January 26, 2022

Armbrust Inc.
Landon Morales
President
Armbrust Inc, 3813 Helios Way Building B, Suite 290, Pflugerville, TX 78660 USA.
3813 Helios Way Building B, Suite 290
Pflugerville, Texas 78660

Re: K210101
Trade/Device Name: Armbrust American Made Surgical Mask, model AA-US-SURGICAL-01
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 9, 2021
Received: December 21, 2021

Dear Landon Morales:

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,

Liqun Zhao -S

For 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)*
K210101

Device Name
Armbrust American Made Surgical Mask, model AA-US-SURGICAL-01

Indications for Use *(Describe)*

The Armbrust American made Surgical Mask, model AA-US-SURGICAL-01 is intended to be worn by adults to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material within a professional healthcare environment. These surgical masks are 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. For adult use.

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 – K210101

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

I. Sponsor	Armbrust Inc. 3813 Helios Way Building B, Suite 290 Pflugerville, TX 7866
II. 510(k) Contact Person:	Landon Morales President, Armbrust Inc. Email: landon@armbrustusa.com Phone: 561-809-1586 Date : January 24, 2022

III. Device

Name of the Device:	Armbrust American Made Surgical Mask, model AA-US-SURGICAL-01
Common Name:	Mask, Surgical
Classification Name:	Surgical Apparel (21 CFR §878.4040)
Device Product Code:	FXX
Regulatory Class:	Class II

IV. Predicate Device

Predicate device 510(k):	K111402
Predicate device name:	Kimberly-Clark KC200 Face Mask(s), Kimberley-Clark KC300 Face Mask(s)

This predicate device has not been subject to a design-related recall.

V. Device Description:

The USA-Made Surgical Mask, model number AA-US-SURGICAL-01, is an adult sized surgical mask with earloops that is designed to cover the user's nose and mouth and provides a physical barrier to fluids and particulate materials. The USA-Made Surgical Mask is composed of three-layers and features flat pleats. The three layers are comprised of a blue in color fluid resistant polypropylene spunbond (outer layer), electrostatically charged polypropylene meltblown layer for filtration (middle layer), and an additional fluid resistant polypropylene spunbond (inner

layer). A malleable nose wire is used in the top of the mask to achieve a proper fit for individuals. The USA-Made Surgical Mask is a single use, disposable device that is provided non-sterile. The surgical mask conforms to ASTM F2100-19, providing a level 3 barrier.

VI. Indications for Use:

The USA-Made Surgical Mask is intended to be worn by adults to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material within a professional healthcare environment. These surgical masks are 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. For adult use.

VII. Comparison of Technological Characteristics with the Predicate Device(s)

Table 1 below is a high-level comparison between the subject device, Armbrust Inc, USA-Made Surgical Mask AA-US-SURGICAL-01 (K210101) and the predicate device, Kimberly-Clark KC200 Face Mask(s), Kimberly-Clark KC300 Face Mask(s) (K111402).

Table 1 - Summary of Technological Characteristics with the Predicate Device

Feature	Subject Device USA-Made Surgical Mask, Model AA-US-SURGICAL-01	Predicate Device Kimberly-Clark, Model KC200 Face Mask(s), KC300 Face Mask(s)	Comparison of Devices
510(k) Number	K210101	K111402	N/A
Manufacturer	Armbrust Inc.	Kimberly-Clark	N/A
Indications for Use	The USA-Made Surgical Mask is intended to be worn by adults to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material within a professional healthcare environment. These surgical masks are 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. For adult use.	The Kimberly-Clark, KC200 Face Mask(s) and KC300 Face Mask(s) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The Kimberly-Clark, KC300 face mask(s) is a single use, disposable device(s), provided non-sterile.	Same

Feature	Subject Device USA-Made Surgical Mask, Model AA-US-SURGICAL-01	Predicate Device Kimberly-Clark, Model KC200 Face Mask(s), KC300 Face Mask(s)	Comparison of Devices
Design Features			
Color, outer fabric	Blue	Orange	Different
Style	Flat, pleated	Flat, pleated	Same
Layers	3	4	Different
Physical state	Single use only	Single use only	Same
Sterility	Non-sterile	Non-sterile	Same
Retention features	Elastic ear loops	Elastic ear loops or ties	Different
Materials critical to functionality	Spunbond polypropylene, Meltblown polypropylene, spunbond polypropylene, Polyester/spandex elastic (earloop), Galvanized iron coated in polypropylene	Polypropylene Spunbond, Polypropylene spunbond (4th layer addition), Polypropylene Meltblown, Polyester cellulose, Polyester Spunlace, Polyester/ Lycra Knit (earloop), Polyester spunbond (ties), malleable nosewire	Same
Dimensions			
Width	175mm ±7mm	6.5” ±0.75”	Different
Height	95mm ±7mm	4” ±0.75”	Different
Performance Specification			
ASTM F2100 Level	Level 3	Level 3	Same
Fluid Resistance (ASTM F1862)	Passed at 160 mmHg	Passed at 160 mmHg	Same
Particulate Filtration Efficiency (PFE)	Passed at >98%	Passed at >98%	Same
Bacterial Filtration Efficiency (BFE)	Passed at >98%	Passed at >98%	Same
Differential Pressure	Passed at <5mmH_2O	Passed at <5mmH_2O	Same
Flammability (16 CFR 1610)	Class 1	Class 1	Same
Biocompatibility			
Cytotoxicity	Non-cytotoxic	Non-cytotoxic	Same
Irritation	Non-irritating	Non-irritating	Same
Sensitization	Non-sensitizing	Non-sensitizing	Same

VIII Non-Clinical (Performance) Testing

For USA-Made Surgical Mask, Model AA-US-SURGICAL-01, the following table summarizes the performance testing conducted per ASTM F2100 standard:

Table 2 - Summary of Non-Clinical (Performance) Testing

Item Tested	Test Method	Purpose	Acceptance Criteria	Results
AA-US-SURGICAL-01	ASTM F1862	Fluid Resistance to Synthetic Blood	160 mmHg	No penetration at 160 mmHg
AA-US-SURGICAL-01	ASTM F2299	Particulate Filtration Efficiency	>98%	Average 99.48%
AA-US-SURGICAL-01	ASTM F2101	Bacterial Filtration Efficiency	>98%	Average 99.4%
AA-US-SURGICAL-01	ASTM F2100	Differential Pressure	<5mmH2O	Average 4.7mm H2O
AA-US-SURGICAL-01	CPSC CS-191-53 (16 CFR 1610)	Flammability	Class 1	IBE, Class 1

IBE= Ignited but extinguished

IX. Biocompatibility Testing:

The biocompatibility evaluation for the USA-Made Surgical Mask, Model AA-US-SURGICAL-01 device was conducted in accordance with the FDA's Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" September 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

Item Tested	Test Description	Test Methodology	Acceptance Criteria	Results
AA-US-SURGICAL-01	Cytotoxicity	ISO 10993-5	No signs of Toxicity	Grade 0, Non-Cytotoxic. Under the conditions of the study, the subject device extract was determined to be non-cytotoxic. PASS.
AA-US-SURGICAL-01	Intracutaneous Irritation	ISO 10993-10	Negligible signs of irritation	Non-irritant. Under the conditions of the study, the subject device non- polar and polar extracts were determined to be

				non- irritating. PASS.
AA-US-SU RGICAL-01	Maximization Sensitization	ISO 10993-10	Negligible signs of sensitization	Non-sensitizer. Under the conditions of the study, the subject device non- polar and polar extracts were determined to be non-sensitizing. PASS.

X. Summary of Clinical Performance Test

No clinical study is included in this submission.

XI. Conclusions for Substantial Equivalence:

The Armbrust Inc USA-Made Surgical Mask, Model: AA-US-SURGICAL-01 and predicate devices, Kimberly-Clark KC200 Face Mask(s), Kimberly-Clark KC300 Face Mask(s) (K111402) have the same intended use and similar technological characteristics.

The conclusions drawn from the non-clinical tests demonstrates that the subject device Armbrust Inc USA-Made Surgical Mask, Model: AA-US-SURGICAL-01 is as safe and as effective as the legally marketed predicate device.