December 11, 2025

O&M Halyard, Inc.
Anureet Singh
Regulatory Affairs Manager
1220 Old Alpharetta Rd
Suite 320
Alpharetta, Georgia 30022

Re: K252941
Trade/Device Name: HALYARD* Adult Face Mask with SO SOFT* Lining and SO SOFT* Earloops
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 15, 2025
Received: September 15, 2025

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 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
DHT4B: Division of Infection Control
and Plastic 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)*
K252941

Device Name
HALYARD* Adult Face Mask with SO SOFT* Lining and SO SOFT* Earloops

Indications for Use *(Describe)*
The HALYARD* Adult 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. These 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Summary

Submitter: O&M Halyard, Inc.
1220 Old Alpharetta Rd, Suite 320
Alpharetta, GA 30005
Phone: 804-723-7000/800-488-8850
Fax: 804-723-7100

Regulatory Contact: Anureet Singh
Regulatory Affairs Manager

Date of Summary: 11 December 2025

Device Trade Name: HALYARD* Adult Face Mask with SO SOFT* Lining and SO SOFT* Earloops

Common Name: Surgical Mask

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

Predicate Device: K232777 - HALYARD* FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender (25868)

Device Description: The HALYARD* Adult Face Mask with SO SOFT* Lining and SO SOFT* Earloops, is a three-layer mask, constructed of well-known non-woven materials. The mask is 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* Adult 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 non-sterile.

Technological Characteristics Comparison Table:

| | **Subject Device:** | **Predicate Device: (K232777)** | **Comparison** |
|---|---|---|---|
| Device Trade Name | HALYARD* Adult Face Mask with SO SOFT* Lining and SO SOFT* Earloops | HALYARD* FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops | Similar – The new trade name replaces the old one |
| 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 |
| Indication for Use | The HALYARD* Adult Face Mask(s) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body | The FLUIDSHIELD* 1 Procedure Mask(s) are intended to be worn to protect both the patient and healthcare personnel from transfer of | Similar – The new trade name |

| | | | |
|---|---|---|---|
| | 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 non-sterile. | 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(s) are single use, disposable device(s), provided nonsterile. | replaces the old one |
| **Material Composition** | | | |
| Outer Layer | Disney Printed Polyester/Cellulose | Lavender Polypropylene Spunbond | Different - Material was tested and is safe and effective |
| Second Layer | White Polypropylene Meltblown | White Polypropylene Meltblown | Same |
| Inner Layer | Polyethylene Terephthalate (Polyester) /Polyethylene Bicomponent | Polyethylene Terephthalate (Polyester) /Polyethylene Bicomponent | Same |
| Bindings | White Polyester Spunlace | White Polyester Spunlace | Same |
| Wire | Polyethylene Coated Steel | Polyethylene Coated Steel | Same |
| Earloop | Polyester/Lycra | Polyester/Lycra | Same |
| On Mask Printing | Ink, blue | Ink, blue | Same |
| **Design Attributes** | | | |
| 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 | 1 | 1 | Same |
| Biocompatibility ISO 10993 | Non-sensitizing<br>Non-toxic<br>Non-irritating | Non-sensitizing<br>Non-toxic<br>Non-irritating | Same |
| Single Use Device | Yes | Yes | Same |

Summary of Non-Clinical Performance Testing

Performance Testing (Bench):

Performance testing of the HALYARD* Adult Face with SO SOFT* Lining and SO SOFT* Earloops, was evaluated, and the results showed that acceptance criteria were met.

| **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 F3502* | *≥80%* | *Pass* |
| *Differential Pressure* | *EN 14683* | *<5.0 mm $H_2O/cm^2$* | *Pass* |

| | | | |
|---|---|---|---|
| *Fluid Resistance* | *ASTM F1862* | *80 mmHg* | *Pass* |
| *Flammability* | *16 CFR Part 1610* | *Class 1* | *Pass* |
| Biocompatibility | ISO 10993 | | Pass |
| *Acute Systemic Toxicity* | *ISO 10993-11*<br>*Systemic Injection Test* | *No Acute Systemic Toxicity*<br>*No signs of toxicity* | *Pass* |
| *Sensitization* | *ISO 10993-10*<br>*Kligman/Guinea Pig Maximization Test* | *Non-sensitizing*<br>*0% sensitization* | *Pass* |
| *Irritation* | *ISO 10993-23*<br>*Intracutaneous Injection Test* | *Non-irritating*<br>*No significant biological reaction* | *Pass* |

Performance Testing (Clinical): No clinical testing required.

Conclusions: The conclusions drawn from the non-clinical tests demonstrate that the subject device, the HALYARD* Adult Face Mask with SO SOFT* Lining and SO SOFT* Earloops, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the HALYARD* FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (K232777).