



May 30, 2025

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

Re: K243010

Trade/Device Name: Fluidshield * 3 Fog-Free Surgical Mask with Wraparound Anti-Glare Visor (28804); Fluidshield * 3 Surgical Mask with SO SOFT* Lining (48208); Fluidshield * 3 Fog-Free Surgical Mask with SO SOFT* Lining (48207); Fluidshield * 3 Fog-Free Surgical Mask with SO SOFT* Lining, with Visor (48237); Fluidshield* 3 Fog-Free Surgical Mask with SO SOFT* Lining, Anti-Glare WrapAround Visor (48247); Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Earloops (28797); Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Earloops, WrapAround Visor (28800); Fluidshield* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (47107); Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with Visor (47137); Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, WrapAround Visor (47147)

Regulation Number: 21 CFR 878.4040

Regulation Name: Surgical Apparel

Regulatory Class: Class II

Product Code: FXX

Dated: September 26, 2024

Received: April 25, 2025

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.

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,


ALLAN GUAN -S

For 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

Indications for Use

510(k) Number (if known)

K243010

Device Name

Fluidshield * 3 Fog-Free Surgical Mask with Wraparound Anti-Glare Visor (28804); Fluidshield * 3 Surgical Mask with SO SOFT* Lining (48208); Fluidshield * 3 Fog-Free Surgical Mask with SO SOFT* Lining (48207); Fluidshield * 3 Fog-Free Surgical Mask with SO SOFT* Lining, with Visor (48237); Fluidshield* 3 Fog-Free Surgical Mask with SO SOFT* Lining, Anti-Glare WrapAround Visor (48247); Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Earloops (28797); Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Earloops, WrapAround Visor (28800); Fluidshield* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (47107); Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with Visor (47137); Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, WrapAround Visor (47147)

Indications for Use (Describe)

The Fluidshield* 3 Surgical Mask(s) and Fluidshield* 3 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* 3 Surgical Masks(s) and Fluidshield* 3 Procedure Face 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.

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510(k) Summary – K243010

Date Summary was Prepared	May 29, 2025
510(k) Submitter	O & M Halyard, Inc. 1220 Old Alpharetta Rd, Suite 320 Alpharetta, Georgia 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	<p><u>Surgical Masks</u></p> <p>Fluidshield * 3 Fog-Free Surgical Mask with Wraparound Anti-Glare Visor (28804)</p> <p>Fluidshield * 3 Surgical Mask with SO SOFT* Lining (48208)</p> <p>Fluidshield * 3 Fog-Free Surgical Mask with SO SOFT* Lining (48207)</p> <p>Fluidshield * 3 Fog-Free Surgical Mask with SO SOFT* Lining, with Visor (48237)</p> <p>Fluidshield* 3 Fog-Free Surgical Mask with SO SOFT* Lining, Anti-Glare WrapAround Visor (48247)</p> <p><u>Procedure Masks</u></p> <p>Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Earloops (28797)</p> <p>Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Earloops, WrapAround Visor (28800)</p> <p>Fluidshield* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (47107)</p> <p>Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with Visor (47137)</p> <p>Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, WrapAround Visor (47147)</p>
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	<p>The subject device(s) are ASTM F2100 Level 3 (orange in color) Surgical and Procedure Mask(s). The Fluidshield* 3 Surgical Mask(s) and Fluidshield* 3 Procedure Masks 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. A malleable nosepiece is placed within the bindings to conform around the wearer's nose.</p> <p>The Fluidshield* 3 Surgical Mask(s) and Fluidshield* 3 Procedure Mask(s) family will be provided in designs with and without a protective visor. The Fluidshield* 3 Surgical Mask(s) and Fluidshield* 3 Procedure Mask(s) family are single use, disposable devices, provided non-sterile.</p>
Indications for Use	<p>The Fluidshield* 3 Surgical Mask(s) and Fluidshield* 3 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* 3 Surgical Mask(s) and Fluidshield* 3 Procedure Face Mask(s) are single use, disposable device(s), provided non-sterile.</p>

	Subject Devices K243010	Predicate Device K111402	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	<p><u>Surgical Masks</u></p> <p>Fluidshield * 3 Fog-Free Surgical Mask with Wraparound Anti-Glare Visor (28804)</p> <p>Fluidshield * 3 Surgical Mask with SO SOFT* Lining (48208)</p> <p>Fluidshield * 3 Fog-Free Surgical Mask with SO SOFT* Lining (48207)</p>	<p>KC200 Procedure Mask</p> <p>KC200 Procedure Mask, fog-free with visor</p> <p>KC200 Surgical Mask, fog-free</p> <p>KC200 Surgical Mask, fog-free with visor</p> <p>KC300 Procedure Mask, Fluidshield*, fog-free</p> <p>KC300 Procedure Mask, Fluidshield*, fog-free with visor</p>	<p>Similar</p> <p>There are differing inner lining materials and differing options than cleared previously.</p>

	<p>Fluidshield * 3 Fog-Free Surgical Mask with SO SOFT* Lining, with Visor (48237)</p> <p>Fluidshield* 3 Fog-Free Surgical Mask with SO SOFT* Lining, Anti-Glare WrapAround Visor (48247)</p> <p><u>Procedure Masks</u></p> <p>Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Earloops (28797)</p> <p>Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Earloops, WrapAround Visor (28800)</p> <p>Fluidshield* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (47107)</p> <p>Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with Visor (47137)</p> <p>Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, WrapAround Visor (47147)</p>	<p>KC300 Surgical Mask, Fluidshield*, fog-free</p> <p>KC300 Surgical Mask, Fluidshield*, fog-free with visor</p>	
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Intended Use	The Fluidshield* 3 Surgical Mask(s) and Fluidshield* 3 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* 3 Surgical Mask(s) and Fluidshield* 3 Procedure Mask(s) are single use, disposable device(s), provided non-sterile.	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 and KC300 face mask(s) is a single use, disposable device(s), provided non-sterile.	Same This submission does not cover the KC 200 Blue Surgical or Procedure Masks.
Materials of Construction for Surgical Mask Family			
Outer Layer	Spunbond polypropylene (or) Polyester Cellulose	Spunbond polypropylene	Similar - Additional material was tested and is safe and effective.
2 nd Layer	Spunbond polypropylene	Spunbond polypropylene	Same
Media Filter	Meltblown polypropylene	Meltblown polypropylene	Same
Inner Layer	Polyethylene Polyester (or) Polyester Cellulose	Polyester Cellulose	Different - Additional material was tested and is safe and effective.
Bindings	Spunbond polypropylene, Polyester spunlace	Spunbond polypropylene, Polyester spunlace	Same
Ties (Surgical)	Spunbond polypropylene	Spunbond polypropylene	Same
Foam	Polyester/Polyester Spunlace	Polyester	Same
Visor (certain designs)	Polyester Film	Polyester Film	Same
Nose Wire	Aluminum	Aluminum	Same
Materials of Construction for Procedure Mask Family			
Outer Layer	Spunbond polypropylene	Spunbond polypropylene	Same
2 nd Layer	Spunbond polypropylene	Spunbond polypropylene	Same
Media Filter	Meltblown polypropylene	Meltblown polypropylene	Same
Inner Layer	Polyethylene Polyester (or) Polyester Cellulose	Polyester Cellulose	Different - Additional material was tested and is safe and effective.
Bindings	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 (some designs)	Polyester Film	Polyester Film	Same
Nose Wire	Aluminum	Aluminum	Same
Design Attributes for Surgical Masks			
# of Layers	4-layer	4-layer	Same
Color	Orange	Orange	Same
Ties (Surgical)	Yes	Yes	Same
Visor	Some Designs	Some Designs	Same
Nose Wire	Enclosed	Enclosed	Same
Design Attributes for Procedure Masks			
# of Layers	4-layer	4-layer	Same
Color	Orange	Orange	Same
Earloops (Procedure)	Yes	Yes	Same
Visor	Some Designs	Some Designs	Same
Performance Data/Product Claims			
Fluid Resistance	3	3	Same
EN 14683	Yes	No	Different
Single Use Device	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same



Non-Clinical Performance Testing

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
Face Mask Performance	ASTM F2100	ASTM F2100 Level 3	Pass (28800, 28804, 47137, 48207)
<i>Bacterial Filtration Efficiency</i>	<i>ASTM F2101</i>	<i>≥98%</i>	<i>Pass</i>
<i>Particulate Filtration Efficiency</i>	<i>ASTM F2299</i>	<i>≥98%</i>	<i>Pass</i>
<i>Differential Pressure</i>	<i>EN 14683</i>	<i><6.0 mmH₂O/cm²</i>	<i>Pass</i>
<i>Fluid Resistance</i>	<i>ASTM F1862</i>	<i>160 mmHg</i>	<i>Pass</i>
<i>Flammability</i>	<i>16 CFR Part 1610</i>	<i>Class 1</i>	<i>Pass</i>
Biocompatibility	ISO 10993		Pass (28800, 28804, 47107, 48207)
<i>Cytotoxicity</i>	<i>ISO 10993-5</i>	<i>Non-cytotoxic</i>	<i>Pass</i>
<i>Sensitization</i>	<i>ISO 10993-10</i>	<i>Non-sensitizing</i>	<i>Pass</i>
<i>Irritation</i>	<i>ISO 10993-10</i>	<i>Non-irritant</i>	<i>Pass</i>

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.