March 16, 2020

O&M Halyard, Inc
Kimberly Lewis
Sr. Manager, Regulatory Affairs
9120 Lockwood Blvd
Mechanicsville, Virginia 23116

Re: K200522
Trade/Device Name: AERO CHROME* Breathable Performance Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: February 28, 2020
Received: March 2, 2020

Dear Kimberly Lewis:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Elizabeth F. Claverie, MS
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200522

Device Name
AERO CHROME* Breathable Performance Surgical Gowns

Indications for Use *(Describe)*

The AERO CHROME* Breathable Performance Surgical Gowns are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The AERO CHROME* Breathable Performance Surgical Gowns meet the Level 4 AAMI PB70:2012 Liquid Barrier classifications.

Non-Sterile Product Codes

Product Code	Device Description	Gown Size
44661NS	AERO CHROME* Breathable Performance Surgical Gown, S	Small
44662NS	AERO CHROME* Breathable Performance Surgical Gown, L	Large
44663NS	AERO CHROME* Breathable Performance Surgical Gown, L - Handi-Bin	Large
44664NS	AERO CHROME* Breathable Performance Surgical Gown, XL	X-Large
44665NS	AERO CHROME* Breathable Performance Surgical Gown, XL - Handi-Bin	X-Large
44666NS	AERO CHROME* Breathable Performance Surgical Gown, XXL	XX-Large
44667NS	AERO CHROME* Breathable Performance Surgical Gown, L, X-Long	Large, X-Long
44668NS	AERO CHROME* Breathable Performance Surgical Gown, XL, X-Long	X-Large, X-Long
44669NS	AERO CHROME* Breathable Performance Surgical Gown, XXL, X-Long	XX-Large, X-Long
44670NS	AERO CHROME* Breathable Performance Surgical Gown with Towel in Overwrap, L - Handi-Bin	Large
44671NS	AERO CHROME* Breathable Performance Surgical Gown with Towel in Overwrap, XL - Handi-Bin	X-Large

Sterile Product Codes

Product Code	Device Description	Gown Size
44672	AERO CHROME* Breathable Performance Surgical Gown with Towel, S	Small
44673	AERO CHROME* Breathable Performance Surgical Gown with Towel, L	Large
44674	AERO CHROME* Breathable Performance Surgical Gown with Towel, XL	X-Large
44675	AERO CHROME* Breathable Performance Surgical Gown with Towel, XXL	XX-Large
44676	AERO CHROME* Breathable Performance Surgical Gown with Towel, XXXL	XXX-Large
44677	AERO CHROME* Breathable Performance Surgical Gown with Towel, L, X-Long	Large, X-Long
44678	AERO CHROME* Breathable Performance Surgical Gown with Towel, XL, X-Long	X-Large, X-Long
44679	AERO CHROME* Breathable Performance Surgical Gown with Towel, XXL, X-Long	XX-Large, X-Long

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

510(k) Number: K200522

Date Prepared: February 28, 2020

510(k) Sponsor:
O&M Halyard Inc.
9120 Lockwood Boulevard
Mechanicsville, VA 23116

Regulatory Contact:
Kimberly Lewis
5405 Windward Pkwy
3rd Floor West
Alpharetta, GA 30004
470-280-4388
Kimberly.lewis@hyh.com

Device Trade Name: AERO CHROME* Breathable Performance Surgical Gowns

Device Common Name: Surgical Gown

FDA Device Product Code: FYA

FDA Device Classification: Class II

FDA Device Name: Gown, Surgical

FDA Regulation Number: 21 CFR 878.4040

Predicate Device: K153255 – AERO CHROME* Breathable Performance Surgical Gowns

Device Description:

The AERO CHROME* Breathable Performance Surgical Gowns have a SMS/F/SMS design (Spunbond-Meltblown-Spunbond/Film/Spunbond-Meltblown-Spunbond) that provides a PB70:2012 Level 4 Liquid Barrier Performance Barrier in the critical zone. The back of the gown has a Spundbond-Meltblown-Spunbond (SMS) fabric which allows for air-breathability with an AAMI Level 1 Liquid Barrier Performance Barrier.

The AERO CHROME* Breathable Performance Surgical Gown is a single use gown, supplied sterile (via Ethylene Oxide) or as bulk non-sterile product. The gowns come in the following various sizes: Small, Large, X-Large, XX-Large, XXX-Large, X-Long XL, X-Long XXL.

Indications for Use:

The AERO CHROME* Breathable Performance Surgical Gowns are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The AERO CHROME* Breathable Performance Surgical Gowns meet the Level 4 AAMI PB70:2012 Liquid Barrier classifications.

Product Codes Subject to this Premarket Notification

Product Code	Device Description
44661NS	AERO CHROME* Breathable Performance Surgical Gown, S (Non-Sterile)
44662NS	AERO CHROME* Breathable Performance Surgical Gown, L (Non-Sterile)
44663NS	AERO CHROME* Breathable Performance Surgical Gown, L - Handi-Bin (Non-Sterile)
44664NS	AERO CHROME* Breathable Performance Surgical Gown, XL (Non-Sterile)
44665NS	AERO CHROME* Breathable Performance Surgical Gown, XL - Handi-Bin (Non-Sterile)
44666NS	AERO CHROME* Breathable Performance Surgical Gown, XXL (Non-Sterile)

44667NS	AERO CHROME* Breathable Performance Surgical Gown, L, X-Long (Non-Sterile)
44668NS	AERO CHROME* Breathable Performance Surgical Gown, XL, X-Long (Non-Sterile)
44669NS	AERO CHROME* Breathable Performance Surgical Gown, XXL, X-Long (Non-Sterile)
44670NS	AERO CHROME* Breathable Performance Surgical Gown with Towel in Overwrap, L - Handi-Bin (Non-Sterile)
44671NS	AERO CHROME* Breathable Performance Surgical Gown with Towel in Overwrap, XL - Handi-Bin (Non-Sterile)
44672	AERO CHROME* Breathable Performance Surgical Gown with Towel, S
44673	AERO CHROME* Breathable Performance Surgical Gown with Towel, L
44674	AERO CHROME* Breathable Performance Surgical Gown with Towel, XL
44675	AERO CHROME* Breathable Performance Surgical Gown with Towel, XXL
44676	AERO CHROME* Breathable Performance Surgical Gown with Towel, XXXL
44677	AERO CHROME* Breathable Performance Surgical Gown with Towel, L, X-Long
44678	AERO CHROME* Breathable Performance Surgical Gown with Towel, XL, X-Long
44679	AERO CHROME* Breathable Performance Surgical Gown with Towel, XXL, X-Long

Technological Characteristic Comparison Table

Attribute	**Predicate Device (AERO CHROME* Breathable Performance Surgical Gown, K153255)**	**Subject Device**	**Comparison Analysis**
FDA Classification Code	FYA	FYA	Identical
FDA Device Classification	Class II	Class II	Identical

Attribute	Predicate Device (AERO CHROME* Breathable Performance Surgical Gown, K153255)	Subject Device	Comparison Analysis
Common Device Name	Surgical Gown	Surgical Gown	Identical
Trade Name	AERO CHROME* Breathable Performance Surgical Gown	AERO CHROME* Breathable Performance Surgical Gown	Identical
Indications for Use	AERO CHROME* Breathable Performance Surgical Gowns are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The AERO CHROME* Breathable Performance Surgical Gowns meet the Level 4 AAMI PB70 Liquid Barrier classifications	AERO CHROME* Breathable Performance Surgical Gowns are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The AERO CHROME* Breathable Performance Surgical Gowns meet the Level 4 AAMI PB70 Liquid Barrier classifications.	Identical
How the Device is Supplied	Sterile or Bulk Non-Sterile	Sterile or Bulk Non-Sterile	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
SAL	10^{-6}	10^{-6}	Identical
Gown Color	Blue	Blue	Identical
Gown Sizes	Small, Large, X-Large, XX-Large, XXX-Large, X-Long XL, X-Long XXL	Small, Large, X-Large, XX-Large, XXX-Large, X-Long XL, X-Long XXL	Identical
Construction Overview	The AERO CHROME* Breathable Performance Surgical Gown is manufactured from a moisture-vapor breathable, repellent, non-woven fabric using a	The AERO CHROME* Breathable Performance Surgical Gown is manufactured from a moisture-vapor breathable, non-woven fabric using a polymer	Similar

Attribute	Predicate Device (AERO CHROME* Breathable Performance Surgical Gown, K153255)	Subject Device	Comparison Analysis
	polymer blend of polypropylene and polyethylene. The front body and sleeve fabric are a three- layer film laminate. This fabric is an S/F/SMS design that is adhesively bonded together. The film itself is a multi-layer polypropylene-based vapor breathable membrane that uses $CaCO_3$ filler to create micropores to allow vapor transmission across the membrane. The polyolefin hot melt adhesive is used to laminate the facing layers to the film layer to complete the composite. Sleeves of the gown are closed with a heat-sealing process to meet AAMI-4 liquid barrier requirements. The back of the AERO CHROME* Breathable Performance Surgical Gown in the non-critical zone is composed of 1.2 osy SMS fabric with an AAMI level 1 liquid barrier protection. The gown film layer is treated with a fluorochemical.	blend of polypropylene and plastomer. The front body and sleeve fabric are a three-layer film laminate. This fabric is an SMS/F/SMS design that is adhesively bonded together. The film itself is a multi-layer polypropylene/plastomer, $CaCO_3$ filled, grey film. The polyolefin hot melt adhesive is used to laminate the facing layers to the film layer to complete the composite. Sleeves of the gown are closed with a heat-sealing process to meet AAMI-4 liquid barrier requirements. The back of the AERO CHROME* Breathable Performance Surgical Gown in the non-critical zone is composed of 1.2 osy SMS fabric with an AAMI level 1 liquid barrier protection.	
Does not contain natural rubber latex	Yes	Yes	Identical

Performance Testing

Predicate Device (AERO CHROME* Breathable Performance Surgical Gowns, K153255)	**Subject Device**	**Comparison Analysis**
ANSI/AAMI PB70: 2012 Level 4 Liquid Barrier Requirements for Critical Zone - Pass	ANSI/AAMI PB70: 2012 Level 4 Liquid Barrier Requirements for Critical Zone - Pass	Identical
ANSI/AAMI PB70: 2012 Level 1 Liquid Barrier Requirements for Non-Critical Zone - Pass	ANSI/AAMI PB70: 2012 Level 1 Liquid Barrier Requirements for Non-Critical Zone - Pass	Identical
Biocompatibility per ISO 10993 – Pass the device under the conditions of the study is non-cytotoxic, non-irritant, and non-sensitizing	Biocompatibility per ISO 10993 – Pass the device under the conditions of the study is non-cytotoxic, non-irritant, and non-sensitizing	Identical
Water Vapor Transmission Rate of Materials (MOCON) - Pass	Water Vapor Transmission Rate of Materials (MOCON) - Pass	Similar
Linting per ISO 9073-10 - Pass	Linting per ISO 9073-10 - Pass	Similar
Standard Test Method for Breaking Strength and Elongation of Textile Fabrics per ASTM D5034 - Pass	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics per ASTM D5034 - Pass	Similar
Peel Strength per STM-00197 - Pass	Peel Strength per STM-00197 - Pass	Similar
Hydrohead Testing – Pass	Hydrohead Testing – Pass	Similar
Abrasion Testing per STM-00149 - Pass	Abrasion Testing per STM-00149 - Pass	Similar
16 CFR, Chapter II – Consumer Product Safety Commission Part 1610 – Standard for the Flammability of Clothing Textiles Class 1 - Pass	16 CFR, Chapter II – Consumer Product Safety Commission Part 1610 – Standard for the Flammability of Clothing Textiles Class 1 – Pass	Identical
Air Permeability (Back of Gown) per STM-00162, NWSP 070.1.RO - Pass	Air Permeability (Back of Gown) per STM-00162 - Pass	Similar

Testing conducted to support the changes of the subject device shows that the AERO CHROME* Breathable Performance Surgical Gown is similar to the predicate device AERO CHROME* Breathable Performance Surgical Gown (K153255) in design, intended use, sterility, and technological characteristics. In the critical zone, the AERO CHROME* Breathable Performance Surgical Gowns meet the Level 4 AAMI

PB70:2012 Liquid Barrier classification. The back of the gown meets the Level 1 AAMI PB70:2012 Liquid Barrier classification.

Summary of Non-Clinical Testing

Standard/Reference	Test Method	Data Generated	Meets Requirements
Spray Impact (Critical Zones)	AATCC 42	Water Resistance	Pass
Hydrostatic Pressure (Critical Zones)	AATCC 127	Water Resistance	Pass
Liquid Barrier Performance	ANSI/AAMI PB70:2012 Level 4	Water Resistance	Pass
Spray Impact (Non-Critical Zones)	AATCC 42	Water Resistance	Pass
Liquid Barrier Performance	ANSI/AAMI PB70:2012 Level 1	Water Resistance	Pass
Grab Tensile, Peak Stretch, and Peak Energy - Nonwovens	ASTM D5034 – 9 2017	Tensile Strength	Pass
Abrasion Resistance of Nonwoven Fabrics	NWSP 020.5.RO (15) 2015	Abrasion Resistance	Pass
Synthetic Blood Penetration	ASTM F1670 (2017)	Resistance to Penetration	Pass
Water Vapor Transmission Rate	NWSP 070.4.RO (15) 2015	Water Vapor Transmission	Pass
180 Degree Peel Strength of Non-Elastic Laminated Nonwovens	STM-00197 Rev 1	Peel Strength	Pass
Linting	ISO 9073-10 2003	Particulate	Pass
Standard for the Flammability for Clothing Textiles	16 CFR 1610	Flammability	Pass
ISO L929 MEM Elution Cytotoxicity	ISO 10993-5:2009	Cytotoxicity	Pass
ISO Indirect Primary Skin Irritation Test	ISO 10993-10:2010	Irritation	Pass
ISO Kligman Maximization Test	ISO 10993-10:2010	Sensitization	Pass
EO Sterilization Residuals	ISO 109937-7:2008 (R) 2012	EO Residuals	Pass
Laster Ignition Resistance	ISO 11810-1:2015	Laser Resistance	Pass

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device.