January 8, 2024

Owens & Minor (O&M) Halyard, Inc.
Anureet Singh
Regulatory Affairs Manager
9120 Lockwood Blvd
Mechanicsville, Virginia 23116

Re: K232894
Trade/Device Name: HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining (39123), HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining and Visor (39124)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 15, 2023
Received: September 18, 2023

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232894

Device Name
HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining (39123), HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining and Visor (39124)

Indications for Use *(Describe)*
The Expanded Chamber 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 to blood and body fluids. This is a 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.

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510(k) Summary – K232894

Date of Summary	January 8, 2024
510(k) Submitter	O&M Halyard, Inc. 9120 Lockwood Boulevard Mechanicsville, VA 23116 Phone: 804-723-7000/800-488-8850 Fax: 804-723-7100
Primary Contact for this 510(k) Submission	Anureet Singh Regulatory Affairs Manager
Marketed Common Name	Surgical Mask
Device Submission Trade Name and Description	HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining (39123), HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining and Visor (39124)
Device Product Code, Class and Classification Name	FXX II Surgical Mask (21 CFR 878.4040)
Predicate Device	FLUIDSHIELD Surgical Mask with Expanded Chamber (K143287)
Subject Device Description	The subject devices are ASTM F2100 Level 2 (blue and white in color) Surgical Masks. The HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining (39123) and HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining and Visor (39124) are a four- layer mask, constructed of well-known non-woven materials used in facial protection. A malleable nosepiece is placed within the bindings for comfort and individualized fit around the wearer's nose. When compared to a pleated/flat mask, the subject devices have a “duckbill” shape, which expands the volume of the chamber created when the mask is worn. The HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber that are the subject of this submission are provided with a visor (39124). These masks are single use, disposable devices, provided non-sterile. The subject devices, the HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining (39123) and HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining and Visor (39124), are the same devices as cleared under K143287.
Indications for Use	The Expanded Chamber 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

Technological Characteristics Comparison Table

	Subject Device HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining (39123)	**Subject Device** HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining and Visor (39124)	**Predicate Device** FLUIDSHIELD Surgical Mask with Expanded Chamber (K143287)	**Comparison**
FDA Product Code	FXX	FXX	FXX	Same
FDA Classification	Class II	Class II	Class II	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	21 CFR 878.4040	Same
Common Name	Surgical Mask	Surgical Mask	Surgical Mask	Same
Device Trade Name	HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining (39123)	HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining and Visor (39124)	FLUIDSHIELD Surgical Mask with Expanded Chamber	Same
Indications for Use	The Expanded Chamber 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	The Expanded Chamber 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	The Expanded Chamber Surgical Face 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	Same

Design Attributes				
	Subject Device HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining (39123)	**Subject Device** HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining and Visor (39124)	**Predicate Device** FLUIDSHIELD Surgical Mask with Expanded Chamber (K143287)	**Comparison**
Outer Layer	Spunbond polypropylene	Spunbond polypropylene	Spunbond polypropylene	Same
Middle Layer 1	Spunbond polypropylene	Spunbond polypropylene	Spunbond polypropylene	Same
Middle Layer 2	Meltblown polypropylene	Meltblown polypropylene	Meltblown polypropylene	Same
Inner Layer	Polyethylene/polyester	Polyethylene/polyester	Polyethylene/polyester	Same
Bindings	Spunbond polypropylene	Spunbond polypropylene	Spunbond polypropylene	Same
Ties	Polyester spunlace	Polyester spunlace	Polyester spunlace	Same
Visor	[redacted]	Polyester	Polyester	Same
Nose wire	Polyethylene coated galvanized steel	Polyethylene coated galvanized steel	Polyethylene coated galvanized steel	Same
Number of Layers	4	4	4	Same
Color	Blue print	Blue print	Blue print	Same
Style	Duckbill with ties	Duckbill with ties	Duckbill with ties	Same
ASTM Level	2	2	2	Same
Single Use	Yes	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Shelf Life	5-year	5-year	5-year	Same

Summary of Non-Clinical Performance Testing:

Performance testing of the HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining was evaluated, and the results showed that acceptance criteria were met.

Purpose	**Test**	**Acceptance Criteria**	**Result**
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		Pass
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:

N/A.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining (39123) and HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining and Visor (39124) are as safe, as effective and performs as well as or better than the legally marketed FLUIDSHIELD Surgical Mask with Expanded Chamber (K143287).