July 1, 2024

Owens & Minor (O&M) Halyard, Inc.
Caitlin Senter
Director, Global Regulatory Affairs
9120 Lockwood Blvd
Mechanicsville, Virginia 23116

Re: K232777
Trade/Device Name: FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender (25868); FLUIDSHIELD* 1 FogFree Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender, Wrap Around Visor (41798)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 16, 2024
Received: May 17, 2024

Dear Caitlin Senter:

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

DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality 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)*
K232777

Device Name
FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender (25868), FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender, Wrap Around Visor (41798)

Indications for Use *(Describe)*
The FLUIDSHIELD* 1 Procedure 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. FLUIDSHIELD* 1 Procedure Mask(s) are single use, disposable device(s), provided non-sterile.

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 – K232777

Date of Summary	July 1, 2024
510(k) Submitter	O & M Halyard, Inc. 1 Edison Drive Alpharetta, GA 30005
Primary Contact for this 510(k) Submission	Caitlin Senter, MS, RAC Tel: 678-221-7330 Email: caitlin.senter@owens-minor.com
Marketed Common Name	Procedure Mask
Device Submission Trade Name and Description	FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender (25868); FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender, Wrap Around Visor (41798)
Device Product Code, Class and Classification Name	FXX II Surgical Apparel (21 CFR 878.4040)
Predicate Device	K110455 Kimberly-Clark KC100 Face Masks FXX Surgical Mask Surgical Apparel (21 CFR 878.4040)
Subject Device Description	The subject devices are ASTM F2100 Level 1 (lavender in color) Procedure Masks. The ASTM F2100 Level 1 Procedure Mask family of products are a three-layer mask, constructed of well-known non-woven materials used in facial protection. The FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender (25868) includes a malleable nosepiece. The FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender, Wrap Around Visor (41798) includes a visor and nose foam. These masks are single use, disposable devices, provided non-sterile.
Indications for Use	The FLUIDSHIELD* 1 Procedure 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. FLUIDSHIELD* 1 Procedure Mask(s) are single use, disposable device(s), provided non-sterile.

Technological Characteristics Comparison Table				
	Subject Device FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender (25868)	**Subject Device** FLUIDSHIELD* 1 Fog-Free Procedure Mask with SOO SOFT* Lining and SO SOFT* Earloops, Lavender, Wrap Around Visor (41798)	**Predicate Device** KC100 Face Masks (K110455)	**Comparison**
FDA Product Code	FXX	FXX	FXX	Same
FDA Classification	Class II	Class II	Class II	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	21 CFR 878.4040	Same
Common Name	Surgical Mask	Surgical Mask	Surgical Mask	Same
Device Trade Name	FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender (25868)	FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender, Wrap Around Visor (41798)	KC100 Procedure Mask	Different
Indications for Use	The FLUIDSHIELD* 1 Procedure 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. FLUIDSHIELD* 1 Procedure Mask(s) are single use, disposable device(s), provided non-sterile.	The FLUIDSHIELD* 1 Procedure 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. FLUIDSHIELD* 1 Procedure Mask(s) are single use, disposable device(s), provided non-sterile.	The Kimberly-Clark KC100 Face Mask(s) is 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 KC100 face mask(s) is a single use, disposable device(s), provided	Same The device trade names are different

			non-sterile.	
Over-the-Counter / Prescription	OTC	OTC	OTC	Same

Design Attributes				
Number of Layers	3	3	3	Same
Color	Lavender	Lavender	Yellow, blue, green, white, lavender	Same
Style	Pleated with earloops	Pleated with earloops	Pleated with earloops	Same
Outer Layer	Spunbond polypropylene	Spunbond polypropylene	Spunbond polypropylene	Same
Middle Layer	Meltblown polypropylene	Meltblown polypropylene	Meltblown polypropylene	Same
Inner Layer	Polyethylene/polyester	Polyethylene / polyester	Polyethylene / polyester	Same
Bindings	Polyester spunlace / polyester spunbond	Polyester spunlace / polyester spunbond	Polyester spunlace / polyester spunbond	Same
Earloop	Polyester/lycra	Polyester / lycra	Polyester / lycra	Same
Nose wire	Polyethylene coated steel wire / malleable aluminum	Polyethylene coated steel wire / malleable aluminum	Aluminum or polyethylene coated steel	Same
Visor	None	Polyester film	Includes models with polyester film visor and models without a visor	Same
Nose Foam	None	Blue polyester foam	Includes models with blue polyester nose foam and models without nose foam	Same
Mask Dimension Length	6.875” ± 0.125”	6.875” ± 0.125”	6.875” ± 0.125”	Same
Mask Dimension Width (Flat)	3.625” +/- 0.125”	3.625” +/- 0.125”	3.625” +/- 0.125”	Same
Performance Data/Product Claims				
ASTM F2100 Level	1	1	1	Same
EN 14683	Type II	No	No	Different
Single Use	Yes	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Fluid Resistance ASTM F1862	80 mmHg	80 mmHg	80 mmHg	Same

Particulate Filtration Efficiency ASTM F2299	≥ 95%	≥ 95%	≥ 95%	Same
Differential pressure	< 5.0 mmH_2O/cm^2	< 5.0 mmH_2O/cm^2	< 5 mmH_2O/cm^2	Same
Bacterial Filtration Efficiency ASTM F2101	≥ 95%	≥ 95%	≥ 95%	Same
Flame Resistance 16 CFR 1610	Class 1	Class 1	Class 1	Same
ISO 10993-5	Under the conditions of the testing, not cytotoxic	Under the conditions of the testing, not cytotoxic	Under the conditions of the testing, not cytotoxic	Same
ISO 10993-10	Under the conditions of the testing, not a sensitizer and not an irritant	Under the conditions of the testing, not a sensitizer and not an irritant	Under the conditions of the testing, not a sensitizer and not an irritant	Same

Summary of Non-Clinical Testing:

Test	Purpose	Criteria	Result
ASTM F2101	To demonstrate adequate bacterial filtration efficiency	Under the conditions of the study, at least 95% efficiency	Pass
EN 14683:2019+AC Annex C	To demonstrate acceptable breathability	Under the conditions of the study, at most 5.0 mm H_2O/cm^2	Pass
ASTM F2299	To demonstrate adequate particulate filtration efficiency	Under the conditions of the study, at least 95% efficiency	Pass
ASTM F1862	To demonstrate adequate resistance to liquids	Under the conditions of the study, passing at 80 mmHg conditions	Pass
16 CFR 1610	To evaluate flame spread resistance	Class 1 under the conditions of the testing	Pass
ASTM F2100-19	To evaluate mask performance	Level 1 under the conditions of the evaluation	Pass
EN ISO 11737-1 Bioburden	To evaluate microbial cleanliness	Under the conditions of the study, at most 30 CFU/g	Pass
ISO 10993-5	To evaluate the cytotoxic potential of the mask	Under the conditions of the study, non-cytotoxic	Pass
ISO 10993-10 Sensitization	To evaluate the sensitization potential of the mask	Under the conditions of the study, not a sensitizer	Pass
ISO 10993-10 Irritation	To evaluate the irritation potential of the mask	Under the conditions of the study, not an irritant	Pass

Summary of Clinical Testing

No clinical testing was performed in support of this submission.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender (25868), FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender, Wrap Around Visor (41798) are as safe, as effective and perform as well as or better than the legally marketed predicate device KC100 Face Masks (K110455).