November 22, 2022

PRIMED Medical Products Inc.
Mitra Fard
Regulatory Affairs Specialist
200, 2003-91 St. SW
Edmonton, AB T6X 0W8
Canada

Re: K213427
Trade/Device Name: PRIMED Pediatric Facemask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: OXZ
Dated: October 26, 2022
Received: October 27, 2022

Dear Ms. 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 (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,

Katherine D. Kavlock -S

for
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

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)*
K213427

Device Name
PRIMED Pediatric Facemask

Indications for Use *(Describe)*

The PRIMED level 1 Pediatric Facemask is a single use, disposable device that is intended to be used by patient/child 4 to 12 years old in healthcare setting under an adult supervision to provide a barrier for the respiratory tract from microorganisms, body fluids and particulate material.

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."

PRIMED Pediatric Facemask **510(k) Summary**

Summary Date:	November 21, 2022
Manufacturer Information:	PRIMED Medical Products Inc.
Address:	200, 2003-91 St. SW, Edmonton, AB, Canada, T6X 0W8
Phone Number Fax Number Email Contact person:	+1.877.877.4633 +1.780.497.7670 mitra.fard@primed.ca Mitra Fard
Common name of the device	Pediatric Facemask
Trade or Proprietary Name:	PRIMED Pediatric Facemask
Classification name for the device	Surgical Apparel
Classification regulation: Class:	878.4040 2
Product Code:	OXZ (Pediatric/Child Facemask)
Predicate device(s)	Dukal level 1 Pediatric face mask 510(k)#: K210321 Kimberly-Clark Child's Facemask 510(k)#: K113340
Device Description	The PRIMED level 1 Pediatric Facemask is a single use, disposable device intended to be used by patient/child 4 to 12 years old in healthcare setting under an adult supervision to prevent the transmission of microorganism.

Product Description:

PRIMED Pediatric Mask (PG4-1680) is composed of 4 layers of non-woven material bounded together and pleated to form a mask. This mask is appropriately sized to the smaller faces of children between ages of 4 to 12 years old. PRIMED pediatric mask meets the requirements of ASTM F2100 for level 1 procedure mask while providing a lower differential pressure this mask is single use, disposable and is provided non-sterile. All of materials used in this device are typical materials commonly used in the construction of legally marketed surgical/ procedure masks with a safe history of use. The mask is not made with natural rubber latex.

Available Models

PG4-1680 Pediatric Mask, ASTM Level 1, Earloop, Dinosaur pattern,

Indication for Use:

The PRIMED level 1 Pediatric Facemask is a single use, disposable device that is intended to be used by patient/child 4 to 12 years old in healthcare setting under an adult supervision to provide a barrier for the respiratory tract from microorganisms, body fluids and particulate material.

Summary of the Technological Characteristics of PRIMED Pediatric Facemask and the predicate

Elements of comparison	Proposed PRIMED Pediatric mask	Primary Predicate	Secondary Predicate	Comparison
Manufacturer	PRIMED Medical Products Inc.	Kimberly-Clark	Dukal	
510(k) Number	K213427	K113340	K210321	
Product Code:	OXZ	OXZ	OxZ	Similar
Regulation number	21 CFR 878.4040	21 CFR 878.4040	21 CFR 878.4040	Similar
Indication for use	The PRIMED level 1 Pediatric Facemask is a single use, disposable device that is intended to be used by patient/child 4 to 12 years old in healthcare setting under an adult supervision to provide a barrier for the respiratory tract from microorganisms, body fluids and particulate material.	The Kimberly-Clark Pediatric/ Child Facemask is intended to be worn by the patient/child (recommended ages 4-12) to provide protection for the respiratory tract. It is a single use, disposable device that is provided non-sterile. This Face Mask is recommended for use in a healthcare selling with appropriate adult supervision	The Dukal Level 1 Pediatric Face Masks are intended to be worn by the patient/child to cover the nose and mouth to provide a barrier for the respiratory tract from microorganisms, body fluids, and particulate material. Recommended ages are 4-12. The face mask is specifically for use with patients whose age or illness may prevent them from taking necessary precautions in situations where transfer of microorganisms, body fluids, and particulates can occur. The face masks are recommended for use in a healthcare setting with appropriate adult supervision. The Dukal Level 1 Pediatric	Similar

Elements of comparison	Proposed PRIMED Pediatric mask	Primary Predicate	Secondary Predicate	Comparison
			Face Masks are single use, disposable devices that are provided non-sterile.	
Material	Non- woven	Non-woven	Non-woven	Similar
Bacterial Filtration (ASTM F2101)	>99%	99.6%	>99%	Similar
Particulate Filtration (ASTM F2299)	>99%	98.5%	>99%	Similar
Differential Pressure (MIL M 3654C)	<3.7 mmH_2O/cm^2	2.6 mmH_2O/cm^2	<3.1 mmH_2O/cm^2	Similar
Fluid Resistance (ASTM F1862)	> 80mmHg	Not applicable	> 80mmHg	Similar
Flammability (16 CFR 1610)	Class I	Class I	Class I	Similar
Cytotoxicity	Non-cytotoxic	Non-cytotoxic	Non-cytotoxic	Similar
Irritation	Not an irritant	Not an irritant	Not an irritant	Similar
Sensitization	Not a sensitizer	Not a sensitizer	Not a sensitizer	Similar
Migration of certain Elements) EN71-3	Pass	Pass	Tested under EN 71.3	Similar
Total lead content	Tested under CPSC-CH-E1002-08.3	Not Available	Tested under CPSC-CHE1002-08.3 & CPSC-CH-E1001-08.3	Similar
Phthalate Analysis	Tested under CPSC-CH-C1001-09.3	Not Available	Tested under CPSC-CHC1001-09.4	Similar
Sharp edge hazard	Meet the requirements of 16 CFR 1500.48 and 16 CFR 1500.49 when after simulating use and abuse of toys as per 16CFR 1500.53	Not Available	ested under ASTM F963-17 (sec. 4.6, 4.7, and 4.9), 16 CFR Part 1500, 16 CFR Part 1501	Similar
Mask construction and technological features	PRIMED Pediatric Child mask is generally composed of a filter layer that is ultrasonically bonded between layers of nonwoven fabric. This mask is appropriately sized to the smaller faces of children between ages of 4 to 12 years old. The PRIMED single use, non-sterile Pediatric/Child Facemask meet requirements of level 1 masks as per ASTM F2100. All of materials used in this device are typical materials commonly used in the construction of legally marketed surgical masks with a safe history of use. The masks are	The Kimberly-Clark Pediatric/Child Facemask is a three layer mask, constructed of nonwoven polyester blends and polypropylene materials. Bindings are nonwoven polyester and earloops are knitted polyester/lycra. A malleable nosepiece is placed within the bindings for comfort and individualized fit around the wearer's nose. The Pediatric/Child Facemask is appropriately sized to the smaller faces of children across a diverse population. The Pediatric/Child Facemask is a single use, disposable device, provided non-sterile.	The Dukal Level 1 Pediatric Face Mask is manufactured using ultrasonic hot sealing, composed of three layers of materials and pleated to form the mask. The inner layer is composed of Polypropylene (Spunbond), the middle layer is Polypropylene (Meltblown) filter material, and the outer layer is polypropylene (Spunbond). Decorative patterns are printed with colored inks. Masks are held in place on wearer with polyester/spandex elastic earloop and contain a malleable aluminum wire nose piece. The Pediatric/Child's Face Mask is appropriately sized to the smaller faces of children across a diverse population. All of the materials used in this device	Similar

Elements of comparison	Proposed PRIMED Pediatric mask	Primary Predicate	Secondary Predicate	Comparison
	not made with natural rubber latex.		are typical materials commonly used in the construction of Surgical Masks and are being used in current legally marketed devices. This product is not made with natural rubber latex.	
Anthropometry	Based on an anthropometric study sample that is representative of the US population in both gender and racial distribution, the Dukal Level 1 Pediatric Face Mask will provide adequate coverage to children 4 to 12 years old with face width of 8.5 to 12.8 cm and lower face length of 8.5 to 11.4 cm	Not available	Based on an anthropometric study sample that is representative of the US population in both gender and racial distribution, the Dukal Level 1 Pediatric Face Mask will provide adequate coverage to children between the ages of 4-12 years old of weight between 25-176 pounds, and of height between 3'00" – 5'08'".	Similar

Summary of Testing:

PRIMED pediatric masks are tested to below listed standards:

Standard		Result
ASTM F2100:2020	Standard Specification for Performance of Materials Used in Medical Face Masks	Meet and exceed requirement of Level 1 procedure mask
ASTM F2101: 2019	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus	>99 %
ASTM F2299:2003	Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres	>99%
ASTM F1862: 2017	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood	>80 mmHg
EN 14683:2019	Medical Face Masks—Requirements and Test Methods: Determine breathing resistance or differential pressure as directed in EN 14683:2019, Annex C.	< 3.7 mmH_2O/cm^2
16 CFR part 1610	Standard for the Flammability of Clothing Textiles	Class 1
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Pass
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass
EN 71-3: 2013	Migration of certain elements	pass
CPSC 16 CFR 1500.48	Technical requirements for determining a sharp point in toys and other articles for use by children under 8 years old after simulating use and abuse of device as per CPSC 16 CFR 1500.53	pass
CPSC 16 CFR 15003.49	Technical requirements for determining a sharp metal or glass edge in toys and other articles for use by children	Pass

Standard		Result
	under 8 years old, after simulating use and abuse of device as per CPSC 16 CFR 1500.53	
CPSC-CH-E1002-08.3	Standard operation procedure for determining total Lead in non-metal children product	Pass
CPSC-CH-C1001-09.3	Analysis of Phthalate	Pass

Conclusion:

Based on the test results and comparison of PRIMED Pediatric Facemasks with the predicate devices, it can be concluded that PRIMED Pediatric mask is substantially equivalent and as safe and as effective as the predicate devices.