June 14, 2024

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

Re: K232812
Trade/Device Name: Fluidshield* 2 Fog-Free Surgical Mask (62113); Fluidshield* 2 Fog-Free Surgical Mask with Wraparound Visor (62114); Fluidshield* 2 Procedure Mask with SO SOFT* Earloops (62115); Fluidshield* 2 Procedure Mask with SO SOFT* Earloops and WrapAround Visor (62116)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 9, 2024
Received: May 9, 2024

Dear Angela Bunn:

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)*
K232812

Device Name
Fluidshield * 2 Fog-Free Surgical Mask (62113)
Fluidshield * 2 Fog-Free Surgical Mask with Wraparound Visor (62114)
Fluidshield * 2 Procedure Mask with SO SOFT* Earloops (62115)
Fluidshield * 2 Procedure Mask with SO SOFT* Earloops and WrapAround Visor (62116)

Indications for Use *(Describe)*

The Fluidshield* 2 Surgical Mask 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 Fluidshield* 2 Surgical Mask is a single use, disposable device, provided non-sterile.
The Fluidshield* 2 Procedure Mask 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 Fluidshield* 2 Procedure Mask is a single use, disposable device, 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.

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510(k) Summary K232812

Date Summary was Prepared	June 14, 2024
510(k) Submitter	O & M Halyard, Inc. 1 Edison Drive Alpharetta, GA 30005
Primary Contact for this 510(k) Submission	Angela L. Bunn, RAC Tel: 470-347-7147 Email: angela.bunn@owens-minor.com
Marketed Common Name	Surgical Mask and Procedure Mask
Device Submission Trade Name and Description	Fluidshield * 2 Fog-Free Surgical Mask (62113) Fluidshield * 2 Fog-Free Surgical Mask with Wraparound Visor (62114) Fluidshield * 2 Procedure Mask with SO SOFT* Earloops, (62115) Fluidshield* 2 Procedure Mask with SO SOFT* Earloops and WrapAround Visor (62116)
Device Common Name	Surgical Mask and Procedure Mask
Device Product Code and Classification Name	FXX Class II, 21 CFR §878.4040 Surgical Apparel
Predicate Device	KC 200 Fluidshield* Surgical Masks and Procedure Masks and KC 300 Fluidshield* Surgical Masks and Procedure Masks (K111402)
Subject Device Description	The subject device(s) are ASTM Level 2 Surgical and Procedure Mask(s). Fluidshield* 2 Surgical Mask(s), Fluidshield* 2 Procedure Mask(s) family of products are a four-layer mask, constructed of well-known non-woven

	materials used in facial protection. The Surgical Masks are provided with ties while the Procedure Masks are provided with earloops and a malleable nosepiece. The Fluidshield* 2 Surgical Mask(s), Fluidshield* 2 Procedure Mask(s) family will be provided in designs with and without a protective visor. The Fluidshield* 2 Surgical Mask(s), Fluidshield* 2 Procedure Mask(s) family are single use, disposable devices, provided non-sterile.
Indications for Use	The Fluidshield* 2 Surgical Mask 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 Fluidshield* 2 Surgical Mask is a single use, disposable device, provided non-sterile. The Fluidshield* 2 Procedure Mask 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 Fluidshield* 2 Procedure Mask is a single use, disposable device, provided non-sterile.

Technological Characteristics Comparison Table			
	Subject Device	**Predicate Device (K111402) KC 300 and KC 200 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	Fluidshield * 2 Fog-Free Surgical Mask (62113) Fluidshield * 2 Fog-Free Surgical Mask with Wraparound Visor (62114) Fluidshield * 2 Procedure Mask with SO SOFT* Earloops, (62115) Fluidshield* 2 Procedure Mask with SO SOFT* Earloops and WrapAround Visor (62116)	KC200 Procedure Mask KC200 Procedure Mask, fog-free with visor KC200 Surgical Mask, fog-free KC200 Surgical Mask, fog-free with visor KC300 Procedure Mask, Fluidshield*, fog-free KC300 Procedure Mask, Fluidshield*, fog-free with visor KC300 Surgical Mask, Fluidshield*, fog-free KC300 Surgical Mask, Fluidshield*, fog-free with visor	Similar
Intended Use	The Fluidshield* 2 Surgical Mask 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 Fluidshield* 2 Surgical Mask is a single use, disposable	The Kimberly-Clark, KC200 and KC300 Face 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 Kimberly-Clark, KC200	Same This submission covers the KC 300 and KC 200 Blue Surgical or Procedure Masks.

	device, provided non-sterile. The Fluidshield* 2 Procedure Mask 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 Fluidshield* 2 Procedure Mask is a single use, disposable device, provided non-sterile.	and KC300 face mask(s) is a single use, disposable device(s), provided non-sterile.	

Materials of Construction for Surgical Mask Family (Codes 62113 and 62114)

Structure	Material of Layer for K232812	Material cleared under K111402	Same or Different
Code 62113 Materials of Construction			
Outer Layer	Polyester Cellulose	Spunbond polypropylene (or) Polyester Cellulose	Same
2nd Layer	Spunbond polypropylene	Spunbond polypropylene	Same
Media Filter	Meltblown polypropylene	Meltblown polypropylene	Same
Inner Layer	Polyester Cellulose	Polyester Cellulose	Same
Top Binding	Spunbond polypropylene	Spunbond polypropylene, Polyester spunlace	Same
Lower Binding	Spunbond polypropylene	Spunbond polypropylene, Polyester spunlace	Same
Ties (Surgical)	Spunbond polypropylene	Polyester spunlace	Different
Foam	Polyester/Polyester Spunlace laminate	Polyester/Polyester Spunlace laminate	Same
Foam	Polyester	Polyester	Same
Nose Wire	Aluminum	Aluminum	Same
Code 62114 Materials of Construction			
Outer Layer	Polyester Cellulose	Spunbond polypropylene (or) Polyester Cellulose	Same
2nd Layer	Spunbond polypropylene	Spunbond polypropylene	Same
Media Filter	Meltblown polypropylene	Meltblown polypropylene	Same
Inner Layer	Polyester Cellulose	Polyester Cellulose	Same
Top Binding	Spunbond polypropylene	Spunbond polypropylene (or) Polyester spunlace	Same
Lower Binding	Polyester spunlace	Spunbond polypropylene (or) Polyester spunlace	Same
Ties (Surgical)	Polyester spunlace	Polyester spunlace	Same
Foam	Polyester	Polyester/Polyester	Same

		Spunlace laminate	
Visor	Polyester Film	Polyester Film	Same
Nose Wire	Aluminum	Aluminum	Same
Materials of Construction for Procedure Mask Family (Codes 62115, 62116)			
Structure	Material of Layer for K232812	Material cleared under K111402	Same or Different
Code 62115 Materials of Construction			
Outer Layer	Polyester Cellulose	Spunbond polypropylene (or) Polyester Cellulose	Same
2nd Layer	Spunbond polypropylene	Spunbond polypropylene	Same
Media Filter	Meltblown polypropylene	Meltblown polypropylene	Same
Inner Layer	Polyester Cellulose	Polyester Cellulose	Same
Top Binding	Polyester spunlace	Polyester spunlace	Same
Lower Binding	Polyester spunlace	Polyester spunlace	Same
Earloops (Procedure)	Polyester lycra	Polyester lycra	Same
Nose Wire	Aluminum	Aluminum	Same
Code 62116 Materials of Construction			
Outer Layer	Polyester Cellulose	Spunbond polypropylene (or) Polyester Cellulose	Same
2nd Layer	Spunbond polypropylene	Spunbond polypropylene	Same
Media Filter	Meltblown polypropylene	Meltblown polypropylene	Same
Inner Layer	Polyester Cellulose	Polyester Cellulose	Same
Top Binding	Polypropylene spunbond	Polyester spunlace	Different
Lower Binding	Polyester spunlace	Polyester spunlace	Same
Earloops (Procedure)	Polyester lycra	Polyester lycra	Same
Foam	Polyester foam/polyester spunlace laminate	Polyester foam/polyester spunlace laminate	Same
Visor	Polyester Film	Polyester Film	Same
Nose Wire	Aluminum	Aluminum	Same

Design Attributes for Surgical Masks			
# of Layers	4-layer	4-layer	Same
Color	Blue with Orange Print	Blue with Orange Print	Same
Ties (Surgical)	Yes	Yes	Same
Visor	Some designs contain a visor	Some designs contain a visor	Same
Nose Wire	Enclosed	Enclosed	Same
Design Attributes for Procedure Masks			
# of Layers	4-layer	4-layer	Same
Color	Blue	Blue	Same
Earloops (Procedure)	Yes	Yes	Same
Visor	Some designs contain a visor	Some designs contain a visor	Same
Performance Data/Product Claims			
Fluid Resistance Level	2	2 and 3	Same
EN 14683	Yes	No	Different

Single Use Device	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same

Non-Clinical Performance Testing Standards

Non-clinical tests were conducted to verify that the proposed device(s) met all design specifications as was same/similar to the predicate device(s). The test results demonstrated that the proposed device complies with the following standards:

Purpose	Test	Acceptance Criteria	Result
Level 2 - Face Mask Performance	ASTM F2100	ASTM Level 2	Pass
Bacterial Filtration Efficiency	ASTM F2101	≥98%	Pass
Particulate Filtration Efficiency	ASTM F2299	≥98%	Pass
Differential Pressure	EN 14683	<6.0 mmH2O/cm2	Pass
Fluid Resistance	ASTM F1862	120 mmHg	Pass
Flammability	16 CFR Part 1610	Class 1	Pass
Biocompatibility	ISO 10993		
Cytotoxicity	ISO 10993-5	Non-cytotoxic	Pass
Sensitization	ISO 10993-10	Non-sensitizing	Pass
Irritation	ISO 10993-10	Non-irritant	Pass

Summary of Clinical Performance Testing:

Not applicable

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the Fluidshield* 2 Surgical Mask(s), and Fluidshield* 2 Procedure Mask(s) are as safe, as effective and perform as well as or better than the legally marketed KC200 and KC300 Face Masks (K111402).