



March 18, 2026

O&M Halyard, Inc.
Anureet Singh
Regulatory Affairs Manager
1220 Old Alpharetta Rd.
Suite 320
Alpharetta, Georgia 30005

Re: K251967

Trade/Device Name: HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops; HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with WrapAround Visor

Regulation Number: 21 CFR 878.4040

Regulation Name: Surgical Apparel

Regulatory Class: Class II

Product Code: FXX

Dated: February 11, 2026

Received: February 12, 2026

Dear Anureet Singh:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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)

K251967

Device Name

HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops;

HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with WrapAround Visor

Indications for Use (Describe)

The HALYARD* FLUIDSHIELD* 3 Fog-Free 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. These are single use, disposable device(s), provided nonsterile.

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 **K251967**

Submitter: O&M Halyard, Inc.
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Fax: 804-723-7100

Regulatory Contact: Anureet Singh
Regulatory Affairs Manager

Date of Summary: 3 March 2026

Device Trade Name: HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops; HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with WrapAround Visor

Common Name: Surgical Mask

Classification Name: Mask, Surgical (21 CFR 880.4040, Product Code FXX)

Predicate Device: K111402 (KC300 Procedure Face Masks)

Device Description: The HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, and HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with WrapAround Visor, are four-layer masks, constructed of well-known non-woven materials. Both masks are provided with earloops and a malleable nosepiece, placed within the bindings for comfort, to conform to the curvature of the wearer's nose.

Indications for Use:

The HALYARD* FLUIDSHIELD* 3 Fog-Free 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. These are single use, disposable device(s), provided nonsterile.

Technological Characteristics Comparison Table:

	Subject Device: (K251967)	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	HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops; HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with WrapAround Visor	KC300 Procedure Mask, Fluidshield*, Fog-Free	Similar – The new trade name replaces the old one
Indication for Use	The HALYARD* FLUIDSHIELD* 3 Fog-Free 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. These are single use, disposable device(s), provided nonsterile.	The Kimberly-Clark, KC200 and KC300 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, KC200 and KC300 face mask(s) is a single use, disposable device(s), provided non-sterile.	Similar – The new trade name replaces the old one
Material Composition for Non-Visor Mask			
Outer Layer	Blue Polypropylene Spunbond	Orange Polypropylene Spunbond	Similar
Second Layer	White Polypropylene Spunbond	Orange Polypropylene Spunbond	Similar
Third Layer	White Polypropylene Meltblown	White Polypropylene Meltblown	Same
Inner Layer	Polyethylene Terephthalate (Polyester) /Polyethylene BICO	White Polyester Cellulose	Different
Top Binding	White Polyester Spunlace	White Polyester Spunlace	Same
Lower Binding	White Polyester Spunlace	White Polyester Spunlace	Same
Wire	Aluminum	Aluminum	Same
Foam	Blue Polyester Foam/Spunlaced Polyester Laminate	Blue Polyester Foam/Spunlaced Polyester Laminate	Same
Earloop	Polyester/Lycra	Polyester/Lycra	Same
On Mask Printing	Ink, blue	Ink, blue	Same
Design Attributes for Non-Visor Mask			
Style	Flat Pleated	Flat Pleated	Same
Dimension (width)	6.875" ± 0.125"	7" ± 0.125"	Similar
Dimension (length)	3.625" ± 0.125"	3.625" ± 0.125"	Same
Method for Bonding Layers	Ultrasonic bonding	Ultrasonic bonding	Same
Material Composition for Visor Mask			
Outer Layer	Blue Polypropylene Spunbond	Orange Polypropylene Spunbond	Similar
Second Layer	White Polypropylene Spunbond	Orange Polypropylene Spunbond	Similar
Third Layer	White Polypropylene Meltblown	White Polypropylene Meltblown	Same
Inner Layer	Polyethylene Terephthalate (Polyester) /Polyethylene BICO	White Polyester Cellulose	Different
Top Binding	White Polypropylene Spunbond	White Polypropylene Spunbond	Same
Lower Binding	White Polyester Spunlace	White Polyester Spunlace	Same
Wire	Aluminum	Aluminum	Same
Foam	Blue Polyester Foam/Spunlaced Polyester Laminate	Blue Polyester Foam/Spunlaced Polyester Laminate	Same

Earloop	Polyester/Lycra	Polyester/Lycra	Same
Visor with Binding	Polyester Film with Black Polyester Spunlace	Polyester Film with Black Polyester Spunlace	Same
Design Attributes for Visor Mask			
Style	Flat Pleated	Flat Pleated	Same
Dimension (width)	6.875" ± 0.125"	6.875" ± 0.125"	Same
Dimension (length)	3.625" ± 0.125"	3.625" ± 0.125"	Same
Method for Bonding Layers	Ultrasonic bonding	Ultrasonic bonding	Same
Performance Data/Product Claims			
ASTM F2100 Level	3	3	Same
EN14683 Type	IIR	N/A	Different
Biocompatibility ISO 10993	Non-sensitizing Not acutely toxic Non-Irritating	Non-sensitizing Not acutely toxic Non-Irritating	Same
Single Use Device	Yes	Yes	Same
Shelf Life	5 year	N/A	Different

Summary of Non-Clinical Performance Testing
Performance Testing
(Bench):

Performance testing of the HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, and the HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with WrapAround Visor, was evaluated, and the results showed that acceptance criteria were met.

Purpose	Test	Acceptance Criteria	Result
Face Mask Performance	ASTM F2100	ASTM F2100 Level 3	Pass
Bacterial Filtration Efficiency	ASTM F2101	≥98%	Pass
Particulate Filtration Efficiency	ASTM F2299	≥98%	Pass
Differential Pressure	EN 14683	<6.0 mm H ₂ O/cm ²	Pass
Fluid Resistance	ASTM F1862	160 mmHg	Pass
Flammability	16 CFR Part 1610	Class 1	Pass
Microbial Cleanliness	ISO 11737-1	≤30 cfu/g	Pass
Biocompatibility	ISO 10993		Pass
Systemic Toxicity	ISO 10993-11 Systemic Injection Test	Under the conditions of the testing, no signs of acute toxicity	Pass
Sensitization	ISO 10993-10 Kligman/Guinea Pig Maximization Test	Under the conditions of the testing, non-sensitizing 0% sensitization	Pass
Irritation	ISO 10993-23 Intracutaneous Injection Test	Under the conditions of the testing, non-irritating and no significant biological reaction	Pass
Cytotoxicity	ISO 10993-5 L929 MEM Elution Test	Under the conditions of the testing of the mask body, non-cytotoxic	Pass

(Clinical): No clinical testing required to support the submission.

Conclusions: The conclusions drawn from the non-clinical tests demonstrate that the subject device, the HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops; HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with WrapAround Visor, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the KC300 Procedure Face Masks (K111402).