August 26, 2024

Primed Medical Products Inc.
Mitra Fard
Manager, Regulatory Affairs
200, 2003-91 St. SW
Edmonton, AB T6X0W8
Canada

Re: K240286
Trade/Device Name: PRIMED Surgical Masks and PRIMED Procedure Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 22, 2024
Received: July 25, 2024

Dear Mitra Fard:

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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240286

Device Name
PRIMED Surgical Masks and PRIMED Procedure Masks

Indications for Use *(Describe)*
PRIMED Surgical Masks and PRIMED Procedure Masks are single use, non-sterile products intended to be worn by operating room and health care personnel in health care setting and during surgical procedures to protect both the patient and the operating room personnel from transfer of microorganisms, body fluids and particulate materials.

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.

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"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."

Summary Date:	July 22, 2024
Manufacturer:	PRIMED Medical Products Inc.
Address:	200, 2003-91 St. SW, Edmonton, AB, Canada, T6X 0W8
Phone Number	+1.877.877.4633
Fax Number	+1.780.497.7670
Email	mitra.fard@primed.com
Contact person:	Mitra Fard
Common name of the device	Mask, Surgical
Trade or Proprietary Name:	PRIMED Surgical Masks and PRIMED Procedure Masks
Models	PG4-1001: ASTM Level 1, Procedure Ear Loop, Yellow Mask, PG4-1223: ASTM Level 3, Procedure Ear Loops, Black Mask, PG4-2001: ASTM Level 1, Surgical Ties, Blue Mask, PG4-4053: ASTM Level 3, Anti-fog Tape, Surgical Ties, Green Mask, PG4-5033: ASTM Level 3 Soft Mask, Anti-fog, Anti-Glare, Surgical Ties, Visor White, PG4-5553: ASTM Level 3 Visor Anti-Fog Anti-Glare Surgical Ties Indigo Mask
Regulation Description	Surgical Apparel
Review Panel	General and Plastic Surgery
Regulation number	21 CFR 878.4040
Device Class:	2
Product Code:	FXX
Predicate device(s)	PRIMAGARD Surgical Masks, # K081633

Device Description:

PRIMED Surgical masks and PRIMED Procedure masks are single use, non-sterile masks composed of a melt-blown filter layer placed between layers of non-woven inner and SS outer layer(s) material. PRIMED Medical Products Inc. offers various models in two main categories: Procedure masks with ear loops and Surgical masks with head ties. The level of protection varies based on the basis weight of the inner layer and the number of outer layers used in the mask's construction, in accordance with ASTM F2100:2023 specifications.

Indication for Use:

PRIMED Surgical Masks and PRIMED Procedure Masks are single use, non-sterile products intended to be worn by operating room and health care personnel in health care setting and during surgical procedures to protect both the patient and the operating room personnel from transfer of microorganisms, body fluids and particulate materials.

Here below is the summary of the technological characteristics and the performance of the proposed device compared to the predicate device.

Table 1: Technological Characteristics Comparison Table

Elements of Comparison	Proposed device	Predicate	comments
Trade name	PRIMED Surgical Masks and PRIMED Procedure Masks	PRIMAGARD Surgical Masks	-
510k number	K240286	K081633	-
Manufacturer	PRIMED Medical Products Inc.	PRIMED Medical Products Inc.	-
Regulation number	21 CFR 878.4040	21 CFR 878.4040	Same
Product code	FXX	FXX	Same
Common name	Mask, Surgical	Mask, Surgical	Same
Intended use	PRIMED Surgical Masks and PRIMED Procedure Masks are single use, non-sterile products intended to be worn by operating room and health care personnel in health care setting and during surgical procedures to protect both the patient and the operating room personnel from transfer of microorganisms, body fluids and particulate materials.	PRIMAGARD Surgical Masks are surgical apparel as identified in 21 CFR 878.4040 and are intended to be worn by operating room personnel during procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids and particulate material.	Similar
ASTM F2100 level	Level 1 and Level 3	Level 1, Level 2 and Level 3	Similar
Biocompatibility	Under the conditions of the testing, not a sensitizer, not an irritant, and not cytotoxic	Under the conditions of the testing, not a sensitizer, not an irritant, and not cytotoxic	Same
Single use vs. reusable	Single Use	Single Use	Same
Sterile vs. non-sterile	Non-sterile	Non-sterile	Same
Outer layer	Spunbond material	PSB PP material	Similar - PRIMED masks have different inner layer and different basis weight of outer and filter layer. The testing demonstrates the safety and effectiveness of the masks
Filter layer	Meltblown PP	Meltblown PP	
Inner layer	SSS material Wetlaid Cellulose ES material	Wetlaid Cellulose	
Ear loop	Spandex Polyester Ear loops	Spandex Polyester Ear loops	
Head Tie	SSS Head tie	Spunlace viscose	
Nose piece	Annealed Aluminium Plastic coated nosepiece	Aluminium nosepiece	
Color	White, Yellow, Green, Blue, Black, Indigo colour	Blue, White, Green, Indigo	Similar – masks are tested. Additional colours in the new masks do not introduce any additional safety or performance concern
Design	Pleated design Pleated Omega design	Pleated design Pleated Omega design Duckbill design	Similar

Elements of Comparison	Proposed device	Predicate	comments
Welding	Ultrasonic welding pattern	Ultrasonic welding pattern	same
Accessories	Anti-fog, visor	Anti-fog, visor	Same

Summary of non-clinical testing:

Table 2: Summary of the Non-Clinical Tests:

ASTM F2100-23			
Test Performed	Test method	Acceptance Criteria	Results (Pass/Fail)
Bacterial Filtration Efficiency	ASTM F2101	Level 1: ≥ 95%, Level 3: ≥ 98%	Pass
Sub-micron Particulate Filtration	ASTM F3502	Level 1: ≥ 80%, Level 3: ≥ 85%	Pass
Differential Pressure	EN 14683	Level 1: < 5 mmH_2O/cm^2, Level 3: < 6 mmH_2O/cm^2	Pass
Resistance to Penetration by synthetic Blood	ASTM F1862	Level 1: 80 mmHg, Level 3: 160 mmHg	Pass
Flammability	16 CFR 1610	Class I	Pass
Cytotoxicity	ISO 10993-5	Under the conditions of the testing, non-Cytotoxic	Pass
Sensitization	ISO 10993-10	Under the conditions of the testing, non sensitizing	Pass
Irritation	ISO 10993-23	Under the conditions of the testing, not an irritant	Pass

Summary of clinical testing:

N/A

Conclusion:

Based on the non-clinical testing performed, it can be concluded that the subject device, PRIMED Surgical masks and PRIMED Procedure masks are as safe, as effective and perform as well as or better than the legally marketed predicate device, K081633, PRIMAGARD Surgical Masks.