) was calculated by totaling all of the individual site scores for each animal and dividing by 15 (3 scoring time points x 5 test or control sites). The overall mean for each test article extract and control extract was calculated by adding the mean score for all three animals together and dividing by 3. The difference between the overall mean score of the test article extract and corresponding control extract was calculated by subtracting the overall mean score for the control extract from the overall mean score for the test article extract. If the overall mean score of the test article extract was less than the overall mean score of the corresponding control extract, 0.0 was reported. The requirements of the test were met if the difference between the test extract overall mean score and corresponding control overall mean score was 1.0 or less. | All animals appeared normal throughout the study.<br><br>All injection sites appeared normal immediately following injection. |
| ISO 10993-10:2010 | Irritation | No statistical analysis of the data will be performed. All erythema grades and edema grades (24, 48 and 72 hours) will be calculated separately for each test and control for each individual animal. The score of a test article or control on each individual animal will be calculated by dividing each of the totals by 15 (3 scoring time points x 5 sites). The overall mean will be determined for each test and control by adding the scores for the 3 animals and dividing by 3. The difference between the overall mean score of the test article extracts and corresponding control extracts will be calculated by subtracting the overall mean score for the control from the overall mean score for the test article extract. If the overall mean score of the test article extracts is less than the overall mean score of the corresponding control extracts, 0.0 will be recorded for the overall mean difference between test and control. If at any observation period the average reaction to the test article extract is questionably greater than the average reaction to the control, the test will be repeated using three additional rabbits. The requirements of the test are met if the difference between the test article extract | All animals appeared normal throughout the study.<br><br>All injection sites appeared normal immediately following injection. |

| Test Method/ Standard | Purpose | Acceptance Criteria | Results |
|---|---|---|---|
| | | overall mean score and the corresponding control overall mean score is 1.0 or less. Ischemia or necrosis present at the majority of the test sites of all animals for any scoring interval will be considered as significant regardless of the calculated result. The test article may fail if either of these findings are observed at the majority of the test sites of all animals. If the SC control sites on any animal exhibits a score 22, or if the SO control sites exhibits a score 23, the rabbit will be replaced exhibiting the reaction. The replacement animal will be injected with the appropriate test article extract and control using fresh preparations. | |

### 5.10 Performance Testing - Bench

Performance bench tests of Altor Safety 3-Ply Surgical Mask have been performed, see **Table 3**. The results from the performance bench testing demonstrate that Altor Safety 3-Ply Surgical Mask has met the acceptance criteria of the standard

**Table 3. Performance Testing Summary And Standards Applied**

| Test Method / Standard | Purpose | Acceptance Criteria | Results |
|---|---|---|---|
| Bacterial Filtration Efficiency (BFE) ASTM F2101-19 | Bacterial Filtration | As per Bacterial Filtration Efficiency (BFE) ASTM F2101-19 | Lot 1-99.60% BFE<br>Lot 2-99.80% BFE<br>Lot 3-99.75% BFE |
| Differential Pressure (Delta P) EN 14683:2019 | Breathability | As per Differential Pressure (Delta P) EN 14683:2019 | 2.6mmH 2 O/cm 2 (2 lots have an average of 2.7) |
| Synthetic Blood Penetration Resistance ASTM F1862 ISO 22609 | Fluid Resistance | As Per Synthetic Blood Penetration Resistance ASTM F1862 ISO 22609 | Lot 1:31 out of 32 pass at 120mmHg<br><br>Lot 2:32 out of 32 pass at 120mmHg<br><br>Lot 3: 32 out of 32 |

| Test Method / Standard | Purpose | Acceptance Criteria | Results |
|---|---|---|---|
| | | | pass at 120mmHg |
| Latex Particle Challenge ASTM F2299 | Penetration by Particulates | As Per Latex Particle Challenge ASTM F2299 | Lot 1 : ≥99%<br>Lot 2: ≥99%<br>Lot 3: ≥99% |
| Flammability of Clothing Textiles per 16 CFR Part 1610 | Flammability | As Per Flammability of Clothing Textiles per 16 CFR Part 1610 | Class I Flammability Rating |

### 5.11 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Altor Safety 3-Ply Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed device