



Food and Drug Administration
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April 13, 2016

Halyard Health, Inc.
David Lee
Associate Director, Regulatory Affairs
5405 Windward Parkway
Alpharetta, Georgia 30004

Re: K153255
Trade/Device Name: Aero Chrome* Breathable Performance Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: March 7, 2016
Received: March 8, 2016

Dear David Lee:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(k) Number (if known)

K153255

Device Name

Aero Chrome* Breathable Performance Surgical Gown

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 requirements of the AAMI PB70:2012 Liquid Barrier classifications.

The **Aero Chrome* Breathable Performance Surgical Gowns** are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization

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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This submission addresses the **Aero Chrome* Breathable Performance Surgical Gown** models described below.

STERILE CODES

PRODUCT STOCK CODE	DESCRIPTION	GOWN SIZE
44672	Aero Chrome* Breathable Performance Surgical Gown, S	Small
44673	Aero Chrome* Breathable Performance Surgical Gown, L	Large
44674	Aero Chrome* Breathable Performance Surgical Gown, XL	Xlarge
44675	Aero Chrome* Breathable Performance Surgical Gown, XXL	XXLarge
44676	Aero Chrome* Breathable Performance Surgical Gown, XXXL	XXXLarge
44677	Aero Chrome* Breathable Performance Surgical Gown, L, X-Long	Large Xlong
44678	Aero Chrome* Breathable Performance Surgical Gown, XL, X-Long	XLarge Xlong
44679	Aero Chrome* Breathable Performance Surgical Gown, XXL, X-Long	XXLarge Xlong

NON-STERILE CODES

PRODUCT STOCK CODE	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	Xlarge
44665NS	Aero Chrome* Breathable Performance Surgical Gown, XL - Handi-Bin	Xlarge
44666NS	Aero Chrome* Breathable Performance Surgical Gown, XXL	XXLarge
44667NS	Aero Chrome* Breathable Performance Surgical Gown, L, X-Long	Large Xlong
44668NS	Aero Chrome* Breathable Performance Surgical Gown, XL, X-Long	XLarge Xlong
44669NS	Aero Chrome* Breathable Performance Surgical Gown, XXL, X-Long	XXLarge Xlong

510(k) Summary

Date Summary was Prepared: April 13, 2016

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Device Trade Name: **Aero Chrome* Breathable Performance Surgical Gown (hereinafter described as "Aero Chrome*")**

Device Common Names Surgical Gown

Device Product Codes, Classification Name and Regulation: FYA
Class II
878.4040 Surgical Apparel

**Halyard* Health 510(k) for the Aero Chrome*
Breathable Performance Surgical Gown**

Predicate Device

The **Aero Chrome* Breathable Performance Surgical Gown** under submission is substantially equivalent to the predicate device, the **Aero Blue* Performance Surgical Gown (K140539)**.

**Device
Description:**

The **Aero Chrome* Breathable Performance Surgical Gowns** have a Spunbond/Film/Spunbond/Meltblown/Spunbond design (SFSMS) that provides AAMI Level 4 liquid barrier protection in the critical zones of the gown. The back of the **Aero Chrome* Breathable Performance Surgical Gown** in the non-critical zone has a SMS Spunbond/meltblown/spunbond) fabric that is air-breathable and provides AAMI Level 1 liquid barrier protection. The **Aero Chrome* Breathable Performance Surgical Gowns** are single use, disposable medical device that will be provided in a variety of sterile and non-sterile packaging configurations described below.

Intended 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 requirements of the AAMI PB70:2012 Liquid Barrier classifications.

The **Aero Chrome* Breathable Performance Surgical Gowns** are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization

This submission covers the **Aero Chrome* Breathable Performance Surgical Gowns** models described below.

**Halyard* Health 510(k) for the Aero Chrome*
Breathable Performance Surgical Gown**

Product Code and Description

STERILE CODES

PRODUCT STOCK CODE	DESCRIPTION	GOWN SIZE
44672	Aero Chrome* Breathable Performance Surgical Gown, S	Small
44673	Aero Chrome* Breathable Performance Surgical Gown, L	Large
44674	Aero Chrome* Breathable Performance Surgical Gown, XL	Xlarge
44675	Aero Chrome* Breathable Performance Surgical Gown, XXL	XXLarge
44676	Aero Chrome* Breathable Performance Surgical Gown, XXXL	XXXLarge
44677	Aero Chrome* Breathable Performance Surgical Gown, L, X-Long	Large Xlong
44678	Aero Chrome* Breathable Performance Surgical Gown, XL, X-Long	XLarge Xlong
44679	Aero Chrome* Breathable Performance Surgical Gown, XXL, X-Long	XXLarge Xlong

NON-STERILE CODES

PRODUCT STOCK CODE	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	Xlarge
44665NS	Aero Chrome* Breathable Performance Surgical Gown, XL - Handi-Bin	Xlarge
44666NS	Aero Chrome* Breathable Performance Surgical Gown, XXL	XXLarge
44667NS	Aero Chrome* Breathable Performance Surgical Gown, L, X-Long	Large Xlong
44668NS	Aero Chrome* Breathable Performance Surgical Gown, XL, X-Long	XLarge Xlong
44669NS	Aero Chrome* Breathable Performance Surgical Gown, XXL, X-Long	XXLarge Xlong

**Halyard* Health 510(k) for the Aero Chrome*
Breathable Performance Surgical Gown**

Summary of Non-Clinical Testing

Standard or Reference	Test Method	Data Generated	Meets Requirement
Standard for the Flammability for Clothing Textiles	16 CFR 1610	Flammability	Pass
ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5:	Cytotoxicity	Cytotoxicity	Pass, under the conditions of the study non-cytotoxic
ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10	Skin Irritation Study	Irritation	Pass, under the conditions of the study a negligible irritant
ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10	Sensitization Test	Sensitization	Pass, under the conditions of the study non-sensitizing
ISO 10993-7:2008, Ethylene Oxide sterilization residuals	EO residuals	EO residuals	Pass
Laser Ignition Resistance	ISO 11810-1 (2005)	Laser resistance	Pass
AAMI Liquid Barrier Performance in Critical Zone (body, sleeves, and ties)	AAMI PB70:2012 Level 4	Resistance to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage	Pass
AAMI Liquid Barrier Performance Level 1 in non-critical side seams, raglan sleeve to shoulder seams, and SMS area in back of gown	AAMI PB70:2012 Level 1	Water resistance	Pass
Spray Impact (1.2 oz SMS in non-critical zone on back)	AATCC 42:2013	Water resistance	Pass
Grab Tensile, Peak Stretch, and Peak Energy – Nonwovens	ASTM D5034 (2009)	Tensile Strength	Pass
Abrasion Resistance and Surface Bonding of SMS Laminates	WSP 20.5 (2008)	Abrasion resistance	Pass
Synthetic Blood Penetration (fabric only in critical zone)	ASTM-1670-08 (2008)	Resistance to penetration	Pass
Mass Per Area (<i>Basis Weight</i>) of Materials	D3776 (2009)	Fabric basis weight	Pass
Water Vapor Transmission Rate Through Nonwovens and Plastic Films	WSP 70.4 (2008)	Water Vapor Transmission	Pass
Degree Peel Strength of Laminated Nonwovens – Raw Materials	STM-00197(2010)	Peel Strength	Pass
Resistance to Linting Dry Particle Generation	INDA WSP 160.1 (2009)	Particulate	Pass

Test results establish that the product met the predetermined specifications.

**Halyard* Health 510(k) for the Aero Chrome*
Breathable Performance Surgical Gown**

Substantial Equivalence Table

Attribute	Device Under Submission: Aero Chrome* Breathable Performance Surgical Gown	Predicate Device of this 510(k): K140539 Aero Blue* Performance Surgical Gown
Indications for Use	<p>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 requirements of the AAMI PB70:2012 Liquid Barrier classifications.</p> <p>The Aero Chrome* Breathable Performance Surgical Gowns are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization</p>	<p>Aero Blue* 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 Blue* Performance Surgical Gowns meet the Level 3 requirements of the AAMI PB70: 2012 Liquid Barrier classifications.</p> <p>The Aero Blue* Performance Surgical Gowns, are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.</p>
How supplied	Sterile (10 ⁻⁶) or bulk non-sterile	Same
Sterilization Method	Ethylene Oxide	Same
SAL	10 ⁻⁶	Same
Gown color	Gray	Blue
Gown sizes	Small, Large, X-Large, XX-Large, XXX-Large, L X-Long, XXL X- Long	Small, Large, X-Large, XX-Large, XXX-Large
Construction Overview	<p>The Aero Chrome* Breathable Performance Surgical Gowns under submission are manufactured from a moisture-vapor breathable, repellent, non-woven fabric using a polymer blend of polypropylene and polyethylene. The front body and sleeve fabric is a three layer film laminate. This fabric is an SFSMS design Spunbond/Film/Spunbond-Meltblown-Spunbond that is adhesively bonded together. The Aero Chrome* Breathable Performance Surgical Gowns in the critical zone meet AAMI-4 liquid barrier requirements, while back of gown in the non-critical zone is composed of a breathable SMS fabric with an AAMI level 1 liquid barrier protection.</p>	<p>The Aero Blue Performance Surgical Gown is manufactured from a moisture-vapor breathable, repellent, non-woven fabric using a polymer blend of polypropylene and polyethylene. The front body and sleeve fabric is a three layer film laminate. This fabric is an SFSMS design Spunbond/Film/Spunbond-Meltblown-Spunbond that is adhesively bonded together. Front of Gown meets meet AAMI-3 liquid barrier requirements, while back of Gown in the non-critical zone is composed of a breathable SMS fabric with an AAMI level 1 liquid barrier protection.</p>

**Halyard* Health 510(k) for the Aero Chrome*
Breathable Performance Surgical Gown**

Not made with natural rubber latex	Yes	Same
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Performance Testing

Attribute	Device Under Submission: Aero Chrome* Breathable Performance Surgical Gowns	Predicate Device of this 510(k): K140539 Aero Blue* Performance Surgical Gown,
Performance Testing in Critical Zone	ANSI/AAMI PB70: 2012 Level 4 Liquid Barrier Requirements - Pass	ANSI/AAMI PB70: 2012 Level 3
	W SP 70.4 (STM-00164)-Water Vapor Transmission Rate - Pass	Same
	W SP 160.1 (STM-00353) Test Method for Resistance to Linting: Dry Particle Generation with a Modified Gelbo Flex Unit - Pass	Same
	ASTM D 5034 – 2009 Standard Test Method For Breaking Strength and Elongation of Textile Fabrics (Grab Test) - Pass	Same
	ASTM F1670:2008 for fabric in critical zone- Pass	Same
	STM- 00149 (W SP 20.5 2008), Abrasion Resistance Test - Pass	Same
	Biocompatibility per ISO 10993 – Pass , the device under the conditions of the study is non-cytotoxic, non-irritant, and non-sensitizing.	Same, device under the conditions of the study was non-cytotoxic, non-irritant, and non-sensitizing.
	16 CFR, Chapter II--Consumer Product Safety Commission Part 1610 -Standard For The Flammability of Clothing Textiles Class I - Pass	Same
	Laser Ignition Resistance/ ISO 11810- Pass	Same

Conclusion

The performance testing submitted for the **Aero Chrome* Breathable Performance Surgical Gown** demonstrates substantial equivalence to the predicate **Aero Blue* Performance Surgical Gown (K140539)** in intended use, design, materials, performance, and biocompatibility attributes.

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