July 21, 2021

O&M Halyard, Inc
Steve Dowdley
Global Products, Director of Regulatory Affairs
1 Edison Drive
Alpharetta, Georgia 30005

Re: K210688
Trade/Device Name: AERO CHROME* Select Breathable Performance Surgical Gown, AERO CHROME* A-Line Breathable Performance Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: July 16, 2021
Received: July 19, 2021

Dear Steve Dowdley:

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,

Clarence W. Murray, III, PhD
Acting 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 06/30/2023
See PRA Statement below

510(k) Number *(if known)*
K210688

Device Name
AERO CHROME* Select Breathable Performance Surgical Gowns, AERO CHROME* A-Line Breathable Performance Surgical Gowns

Indications for Use *(Describe)*
The AERO CHROME* Select 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 micro-organisms, body fluids, and particulate matter The AERO CHROME* Select Breathable Performance Surgical Gowns meet the Level 4 AAMI PB70:2012 Liquid Barrier classifications

Non-Sterile Product Codes

Product Code	Device Description Gown	Gown Size
44696NS	AERO CHROME* Select Breathable Performance Surgical Gown, L	Large
44697NS	AERO CHROME* Select Breathable Performance Surgical Gown, XL	X-Large
44698NS	AERO CHROME* Select Breathable Performance Surgical Gown, XXL	XX-Large

Sterile Product Codes

Product	Device Description Gown	Gown Size
44699	AERO CHROME*Select Breathable Performance Surgical Gown, L	Large
44706	AERO CHROME* Select Breathable Performance Surgical Gown, XL	X-Large
44707	AERO CHROME* Select Breathable Performance Surgical Gown, XXL	XX-Large

The AERO CHROME* A-Line 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 micro-organisms, body fluids, and particulate matter The AERO CHROME* A-Line Breathable Performance Surgical Gowns meet the Level 4 AAMI PB70:2012 Liquid Barrier classifications.

Sterile Product Codes

Product	Device Description Gown	Gown Size
47580	AERO CHROME* A-Line Breathable Performance Surgical Gown with Towel, XL, X-Long	X-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.

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510(k) Summary

510(k) Number:	K210688
Date Prepared:	March 05, 2021
510(k) Sponsor:	O&M Halyard Inc. 9120 Lockwood Boulevard Mechanicsville, VA 23116
Regulatory Contact:	Steven Dowdley 1 Edison Drive Alpharetta, GA 30005 678-451-8062 Steven.dowdley@hyh.com
Device Trade Names:	AERO CHROME* Select Breathable Performance Surgical Gowns AERO CHROME* A-Line 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:	K200522 – AERO CHROME* Breathable Performance Surgical Gowns

Device Descriptions:	The AERO CHROME* Select 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 is comprised of the identical fabric as the front of the gown and meets AAMI Level 1 Liquid Barrier Performance Barrier. The AERO CHROME* Select 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: Large, X-Large, XX-Large. The AERO CHROME* A-Line 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 is lightweight, air-breathable, and provides AAMI Level 1 protection. The AERO CHROME* A-Line Breathable Performance Surgical Gown is a single use gown, supplied sterile (via Ethylene Oxide) or as bulk non-sterile product. The gowns come in an X-Long, X- Large size.
Indications for Use for AERO CHROME* Select Breathable Performance Surgical Gowns:	The AERO CHROME* Select 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 micro-organisms, body fluids, and particulate matter. The AERO CHROME* Select Breathable Performance Surgical Gowns meet the Level 4 AAMI PB70:2012 Liquid Barrier classifications.
Indications for Use for AERO CHROME* A-Line Breathable Performance Surgical Gowns:	The AERO CHROME* A-Line 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 micro-organisms, body fluids, and particulate matter. The AERO CHROME* A-Line 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
44696NS	AERO CHROME* Select Breathable Performance Surgical Gown, L
44697NS	AERO CHROME* Select Breathable Performance Surgical Gown, XL
44698NS	AERO CHROME* Select Breathable Performance Surgical Gown, XXL
44699	AERO CHROME* Select Breathable Performance Surgical Gown, L
44706	AERO CHROME* Select Breathable Performance Surgical Gown, XL
44707	AERO CHROME* Select Breathable Performance Surgical Gown, XXL
47580	AERO CHROME* A-Line Breathable Performance Surgical Gown with Towel, XL, X-Long

Technological Characteristic Comparison Table

Attribute	Predicate Device (AERO CHROME* Breathable Performance Surgical Gown, K200522)	Subject Device – AERO CHROME* Select Breathable Performance Surgical Gowns, K210688	Subject Device – AERO CHROME* A-Line Breathable Performance Surgical Gowns, K210688	Comparison Analysis
FDA Classification Code	FYA	FYA	FYA	Identical
FDA Device Classification	Class II	Class II	Class II	Identical
Common Device Name	Surgical Gown	Surgical Gown	Surgical Gown	Identical
Trade Name	AERO CHROME* Breathable Performance Surgical Gown	AERO CHROME* Select Breathable Performance Surgical Gown	AERO CHROME* A-Line Breathable Performance Surgical Gown	Similar
Indications for Use	AERO CHROME* Breathable Performance Surgical Gowns are sterile, single use surgical apparel intended to be worn by healthcare professionals	AERO CHROME* Select Breathable Performance Surgical Gowns are sterile, single use surgical apparel intended to be worn by healthcare professionals	AERO CHROME* A-Line Breathable Performance Surgical Gowns are sterile, single use surgical apparel intended to be worn by healthcare professionals	Identical

Attribute	Predicate Device (AERO CHROME* Breathable Performance Surgical Gown, K200522)	Subject Device – AERO CHROME* Select Breathable Performance Surgical Gowns, K210688	Subject Device – AERO CHROME* A-Line Breathable Performance Surgical Gowns, K210688	Comparison Analysis
	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	to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The AERO CHROME* Select Breathable Performance Surgical Gowns meet the Level 4 AAMI PB70 Liquid Barrier classifications.	to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The AERO CHROME* A-Line Breathable Performance Surgical Gowns meet the Level 4 AAMI PB70 Liquid Barrier classifications.	
How the Device is Supplied	Sterile or Bulk Non-Sterile	Sterile or Bulk Non-Sterile	Sterile	Similar
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Identical
SAL	10^{-6}	10^{-6}	10^{-6}	Identical
Gown Color	Grey	Grey	Grey	Identical
Shelf-Life	5 years	5 years	5 years	Identical
Gown Sizes	Small, Large, X-Large, XX-Large, XXX-Large, X-Long XL, X-Long XXL	Large, X-Large, XX-Large	X-Long XL	Similar

Con-struction Overview	The AERO CHROME* Breathable Performance Surgical Gown is manufactured from a moisture-vapor breathable, non-woven fabric using a polymer 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,	The AERO CHROME* Select Breathable Performance Surgical Gown is manufactured from a moisture-vapor breathable, non-woven fabric using a polymer 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,	The AERO CHROME* A-Line Breathable Performance Surgical Gown is manufactured from a moisture-vapor breathable, non-woven fabric using a polymer 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,	Select Gown – Similar A-Line Gown - Identical

Attribute	Predicate Device (AERO CHROME* Breathable Performance Surgical Gown, K200522)	Subject Device – AERO CHROME* Select Breathable Performance Surgical Gowns, K210688	Subject Device – AERO CHROME* A-Line Breathable Performance Surgical Gowns, K210688	Comparison Analysis
	$CaCO_3$ 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.	$CaCO_3$ 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 identical material that comprises the front of the gown also comprises the back of the gown in one continuous material. Therefore, this gown does not have side seams.	$CaCO_3$ 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* A-Line 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	Yes	Identical

Performance Testing

Predicate Device -AERO CHROME* Breathable Performance Surgical Gowns, K200522	**Subject Devices - AERO CHROME* Select Breathable Performance Surgical Gowns and AERO CHROME* A-Line Breathable Performance Surgical Gowns, K210688**	**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	Biocompatibility per ISO 10993 – Pass the device under the conditions of the	Identical

Predicate Device -AERO CHROME* Breathable Performance Surgical Gowns, K200522	Subject Devices - AERO CHROME* Select Breathable Performance Surgical Gowns and AERO CHROME* A-Line Breathable Performance Surgical Gowns, K210688	Comparison Analysis
non-cytotoxic, non-irritant, and non-sensitizing	study is non-cytotoxic, non-irritant, and non-sensitizing	
Water Vapor Transmission Rate of Materials (MOCON) - Pass	Water Vapor Transmission Rate of Materials (MOCON) - Pass	Identical
Linting per ISO 9073-10 - Pass	Linting per ISO 9073-10 - Pass	Identical
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	Identical
Peel Strength per STM-00197 - Pass	Peel Strength per STM-00197 - Pass	Identical
Hydrohead Testing – Pass	Hydrohead Testing – Pass	Identical
Abrasion Testing per STM-00149 - Pass	Abrasion Testing per STM-00149 - Pass	Identical
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

Summary of Non-Clinical Testing

Standard/Reference	Test Method	Data Generated	Meets Requirements
Liquid Barrier Performance	ANSI/AAMI PB70:2012 Level 4	Resistance to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage	Pass

Standard/Reference/ Test Method	Purpose	Acceptance Criteria	Results
Liquid Barrier Performance ANSI/AAMI PB70:2012 Level 1	Determine Water Resistance	Meets standard requirements for Level 1 Liquid Barrier	Pass
Grab Tensile, Peak Stretch, and Peak Energy – Nonwovens ASTM D5034 – 9 2017	Determine Tensile Strength	Meets standard requirements for ASTM D5034 -9 2017	Pass
Abrasion Resistance of Nonwoven Fabrics NWSP 020.5.RO (15) 2015	Evaluate Abrasion Resistance	Meets requirements of standard NWSP 020.5.RO (15) 2015	Pass
Synthetic Blood Penetration ASTM F1670 (2017)	Resistance to Penetration	Meets standard requirements for ASTM F1670 (2017)	Pass
Water Vapor Transmission Rate NWSP 070.4.RO (15) 2015	Water Vapor Transmission	Meets standard requirements for NWSP 070.4.RO (15) 2015	Pass
180 Degree Peel Strength of Non-Elastic Laminated Nonwovens STM-00197 Rev 1	Peel Strength	LSL:≥125 grams	Pass
Linting ISO 9073-10 2003	Particulate	Meets requirement for ISO 9073-10 2003	Pass
Standard for the Flammability for Clothing Textiles16 CFR 1610	Flammability	Meets Class 1 requirements	Pass
ISO L929 MEM Elution Cytotoxicity ISO 10993-5:2009	Cytotoxicity	< Grade 2	Pass
ISO Indirect Primary Skin Irritation Test ISO 10993-10:2010	Irritation	(mild reactivity)	Pass
ISO Kligman Maximization Test ISO 10993-10:2010	Sensitization	< 0.4	Pass
EO Sterilization Residuals ISO 109937-7:2008 (R) 2012	EO Residuals	Meet EO Residual requirements per ISO 1099370 – 7:200(R) 12	Pass
Laser Ignition Resistance ISO 11810-1:2015	Evaluate Laser Induced Hazard	Class 1 rating No ignition	Pass

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject devices in 510(k) submission K210688, the AERO CHROME* Select Breathable Performance Surgical Gown and AERO CHROME* A-Line Breathable Performance Surgical Gown, are as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K200522.