July 2, 2024

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

Re: K232824
Trade/Device Name: FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White (41802); FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White, Wrap Around Visor (41803); FLUIDSHIELD* 1 Surgical Mask with SO SOFT* Lining, White, (41805)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 31, 2024
Received: May 31, 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
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)*
K232824

Device Name
FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White (41802); FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White, Wrap Around Visor (41803); FLUIDSHIELD* 1 Surgical Mask with SO SOFT* Lining, White, (41805)

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

FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White (41802)
FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White, Wrap Around Visor (41803)
FLUIDSHIELD* 1 Surgical Mask with SO SOFT* Lining, White, (41805)

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 (K232824)

Date Summary was Prepared	June 28, 2024
510(k) Submitter	O & M Halyard, Inc. 9120 Lockwood Boulevard Mechanicsville, VA 231161
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 and Surgical Mask
Device Submission Trade Name and Description	**Procedure Mask** FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White (41802) FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White, Wrap Around Visor (41803) **Surgical Mask** FLUIDSHIELD* 1 Surgical Mask with SO SOFT* Lining, White, (41805)
Device Common Name	Procedure Mask and Surgical Mask
Device Product Code and Classification Name	FXX Class II, 21 CFR §878.4040 Surgical Apparel
Predicate Device	Kimberly-Clark KC100 Face Masks (K110455)
Subject Device Description	The subject device(s) are ASTM F2100 Level 1 (white in color) Procedure and Surgical Mask(s). The FLUIDSHIELD* 1 Procedure Mask(s) and FLUIDSHIELD* 1 Surgical Mask(s) family of products are a three-layer mask, constructed of well-known non-woven materials used in facial protection. The Surgical Masks are provided with ties while the Procedure Mask(s) are provided with earloops. A malleable nosepiece is placed within the bindings. The FLUIDSHIELD* 1 Procedure Mask(s) and FLUIDSHIELD* 1 Surgical Mask(s) family will be provided in designs with and without a protective visor. The FLUIDSHIELD* 1 Procedure Mask(s) and FLUIDSHIELD* 1 Surgical Mask(s) family are single use, disposable devices, provided non-sterile.
Indications for Use	The FLUIDSHIELD* 1 Procedure Mask(s) and FLUIDSHIELD* 1 Surgical 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. The FLUIDSHIELD* 1 Procedure Mask(s) and FLUIDSHIELD* 1 Surgical Mask(s) are single use, disposable device(s), provided non-sterile.

Technological Characteristics Comparison Table			
	Subject Device FLUIDSHIELD* 1 Procedure Mask(s) and FLUIDSHIELD* 1 Surgical Mask(s)	**Predicate Device (K110455) Kimberly-Clark KC100 Face Masks**	**Comparison**
FDA Product Code	FXX	FXX	Same
FDA Classification	Class II	Class II	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Common Name	Surgical Mask	Surgical Mask	Same
Device Trade Name	**Procedure Mask(s)** FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White (41802) FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White, Wrap Around Visor (41803) **Surgical Mask(s)** FLUIDSHIELD* 1 Surgical Mask with SO SOFT* Lining, White, (41805)	KC100 Procedure Mask, Lavender, Blue, Yellow, Green, White KC100 Procedure Mask with visor, Lavender, Blue, Yellow, Green, White KC100 Procedure Mask with fog-free strip, Lavender, Blue, Yellow, Green, White	Similar The predicate device was cleared with a multitude of colors while the subject device is offered in white only.
Intended Use	The FLUIDSHIELD* 1 Procedure Mask(s) and FLUIDSHIELD* 1 Surgical 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	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	Same

	infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The FLUIDSHIELD* 1 Procedure Mask(s) and FLUIDSHIELD* 1 Surgical Mask(s) are single use, disposable device(s), provided non-sterile.	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 non-sterile.	
Design Attributes			
# of Layers	3-layer	3-layer	Same
Color	White	White	Same
Earloops (Procedure)	Yes	Yes	Same
Ties (Surgical)	Yes	Yes	Same
Visor	Some Designs	Some Designs	Same
Performance Data/Product Claims			
Fluid Resistance Level	1	1	Same
Single Use Device	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same

Summary of Non-Clinical Performance Testing:

Non-clinical tests were conducted to verify that the proposed device(s) met all design specifications similar to the predicate device(s).

Table:

Purpose	**Test**	**Acceptance Criteria**	**Result**
Face Mask Performance	ASTM F2100	ASTM F2100 Level 1	Pass
Bacterial Filtration Efficiency	*ASTM F2101*	*≥95%*	*Pass*
Particulate Filtration Efficiency	*ASTM F2299*	*≥95%*	*Pass*
Differential Pressure	*EN 14683*	*<5.0 mmH_2O/cm^2*	*Pass*
Fluid Resistance	*ASTM F1862*	*80 mmHg*	*Pass*
Flammability	*16 CFR Part 1610*	*Class 1*	*Pass*
Biocompatibility	ISO 10993		Pass
Cytotoxicity	*ISO 10993-5*	*Non-cytotoxic*	*Pass*
Sensitization	*ISO 10993-10*	*Non-sensitizing*	*Pass*
Irritation	*ISO 10993-10*	*Non-irritant*	*Pass*

The test results demonstrated that the proposed device complies with the following standards:

- ASTM F1862/F1862M: 2017 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

- ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- 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
- ASTM F2100: 2019 Standard Specification for Performance of Materials Used in Medical Face Masks EN 14683:2019+AC: 2019 Annex C Medical face masks - Requirements and test methods
- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritation and skin sensitization

Summary of Clinical Performance Testing:

N/A

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White (41802), FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White, Wrap Around Visor (41803), and FLUIDSHIELD* 1 Surgical Mask with SO SOFT* Lining, White, (41805) are as safe, as effective, and perform as well as or better than the legally marketed KC100 Face Masks (K110455).