April 11, 2023

PADM Medical Inc.
Pablo Batista
Vice President of Engineering Operations
1595 Buffalo Place – Unit A
Winnipeg, Manitoba R3T 1L9
Canada

Re: K221209
Trade/Device Name: PRECISION ECO Compostable / Plant Based Procedural Mask with Earloops
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX

Dear Pablo Batista:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 8, 2023. Specifically, FDA is updating this SE Letter for a typo in the trade name in the Indications for Use Form as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Brent Showalter, Ph.D., OHT6: Office of Orthopedic Devices, (240) 402-1840, brent.showalter@fda.hhs.gov.

Sincerely,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

March 8, 2023

PADM Medical Inc.
Pablo Batista
Vice President of Engineering and Operations
1595 Buffalo Place – Unit A
Winnipeg, Manitoba R3T 1L9
Canada

Re: K221209
Trade/Device Name: PRECISION ECO™ Compostable / Plant Based Procedural Mask with Earloops
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 12, 2023
Received: January 17, 2023

Dear Pablo Batista:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
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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)*
K221209

Device Name
PRECISION ECO™ Compostable / Plant Based Procedural Mask with Earloops

Indications for Use *(Describe)*
The PRECISION ECO™ Compostable / Plant Based Procedural Mask with Earloops is intended to be worn to protect both the patient and healthcare professional from transfer of microorganisms, body fluids, and particulate material. The PRECISION ECO™ Compostable / Plant Based Procedural Mask with Earloops 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Date of Summary Prepared:	March 3rd, 2023
510(K) Number:	K221209
Applicant:	PADM Medical Inc. Unit A - 1595 Buffalo Place Winnipeg, MB R3T 1L9 Canada
Primary Contact:	Pablo Batista Phone: +1 (204) 289 4491 x233 Email: pbatista@precisionadm.com
Device Name	PRECISION ECO™ Compostable / Plant Based Procedural Mask with Earloops
Model Number	Black: 100195 White: 100196
Device Classification Name	Mask, Surgical
Trade Name	PRECISION ECO™ Compostable Procedural Mask with Earloops PRECISION ECO™ Plant Based Procedural Mask with Earloops
Classification	Class II 21 CFR 878.4040
Regulatory Medical Specialty	General and Plastic Surgery
Product Code	FXX
Primary Predicate Device	K211762 Company Name: Altor Safety Device Name: Altor Safety 4-Ply Surgical Mask (Model: 62232)

Indications for Use

The PRECISION ECO™ Compostable / Plant Based Procedural Mask with Earloops is intended to be worn to protect both the patient and healthcare professional from transfer of microorganisms, body fluids, and particulate material. The PRECISION ECO™ Compostable / Plant Based Procedural Mask with Earloops 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.

Device Description

The PRECISION ECO™ Compostable / Plant Based Procedural Masks with Earloops are single use, ASTM Level 3 disposable devices, provided non-sterile. The mask has a four-layer, flat, pleated body with two earloops and a malleable nose piece. All components of the mask design are bonded together via ultrasonic welding, and it does not include any drugs, biologics, or nanoparticles. The mask comes in one configuration with two (2) different color schemes: black *(*100195*)*, and white *(*100196).

TABLE **/** lists all materials used in the mask.

TABLE *I*: MATERIALS

Raw Material	Product Details
Inner Layer *Applicable to both models: 100195 and 100196*	Spunbond nonwoven polylactide resin fabric
Middle Layer *Applicable to both models: 100195 and 100196*	Meltblown nonwoven polylactide resin fabric
Outer Layers (Qty 2) (White) *Applicable to white product: 100196*	Spunbond nonwoven natural polylactide resin fabric
Outer Layers (Qty 2) (Black) *Applicable to black product: 100195*	Spunbond nonwoven black polylactide resin fabric
Nose Piece *Applicable to both models: 100195 and 100196*	Aluminum
Ear Loops (White) *Applicable to white product: 100196*	Round woven polyester/spandex
Ear Loops (Black) *Applicable to black product: 100195*	Round woven polyester/spandex

The following TABLE *II* outlines a comparison of the materials used for each model number (color) of mask. As evident from the materials comparison, the only difference between each device is the colorant used in the outer layers and earloops for each model.

TABLE *II*: COMPARISON BLACK (100195) AND WHITE (100196) MODEL(S)

Raw Material	Black (100195)	White (100196)
Inner Layer	Spunbond nonwoven polylactide resin fabric	Spunbond nonwoven polylactide resin fabric
Middle Layer	Meltblown nonwoven polylactide resin fabric	Meltblown nonwoven polylactide resin fabric
Outer Layers (Quantity 2)	Spunbond nonwoven polylactide resin fabric *with colorant*	Spunbond nonwoven polylactide resin fabric
Nose Piece	Aluminum	Aluminum
Ear Loops	Round woven polyester/spandex *with colorant*	Round woven polyester/spandex

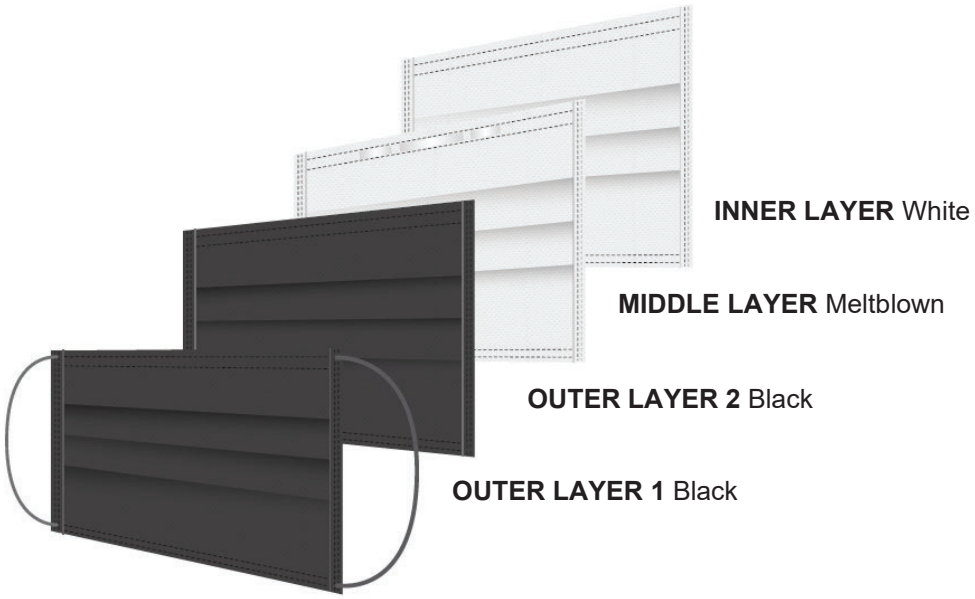

FIGURE 1: DEVICE REPRESENTATIVE ILLUSTRATION (Black product 100195)

Instructions for use for the mask are located on the box artwork and read as follows. Hold mask by ear loops with the nose clip at the top. Ensure the logo side or colored side is facing outward. Place one ear loop around each ear. Bend the nose clip to match the shape of the nose and ensure there are no gaps. While holding the nose clip at the bridge of your nose, pull the mask down under your chin. Properly dispose of the mask by touching only the ear loops

Technical Comparison to Primary Predicate Device

TABLE *III* provides a classification comparison between the PRECISION ECO™ Compostable / Plant Based Procedural Mask with Earloops and the Primary Predicate Device manufactured by Altor Safety.

TABLE *III*: CLASSIFICATION COMPARISON TO PRIMARY PREDICATE DEVICE

Characteristic	Subject Device	Primary Predicate Device	Result
Manufacturer	PADM Medical Inc.	Altor Safety	N/A
Device Name	Surgical Mask	Surgical Mask	N/A
Model	Black: 100195 White: 100196	62232	N/A
510K	Pending.	K211762	N/A
Device Class, product code, regulation #	Class II, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intended Use	The PRECISION ECO™ Compostable / Plant Based Procedural Mask with Earloops is intended to be worn to protect both the patient and healthcare professional from transfer of microorganisms, body fluids, and particulate material. The PRECISION ECO™ Compostable / Plant Based Procedural Mask with Earloops is intended for use in infection control practices to reduce	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	Same

	the potential exposure to blood and body fluids. This is a single use, non-sterile, disposable device.	a single use, non- sterile, disposable device.	

TABLE *IV* provides a comparison of materials used in the PRECISION ECO™ Compostable / Plant Based Procedural Mask with Earloops and the Primary Predicate Device manufactured by Altor Safety.

TABLE *IV*: MATERIALS COMPARISON TO PRIMARY PREDICATE DEVICE(S)

Characteristic	Subject Device	Primary Predicate Device	Result
Color	Black/White	Blue	Different
Disposable	Yes	Yes	Same
Mask Style	Flat pleated	Flat pleated	Same
Outer Layer 1 Material	Polylactide resin spunbond nonwoven fabric	Spunbond polypropylene (SBPP)	Different
Outer Layer 2 Material	Polylactide resin spunbond nonwoven fabric	Spunbond polypropylene (SBPP)	Different
Filter Layer Material	Polylactide resin meltblown nonwoven	Meltblown Polypropylene (MBPP)	Different
Inner Layer Material	Polylactide resin spunbond nonwoven fabric	Spunbond Polypropylene (SBPP)	Different
Nose Piece Material	Aluminum	Virgin polyethylene plastic 24 gauge soft annealed carbon steel, and kraft paper	Different
Earloop Material	Polyester/ spandex	Spandex/nylon	Similar
Earloop Style	Round knitted earloop	Round knitted earloop	Same
Mask Body L X W	(170mm-180mm) x (90mm-100mm)	(171.45mm-177.8mm) x (92mm)	Similar
Earloop	Yes	Yes	Similar

The difference in materials, nose piece material, and mask dimensions does not impact the safety and effectiveness of the subject device as the subject device's performance is equivalent to the Primary Predicate Device. As evident in TABLE *IV*, the base materials and configuration for each product color (black/white) are identical. The colorant is not influencing the performance of the device, due to the extremely low concentration present in the device.

The performance requirements and test criteria are listed in TABLE *V*. The performance testing was conducted on production lots and on artificially aged samples. Accelerated aging was conducted per ASTM 1980-21: Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices. The device met the acceptance criteria for both production lots and artificially aged samples.

TABLE *V*: STANDARDS AND ACCEPTANCE CRITERIA

Characteristic	Test Method	Acceptance Criteria
Bacterial filtration efficiency (BFE)	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	≥ 98%
Sub-micron particulate efficiency at 0.1 µm (PFE)	ASTM F2299: Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres	≥ 98%
Blood Penetration	ASTM F1862: Standard Test Method for Resistance of Medical Face Masks to penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	@160 mm Hg
Differential Pressure	EN 14683:2019 Annex C: Medical face masks - Requirements and test methods	< 6.0 mm H_2O/cm^2
Flammability	16 CFR Part 1610: Standard for the Flammability of Clothing Textiles	Class 1 (≥3.5 s flame spread)
Cytotoxicity	ISO10993-5: Biological evaluation of medical devices -Part 5: Tests for invitro cytotoxicity.	≤ Grade 2
Irritation	ISO10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.	Non-irritant
Sensitization	ISO10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.	Non-sensitizer

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and is substantially equivalent to the legally marketed Primary Predicate Device [K211762].