



May 16, 2024

Owens & Minor (O&M) Halyard, Inc.
Gabriel Dockery
Specialist, Global Regulatory Affairs
9120 Lockwood Blvd
Mechanicsville, Virginia 23116

Re: K232849

Trade/Device Name: Halyard Tri-Layer AAMI 3 Isolation Gown, L, Blue (54310), Halyard Tri-Layer
AAMI 3 Isolation Gown, X-Large, Blue (54311)

Regulation Number: 21 CFR 878.4040

Regulation Name: Surgical Apparel

Regulatory Class: Class II

Product Code: FYC

Dated: April 17, 2024

Received: April 18, 2024

Dear Gabriel Dockery:

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,

The logo for the U.S. Food and Drug Administration (FDA) is displayed in a light blue, semi-transparent font. It consists of the letters 'FDA' in a bold, sans-serif typeface. The 'F' and 'D' are connected at the top, and the 'A' is positioned to the right of the 'D'. The logo is centered horizontally and partially overlaps the signature text below it.

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

Indications for Use

510(k) Number (if known)
K232849

Device Name

Halyard Tri-Layer AAMI 3 Isolation Gown, L, Blue (54310), Halyard Tri-Layer AAMI 3 Isolation Gown, X-Large, Blue (54311)

Indications for Use (Describe)

Halyard Tri-Layer AAMI 3 Isolation Gowns are intended to be worn by healthcare personnel in isolation applications to provide moderate barrier protection for healthcare personnel and patients from microorganism transfer, body fluids, and particulate matter. The gowns are non-sterile, single use, and meet AAMI PB70:2012 level 3 Liquid Barrier performance requirements. Not intended for use in the operating room.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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

510(k)

Number: K232849

Date

Prepared: May 16, 2024

510(k)

Sponsor: O&M Halyard Inc.
9120 Lockwood Boulevard
Mechanicsville, VA 23116

Regulatory

Contact: Gabriel Dockery
1 Edison Drive
Alpharetta, GA 30005
470-280-4388
Gabriel.dockery@hyh.com

Device Trade

Names: Halyard Tri-Layer AAMI 3 Isolation Gowns

Device**Common**

Name: Isolation Gown

FDA Device

Product Code: FYC

FDA Device

Classification: Class II

FDA Device

Name: Gown, Isolation, Surgical

FDA**Regulation**

Number: 21 CFR 878.4040

Predicate

Device: K160361 – PRIMAGARD AAMI PB70:2012 Level 3 gowns

Device**Descriptions:**

The Halyard Tri-Layer AAMI 3 Isolation Gown (“Isolation Gown”) is a single use gown, supplied non-sterile. The gowns come in the following sizes: Large, X-Large. These surgical gowns are apparel that are intended to be worn by healthcare professionals to protect from varying levels of fluid contact (low to moderate). These surgical gowns meet the AAMI PB70:2012 Liquid Barrier Performance Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities, Level 3 Requirements. These Isolation Gowns are manufactured from three-layer full length polypropylene SMS material, with neck tape, elastic cuffs, and waist belt closure systems.

Indications for Use for Halyard Tri-Layer AAMI 3 Isolation Gowns : Halyard Tri-Layer AAMI 3 Isolation Gowns are intended to be worn by healthcare personnel in isolation applications to provide moderate barrier protection for healthcare personnel and patients from microorganism transfer, body fluids, and particulate matter. The gowns are non-sterile, single use, and meet AAMI PB70:2012 level 3 Liquid Barrier performance requirements. Not intended for use in the operating room.

Intended Use : The Halyard Tri-Layer AAMI 3 Isolation Gowns are non-sterile, single use surgical apparel intended to be worn by healthcare professionals for protection from varying levels of fluid contact (low to moderate).

Product Codes Subject to this Premarket Notification

Product Code	Device Description
54310	Halyard Tri-Layer AAMI 3 Isolation Gown, L, Blue
54311	Halyard Tri-Layer AAMI 3 Isolation Gown, X-Large, Blue

Technological Characteristic Comparison Table

Attribute	Subject Device (Halyard Tri-Layer AAMI 3 Isolation Gowns)	Predicate Device – PRIMAGARD Isolation Gown (AAMI PB70 level 3)	Comparison
FDA Classification Code	FYC	FYC	Identical
FDA Device Classification	Class II	Class II	Identical
Common Device Name	Surgical Isolation Gown	Surgical Isolation Gown	Identical
Trade Name	Halyard Tri-Layer AAMI 3 Isolation Gown	PRIMAGARD AAMI PB70:2012 Level 3 Gown	Similar – the difference of Trade Name has no impact on the safety and effectiveness of the device itself. It allows only for the User to easily identify the product.
Indications for Use	Halyard Tri-Layer AAMI 3 Isolation Gowns are intended to be worn by healthcare personnel in isolation applications to provide moderate barrier protection for healthcare personnel and patients from microorganism transfer, body fluids, and particulate matter. The gowns are non-sterile, single use, and meet AAMI PB70:2012 level 3 Liquid Barrier performance requirements. Not intended for use in the operating room.	PRIMAGARD Level 3 Isolation Gowns are intended to be worn by healthcare personnel in isolation applications to provide moderate barrier protection for health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material. The PRIMAGARD Isolation Gowns of this 510(k) meet the requirements of level 3 Liquid Barrier Performance as per AAMI PB70:2012 and are provided non-sterile and are single use only.	Both subject and predicate device are tested to be performant to the same safety and performance level as required by AAMI PB70:2012.
How the Device is Supplied	Bulk Non-Sterile	Bulk Non-Sterile	Identical
Sterilization Method	N/A	N/A	Identical
SAL	N/A	N/A	Identical
Gown Color	Blue	Blue, Yellow	Similar – Color options do not materially impact device safety or performance

Attribute	Subject Device (Halyard Tri-Layer AAMI 3 Isolation Gowns)	Predicate Device – PRIMAGARD Isolation Gown (AAMI PB70 level 3)	Comparison
Shelf-Life	3 years	5 years	Similar – both devices are tested to be performant over their intended shelf life
Gown Sizes	Large, X-Large	Universal, X-Large	Similar – gown sizing does not materially impact device safety or performance.
Construction Overview	The subject devices are comprised of non-woven fabrics, Spunbond / Meltblown / Spunbond (SMS) polypropylene. All construction seams use ultrasonic bonding as seam closure method.	PRIMAGARD Level 3 Isolation Gowns are made of SMS non woven polypropylene material, contain ultrasonic seams, provide full coverage (level 3 as per PB70) and are not made with natural rubber latex.	Identical
Critical Zone	SMS Polypropylene	SMS Polypropylene	Identical
Not made with natural rubber latex	True	True	Identical
ANSI/AAMI PB70: 2012 Level 3 Liquid Barrier Requirements for Critical Zone	Meets standard requirements for Level 3 Liquid Barrier	Meets standard requirements for Level 3 Liquid Barrier	Identical
Grab Tensile, Peak Stretch, and Peak Energy Test	Tested to D5034 – Met Acceptance Criteria	Tested to D5034 – Met Acceptance Criteria	Identical
Tear Strength	Tested to ASTM D5587. Met acceptance criteria	Tested to ASTM D5587. Met acceptance criteria	Identical
Linting	EN ISO 9073-10	Tested to NWSP 160.1.R0. Met acceptance criteria	Similar – Both Standards provide similar reliability and predictive power when determining linting potential.
Seam Strength	ASTM D1683	ASTM D5035	ASTM D1683 methods are more applicable to the attribute being

Attribute	Subject Device (Halyard Tri-Layer AAMI 3 Isolation Gowns)	Predicate Device – PRIMAGARD Isolation Gown (AAMI PB70 level 3)	Comparison
			verified. Thus, this difference does not imply dissimilarity in performance with the predicate device.
Heat Loss	Not Applicable	ASTM F1868	This test is not applicable to the indication of use as described above. Therefore, its omission does not impact safety, performance, or similarity to the predicate device.
Water Vapor Transmission	Not Applicable	Tested to ASTM E96. Met acceptance criteria	This test is not applicable to the indication of use as described above. Therefore, its omission does not impact safety, performance, or similarity to the predicate device.
Air Permeability	Not Applicable	Tested to ASTM D737. Met acceptance criteria	This test is not applicable to the indication of use as described above. Therefore, its omission does not impact safety, performance, or similarity to the predicate device.
Biocompatibility	ISO 10993: Cytotoxicity Sensitization Irritation Title device passed all testing endpoints.	ISO 10993: Cytotoxicity Sensitization Irritation Title device passed all testing endpoints.	Identical

Attribute	Subject Device (Halyard Tri-Layer AAMI 3 Isolation Gowns)	Predicate Device – PRIMAGARD Isolation Gown (AAMI PB70 level 3)	Comparison
Liquid Barrier: Hydrostatic Pressure	AATCC 127 ≥ 50 cm H ₂ O	AATCC 127 ≥ 50 cm H ₂ O	Identical
Liquid Barrier: Impact Penetration	AATCC 42 ≤ 1.0g	AATCC 42 ≤ 1.0g	Identical

Testing that supports the subject devices shows that the Halyard Tri-Layer AAMI 3 Isolation Gowns are similar to the predicate device PRIMAGARD Isolation Gown (AAMI PB70 level 3) (K160361) in design, intended use, sterility, and technological characteristics. The gowns meet the Level 3 AAMI PB70:2012 Liquid Barrier classification.

Summary of Non-Clinical Testing

Test	Method	Acceptance Criteria and Sample Size per lot	Result
Spray Impact - Front/Back/Sleeve Panel	AATCC 42	≤ 1.0g n=35, c=3	Pass
Spray Impact - Sleeve/Armhole Seam/Shoulder Seam	AATCC 42	≤ 1.0g n=35, c=3	Pass
Spray Impact – Front Tie	AATCC 42	≤ 1.0g n=35, c=3	Pass
Static Decay MD	STM-00180	USL 0.5s n=36, c=0	Pass
Static Decay CD	STM-00180	USL 0.5s n=36, c=0	Pass
ISO L929 MEM Elution Cytotoxicity	ISO 10993-5:2009	≤ Grade 2 (mild reactivity)	Pass
ISO Irritation Test	ISO 10993-10:2010	≤ 0.4 Primary Irritation (PII)	Pass
ISO Kligman Maximization Test	ISO 10993-10:2010	Grade < 1	Pass

Grab Strength MD	ASTM D5034	LSL 44N One-sided 95/95 tolerance limit, K-factor 2.309, n=24	Pass
Grab Strength CD	ASTM D5034	LSL 44N One-sided 95/95 tolerance limit, K-factor 2.309, n=24	Pass
Tear Strength MD	ASTM D5733	LSL 10N One-sided 95/95 tolerance limit, K-factor 2.309, n=24	Pass
Tear Strength CD	ASTM D5733	LSL 10N One-sided 95/95 tolerance limit, K-factor 2.309, n=24	Pass

Hydrostatic Pressure – Front/Back/Sleeve/ Panel	AATCC 127	≥ 50 cmH2O n=35, c=3	Pass
Hydrostatic Pressure – Sleeve/Armhole Seam/Shoulder Seam	AATCC 127	≥ 50 cmH2O n=35, c=3	Pass
Hydrostatic Pressure – Front Tie	AATCC 127	≥ 50 cmH2O n=35, c=3	Pass
Basis Weight (Baseline Only)	ASTM D3776	LSL 32.4USL 39.6 Two-sided 95/93.5 tolerance limit, K-factor 2.654,n=18	Pass
Flammability MD (Baseline Only)	CFR 1610	Class 1, ≤ 3.5s n=49, c=0	Pass
Flammability CD (Baseline Only)	CFR 1610	Class 1, ≤ 3.5s n=49, c=0	Pass
Seam Strength - Sleeve Seam	ASTM D1683	LSL 30N One-sided 95/95 tolerance limit,K-factor 2.309, n=24	Pass
Seam Strength - Armhole Seam	ASTM D1683	LSL 30N One-sided 95/95 tolerance limit,K-factor 2.309, n=24	Pass
Lint Generation - SMS	EN ISO 9073-10	Log10 (lint count) ≤ 4,0 n=30	Pass

Summary of Clinical Testing

N/A.

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the Halyard Tri-Layer AAMI 3 Isolation Gowns are as safe, as effective, and perform as well as or better than the K160361 – PRIMAGARD AAMI PB70:2012 Level 3 gowns.