



June 21, 2024

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

Re: K232807

Trade/Device Name: Fluidshield* 1 Procedure Mask with SO SOFT* Lining and SO SOFT Earloops (25869); Fluidshield* 1 Surgical Mask with SO SOFT* Lining (28802)

Regulation Number: 21 CFR 878.4040

Regulation Name: Surgical Apparel

Regulatory Class: Class II

Product Code: FXX

Dated: May 17, 2024

Received: May 17, 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 Office of Product
Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K232807

Device Name

Fluidshield* 1 Procedure Mask with SO SOFT* Lining and SO SOFT Earloops (25869); Fluidshield* 1 Surgical Mask with SO SOFT* Lining (28802)

Indications for Use (Describe)

Fluidshield* 1 Procedure Mask with SO SOFT* Lining and SO SOFT Earloops (25869); Fluidshield* 1 Surgical Mask with SO SOFT* Lining (28802) 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 with SO SOFT* Lining and SO SOFT Earloops (25869); Fluidshield* 1 Surgical Mask with SO SOFT* Lining (28802) 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.

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K232807
510(k) Summary

Date Summary was Prepared	June 21, 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 * 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (25869); Fluidshield * 1 Surgical Mask with SO SOFT* Lining (28802)
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 100 Fluidshield* Surgical Masks and Procedure Masks (K110455)
Subject Device Description	The subject device(s) are ASTM Level 1 (blue in color) Surgical and Procedure Mask(s). The Fluidshield* 1 Procedure Mask and the Fluidshield* 1 Surgical Mask are a three-layer mask, constructed of non-woven materials. The Surgical Masks (28802) are provided with ties while the Procedure Masks (25869) are provided with earloops. A malleable nosepiece is placed within the bindings to conform with the wearer's nose. The Fluidshield* 1 Procedure Mask and the Fluidshield* 1 Surgical Mask are single use, disposable devices, provided nonsterile.

Indications for Use	Fluidshield* 1 Procedure Mask with SO SOFT* Lining and SO SOFT Earloops (25869); Fluidshield* 1 Surgical Mask with SO SOFT* Lining (28802) 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 with SO SOFT* Lining and SO SOFT Earloops (25869); Fluidshield* 1 Surgical Mask with SO SOFT* Lining (28802) are single use, disposable device(s), provided non-sterile.		
Technological Characteristics Comparison Table			
	Subject Device	Predicate Device (K110455) KC 100 Surgical and Procedure 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 * 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (25869); Fluidshield * 1 Surgical Mask with SO SOFT* Lining (28802)	KC100 Surgical Mask KC100 Procedure Mask	Similar

Intended Use	Fluidshield* 1 Procedure Mask with SO SOFT* Lining and SO SOFT Earloops (25869); Fluidshield* 1 Surgical Mask with SO SOFT* Lining (28802) 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 with SO SOFT* Lining and SO SOFT Earloops (25869); Fluidshield* 1 Surgical Mask with SO SOFT* Lining (28802) are single use, disposable device(s), provided non-sterile.	The Kimberly-Clark, KC100 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, KC100 face mask(s) is a single use, disposable devices, provided non-sterile.	Same
Materials of Construction for Surgical Masks (28802)			
Outer Layer	Spunbond polypropylene	Spunbond polypropylene	Same
Media Filter	Meltblown polypropylene	Meltblown polypropylene	Same
Inner Layer	Polyethylene polyester	Polyethylene polyester	Same
Bindings	Polyester polypropylene	Spunbond polypropylene, Polyester spunlace	Same
Ties (Surgical)	Spunbond polypropylene	Polyester spunlace	Different
Nose Wire	Aluminum	Aluminum	Same
Materials of Construction for Procedure Masks (25869)			

Outer Layer	Spunbond polypropylene	Spunbond polypropylene	Same
Media Filter	Meltblown polypropylene	Meltblown polypropylene	Same
Inner Layer	Polyethylene polyester	Polyethylene polyester	Same
Bindings	Polyester spunlace	Polyester spunlace	Same
Earloops (Procedure)	Polyester lycra	Polyester lycra	Same
Nose Wire	Aluminum	Aluminum	Same
Design Attributes for Surgical Masks (28802)			
# of Layers	3-layer	3-layer	Same
Style	Pleated	Pleated	Same
Color	Blue	Blue	Same
Ties (Surgical)	Yes	Yes	Same
Nose Wire	Enclosed	Enclosed	Same
Design Attributes for Procedure Masks (25869)			
# of Layers	3-layer	3-layer	Same
Style	Pleated	Pleated	Same
Color	Blue	Blue	Same
Earloops (Procedure)	Yes	Yes	Same
Performance Data/Product Claims for Surgical Masks (28802)			
Fluid Resistance Level	ASTM F2100:19 Level 1	ASTM F2100 Level 1	Same
EN 14683	Type IIR	No	Different
Single Use Device	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Performance Data/Product Claims for Procedure Masks (25869)			
Fluid Resistance Level	ASTM F2100:19 Level 1	ASTM F2100:07 Level 1	Similar
EN 14683	Type IIR	No	Different
Single Use Device	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same

Summary of Performance Testing:

Test	Purpose	Criteria	Result	
			28802	25869
ASTM F2101	To demonstrate adequate bacterial filtration efficiency	Under the conditions of the study, at least 95% efficiency	Pass	Pass
EN 14683: 2019 +AC Annex C	To demonstrate acceptable breathability	Under the conditions of the study, at most 5.0 mm H ₂ O/cm ²	Pass	Pass
ASTM F2299	To demonstrate adequate particulate filtration efficiency	Under the conditions of the study, at least 95% efficiency	Pass	Pass
ASTM F1862	To demonstrate adequate resistance to liquids	Under the conditions of the study, passing at 80 mmHg conditions	Pass	Pass
16 CFR 1610	To evaluate flame spread resistance	Class 1 under the conditions of the testing	Pass	Pass
ASTM F2100-19	To evaluate mask performance	Level 1 under the conditions of the evaluation	Pass	Pass
ISO 10993-5	To evaluate the cytotoxic potential of the mask	Under the conditions of the study, non-cytotoxic	Pass	Pass
ISO 10993-10 Sensitization	To evaluate the sensitization potential of the mask	Under the conditions of the study, not a sensitizer	Pass	Pass
ISO 10993-10 Irritation	To evaluate the irritation potential of the mask	Under the conditions of the study, not an irritant	Pass	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 (25869); Fluidshield * 1 Surgical Mask with SO SOFT* Lining (28802) are as safe, as effective and perform as well as or better than the legally marketed predicate device KC100 Face Masks (K110455).