DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 21, 2017

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

Re: K162930
Trade/Device Name: Aero Chrome* Select Breathable Performance Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: March 15, 2017
Received: March 17, 2017

Dear David M. 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017

*See PRA Statement below.*

510(k) Number *(if known)* **K162930**

Device Name

**Aero Chrome* Select Breathable Performance Surgical Gown**

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 microorganisms, body fluids, and particulate matter. **The Aero Chrome* Select Breathable Performance Surgical Gowns** meet the Level 4 requirements of the AAMI PB70:2012 Liquid Barrier classifications.

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

| | |
|---|---|
| **Date Summary was Prepared:** | **April 14, 2017** |
| **510(k) Submitter:** | David M. Lee, JD<br>Associate Director of Regulatory Affairs<br>HALYARD HEALTH<br>5405 Windward Parkway<br>Alpharetta, GA 30004<br>470 448 5182<br>David.lee@hyh.com |
| **Primary Contact for this 510(k) Submission:** | David M. Lee, JD<br>Associate Director of Regulatory Affairs,<br>HALYARD HEALTH<br>5405 Windward Parkway<br>Alpharetta, GA 30004<br>470 448 5182<br>David.lee@hyh.com |
| **Device Trade Name:** | **Aero Chrome* Select Breathable Performance Surgical Gown (hereinafter described as "Aero Chrome* Select")** |
| **Device Common Names** | Surgical Gown |
| **Regulation:** | 878.4040 |
| **Device Product Codes and Classification Names:** | FYA<br>Class II<br>Surgical Apparel |
| **Predicate Device** | The **Aero Chrome* Select Breathable Performance Surgical Gown** under submission is substantially equivalent to the predicate device, the **Aero Chrome* Breathable Performance Surgical Gown (K153255).** |
| **Device Description:** | The **Aero Chrome* Select Breathable Performance Surgical Gown** has 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* Select Breathable Performance Surgical Gown** in the non-critical zone also has the same Spunbond/Film/Spunbond/Meltblown/Spunbond fabric (SFSMS) that provides ASTM 1671 liquid barrier protection. The **Aero Chrome* Select Breathable Performance Surgical Gown** is single use, disposable medical device that will be provided in a |

variety of sizes and sterile and non-sterile packaging configurations.

**Intended Use:** 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 microorganisms, body fluids, and particulate matter. **The Aero Chrome* Select Breathable Performance Surgical Gowns** meet the Level 4 requirements of the AAMI PB70:2012 Liquid Barrier classifications.

## Product Codes and Descriptions

**STERILE CODES**

| PRODUCT STOCK CODE | DESCRIPTION | SIZE |
|---|---|---|
| 44699 | Aero Chrome* Select Breathable Performance Surgical Gown | Large |
| 44706 | Aero Chrome* Select Breathable Performance Surgical Gown | X Large |
| 44707 | Aero Chrome* Select Breathable Performance Surgical Gown | XX Large |

**NON-STERILE CODES**

| PRODUCT STOCK CODE | DESCRIPTION | SIZE |
|---|---|---|
| 44696NS | Aero Chrome* Select Breathable Performance Surgical Gown | Large |
| 44697NS | Aero Chrome* Select Breathable Performance Surgical Gown | X Large |
| 44698NS | Aero Chrome* Select Breathable Performance Surgical Gown | XX Large |

### 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 |

| Standard or Reference | Test Method | Data Generated | Meets Requirement |
|---|---|---|---|
| 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 raglan sleeve to shoulder seams | AAMI PB70:2012 Level 1 | Water resistance | Pass |
| Liquid Barrier Performance in Non-Critical Zone fabric on the back of gown | ASTM F1671 | Resistance to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage | 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 and non-critical zone) | ASTM-1670-08 (2008) | Resistance to penetration | Pass |
| Mass Per Area *(Basis Weight)* 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 established that the product met the predetermined specifications.

## Substantial Equivalence Table

| **Attribute** | **Predicate Device: K153255 Aero Chrome* Breathable Performance Surgical Gown** (AAMI Liquid Barrier Level 4) | **Device under submission: Aero Chrome* Select Breathable Performance Surgical Gown** (AAMI Liquid Barrier Level 4) |
|---|---|---|
| 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 requirements of the AAMI PB70:2012 Liquid Barrier classifications.<br><br>**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 | 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 microorganisms, body fluids, and particulate matter. **The Aero Chrome* Select Breathable Performance Surgical Gowns** meet the Level 4 requirements of the AAMI PB70:2012 Liquid Barrier classifications. |
| How supplied | Sterile ($10^{-6}$) or bulk non-sterile | Same |
| Sterilization Method | Ethylene Oxide | Same |
| SAL | $10^{-6}$ | Same |
| Gown color | Gray | Same |
| Gown sizes | Small, Large, X-Large, XX-Large, XXX-Large, L X-Long, XXL X- Long | Large, X-Large, and XX-Large |
| Construction Overview | The **Aero Chrome*** 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*** 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. | Same, except the fabric on the back of the gown in the non-critical zone is made with the same Spunbond/Film/Spunbond-Meltblown-Spunbond fabric (SFSMS) as used on the front of the gown in the critical zone. This fabric on the back of the gown in the non-critical zone meets ASTM F1671.<br><br>Overall finished gown dimensions are not changing from the predicate device. |
| Not made with Natural Rubber Latex | Yes | Same |

**Performance Testing**

| **Attribute** | **Predicate Device: Aero Chrome* Performance Surgical Gown** | **Device under submission in this 510(k): Aero Chrome Select Breathable Performance Surgical Gowns** (AAMI Liquid Barrier Level 4) |
|---|---|---|
| Performance Testing in Critical Zone | ANSI/AAMI PB70: 2012 **Level 4** Liquid Barrier Requirements - **Pass** | Same |
| | WSP 70.4 (STM-00164)-Water Vapor Transmission Rate - **Pass** | Same |
| | WSP 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 (WSP 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 |
| Performance Testing on fabric in Non-Critical Zone on back of gown | AAMI level 1-Pass | Pass ASTM F1671 and ASTM F1670 |

**Conclusion** The performance testing submitted for the **Aero Chrome* Select Breathable Performance Surgical Gown** demonstrates substantial equivalence to the predicate **Aero Chrome* Breathable Performance Surgical Gown (K153255)** in intended use, design, materials, performance, and biocompatibility attributes. Based on the comparisons to the predicate device, the subject device described in this 510(k) Summary, **Aero Chrome* Select Breathable Performance Surgical Gown**, does not raise any different questions or new issues of safety and effectiveness.

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