December 22, 2025

KP Trading Co., Ltd.
Ji Kwon
Director
5,6 Dong 572054, Chorok-ro, Yanggam-myeon
Hwaseong-si, Gyeonggido 18627
Korea, South

Re: K243342/S001
Trade/Device Name: KP Protective Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 20, 2025
Received: November 20, 2025

Dear Ji Kwon:

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.

cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

BIFENG QIAN -S

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)*
K243342

Device Name
KP Protective Face Mask

Indications for Use *(Describe)*
The KP Protective Face Mask is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and operating room personnel from transfer of 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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510(k) SUMMARY
K243342

I. SUBMITTER

Company Name: KP TRADING CO., LTD.
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Date of summary: December 18, 2025

II. SUBJECT DEVICE

Proprietary Name: KP Protective Face Mask
Common Name: Surgical Mask
Classification Name: Surgical Apparel
Regulation Number: 21 CFR 878.4040
Product Code: FXX
Device Class: Class II

III. PREDICATE DEVICE

Predicate Device: Techno Web Surgical Mask
Predicate 510(k) Number: K172500
Product Code: FXX

IV. DEVICE DESCRIPTION

The KP Protective Face Mask is a non-sterile, single-use surgical mask intended to cover the user's nose and mouth, providing a physical barrier to fluids, microorganisms, and particulate matter.

The mask consists of three nonwoven polypropylene layers, including:

- Outer layer: Spunbond non-woven
- Filter layer: Melt-blown polypropylene
- Inner comfort layer: Spunbond non-woven
- Nose wire: Polypropylene-clad adjustable wire
- Attachment: Elastic earloops (A mixture of nylon and polyurethane)

The mask is white, flat-fold style, supplied non-sterile, and packaged in standard pouches.

V. INDICATIONS FOR USE

The KP Protective Face Mask is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and operating room personnel from transfer of microorganisms, body fluids, and particulate material.

VI. COMPARISON TABLE

A comparison between the proposed device and predicate device are shown in the table below for the purpose of presenting the equivalence in relation to effectiveness and safety.

Item	**Primary Predicate Device (K172500)**	**Subject Device (K243342)**	**Comparison**
Regulatory Class	Class II	Class II	Same
Product Code	FXX	FXX	Same
Intended Use	Techno Web Surgical Mask is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and operating room personnel from transfer of microorganisms, body fluids, and particulate material.	KP Protective Face Mask is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and operating room personnel from transfer of microorganisms, body fluids, and particulate material.	Same
Materials			
Outer Cover Web	Felt (Nonwoven filtration web)	Polypropylene Spunbond Non-woven fabric woven fabric (40gsm, SSS)	Similar
Stiffener Web	N/A	N/A	Same

Filter Web	Felt (Nonwoven filtration web)	Polypropylene Melt blown non-woven fabric (40g sm. FFP2 , Water Agent process	Similar
Inner Web	Felt (Nonwoven filtration web)	Polypropylene Spunbond Non-woven fabric (20gsm, SSS)	Similar
Nose-Clip	Aluminum	Polypropylene clad wire	Similar
Staple	N/A	N/A	Same
Ear loop	Ear loop: Nylon	Ear loops: A mixture of Nylon and Polyurethane strap	Similar
Nose Foam	Plastic coating	N/A	Different
Surgical face mask style			
Fold	Flat fold	Flat fold	Same
Layers	Multi (three-layers)	Multi (three layers)	Same

Sterility			
	Non-Sterile Single Use	Non-Sterile Single Use	Same
Specifications and Dimensions			
Color	White	White	Same
Length	177.8mm	205 ± 10mm	Similar
Width	74mm	85.1 ± 6.4mm	Similar
Ear loops Length	138mm	165 ± 16mm	Similar
Performance Specifications			

Particulate Filtration Efficiency (PFE)	Pass ASTM F2299 At least 99.71%	Pass 3 non-consecutive ASTM F3502 (75± 20 nm NaCl): 92.15-95.96%	Similar
Differential Pressure Delta P	Pass — EN 14683:2019 < 6.0 mmH_2O/cm^2 (Level 2)	Pass — ASTM F2100 (Level 2) Tested on 3 non-consecutive production lots Differential pressure range: approx. 4.3–5.5mmH_2O/cm^2	Similar
Fluid Resistance	Pass 10/10 at 120mmHg	Pass 3 non-consecutive lots 32/32 at 120mmHg ASTM F1862/F1862M-17	Similar
Bacterial Filtration Efficiency	Pass ≥ 99 (%)	Pass >99% ASTM F2101-2019	Same
Flammability (CFR 16 1610)	Pass Class I	Pass 16 CFR 1610 (Class I)	Same
Certification			
Surgical face mask	Classified as Surgical Mask	Classified as Surgical Mask	Same
Biocompatibility			
Cytotoxicity (ISO 10993-5)	Biocompatibility assessment performed on patient-contact materials (per publicly available 510(k) Summary)	Sample showed a non-cytotoxic effect	Similar
Irritation (ISO 10993-10:2010)		Primary Irritation Index (PII) = 0; negligible irritation	Similar
Cytotoxicity (ISO 10993-10: 2010)		Sensitization rate = 0%; no skin sensitization observed	Similar

VII. PERFORMANCE TESTING SUMMARY

The KP Protective Face Mask was evaluated in accordance with ASTM F2100-19 Level 2 requirements. Testing included BFE, PFE, Synthetic Blood Penetration, Differential Pressure, Flammability, and Biocompatibility (ISO 10993). All results met acceptance criteria.

Test Method	Purpose	Acceptance	Results
ASTM F2101	Measure filtration efficiency against S. aureus aerosol	≥98% (Level 2)	PASS ≥99%
ASTM F3502-25	Measure submicron particle filtration (0.1µm)	≥85 (Level 2)	PASS ≥85%
ASTM F1862	Evaluate resistance to synthetic blood at pressure	120 mmHg - No penetration	PASS - no penetration
EN 14683 / MIL-M-36954	Measure breathability (ΔP)	< 6.0 mmH_2O/cm^2 (Level 2)	PASS
16 CFR 1610	Evaluate flammability of mask materials	Class 1 (Normal flammability)	PASS - Class 1

Biocompatibility Testing

The relevant standards for biocompatibility testing of the subject device are presented as follows.

Test Method	Purpose	Acceptance	Results
ISO 10993-10:2010	Irritation	Primary irritation index (PII) ≤ 0.4 = negligible irritation	PII = 0.0, No irritation observed
ISO 10993-10:2010	Sensitization	0% sensitization response = Pass	0% sensitization response, no sensitization observed
ISO 10993-5:2019	In vitro Cytotoxicity	≥ 70% cell viability = non-cytotoxic	Non-Cytotoxic

Clinical Testing

Clinical testing is not applicable to the subject device.

VIII. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the KP Protective Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate devices, the Techno Web Surgical Mask (K172500).