

DEC 23 2010

**510(k) Summary for the Kimberly-Clark\* Corporation**  
**MicroCool Breathable High Performance Surgical Gown with AAMI Liquid Barrier**  
**Level 4 claim**

**Date Summary was Prepared:** December 13, 2010

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**Device Trade Name:** Kimberly-Clark\* MicroCool Breathable High Performance Surgical Gown.

**Device Common names:** Sterile surgical gown

**Device Product Codes and Classification Names:** FYA, Class II  
Surgical Gowns (21 CFR 878.4040)

**Predicate Devices:** The predicate device for this Kimberly-Clark\*MicroCool Breathable High Performance Surgical Gown submission is K091357, the Kimberly-Clark *MicroCool Surgical Gown, Breathable High Performance, KC400*

**Device Description:** The MicroCool\* Breathable High Performance Surgical Gowns are manufactured from a breathable, repellent, non-woven, polypropylene fabric. The fabric is a three-layer lamination that resists tearing and penetration by liquids. The gown is constructed from a spunbond/film/spunbond/meltblown/spunbond (SFSMS) design. The film layer is a multi-layer polypropylene-based, breathable film. A C6 fluorochemical treatment is added to the film to retard penetration by low surface tension fluids. A polyolefin hot melt adhesive is used to laminate the facing layers. to the film layer to complete the composite.

**Intended Use:** The Kimberly-Clark\* MicroCOOL\* Breathable High 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 MicroCool\* Breathable High Performance Surgical Gowns meet the Level 4 requirements of the AAMI Liquid Barrier classifications.

The Kimberly-Clark\* MicroCool\* Breathable High 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

**Technological Characteristics and Substantial Equivalence:** The MicroCool\* Breathable High Performance Surgical Gown, that is the subject of this 510(k) is substantially equivalent to the predicate KIMBERLY-CLARK\* MICROCOOL SURGICAL GOWN, BREATHABLE HIGH PERFORMANCE, KC400 (K091357) in intended use, design, and biocompatibility attributes. The performance attributes of the MicroCool\* Breathable High Performance Surgical Gown, is substantially equivalent to the predicate gown including meeting the requirements of AAMI Level 4 liquid barrier requirements.

**Summary of Testing:** The Kimberly-Clark\* MicroCool\* Breathable High Performance Surgical Gown, has been tested in compliance with the requirements of Level 4 liquid barrier performance requirements of ANSI/AAMI PB70: 2003 *"Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities."* The MicroCool\* Breathable High Performance Surgical Gown also meets the requirements of ASTM1671:2003 *Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system.* The MicroCool\* Breathable High Performance Surgical Gown meets the requirements of Flame Resistant CPSC 1610 Class 1. The MicroCool\* Breathable High Performance Surgical Gown has also been tested in compliance with the biocompatibility requirements of ISO 10993 for surface devices with limited contact with breached or compromised surfaces. All results of testing met acceptance criteria.

**Conclusion:** The performance testing submitted for the MicroCool\* Breathable High Performance Surgical Gown demonstrates substantial equivalence to the predicate KIMBERLY-CLARK\* MICROCOOL SURGICAL GOWN, BREATHABLE HIGH PERFORMANCE, KC400 (K091357) in intended use, design, materials, performance, and biocompatibility attributes.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Kimberly-Clark Corporation  
C/O Mr. Ned Devine  
Responsible Third Party Official  
Underwriters Laboratories, Incorporated  
333 Pfingsten Road  
Northbrook, Illinois 60062

DEC 23 2010

Re: K103406

Trade/Device Name: MicroCool\*Breathable High Performance, Surgical Gowns  
Regulation Number: 21 CFR 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: II  
Product Code: FYA  
Dated: December 15, 2010  
Received: December 15, 2010

Dear Mr. Devine:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

DEC 23 2010

510(k) Number (if known): K103406

Device Name: MicroCool\* Breathable High Performance, Surgical Gowns

Indications for Use:

The Kimberly-Clark\* MicroCool\* 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 MicroCool\* Surgical Gown meets the Level 4 requirements of the AAMI Liquid Barrier classifications.

The Kimberly-Clark\* MicroCool\* Surgical Gowns are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

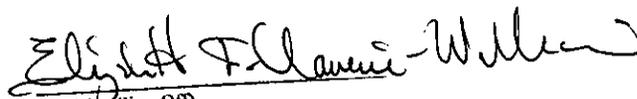
AND/OR

Over-The-Counter Use  X   
(21 CFR 801 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control and Dental Devices  
510(k) Number: K103406

## Addendum

The MicroCool\* Surgical Gowns are available under the following Reference Numbers and descriptions.

New Product OASIS Code	Product Description
<b>Sterile Codes</b>	
92038	MicroCool* Breathable High Performance, Surgical Gown Large, X-Long
92042	MicroCool* Breathable High Performance, Surgical Gown, X-Large, X-Long
92320	MicroCool* Breathable High Performance, Surgical Gown, Large, with Secure-Fit
92321	MicroCool* Breathable High Performance, Surgical Gown, X-Large, with Secure-Fit
92323	MicroCool* Breathable High Performance, Surgical Gown, XX-Large, with Secure-Fit
92330	MicroCool* Breathable High Performance, Surgical Gown, Large, Specialty, with Secure-Fit
92331	MicroCool* Breathable High Performance, Surgical Gown, X-Large, Specialty, with Secure-Fit
92333	MicroCool* Breathable High Performance, Surgical Gown, XX-Large, Specialty, with Secure-Fit
92336	MicroCool* Breathable High Performance, Surgical Gown, Small
92338	MicroCool* Breathable High Performance, Surgical Gown, Small, with Secure-Fit
92340	MicroCool* Breathable High Performance, Surgical Gown, Large
92342	MicroCool* Breathable High Performance, Surgical Gown, X-Large
92344	MicroCool* Breathable High Performance, Surgical Gown, XX-Large
92351	MicroCool* Breathable High Performance, Surgical Gown, Large, Specialty
92353	MicroCool* Breathable High Performance, Surgical Gown, X-Large, Specialty
92354	MicroCool* Breathable High Performance, Surgical Gown, Large, with Secure-Fit
92355	MicroCool* Breathable High Performance, Surgical Gown, X-Large, with Secure-Fit,
92357	MicroCool* Breathable High Performance, Surgical Gown, XX-Large, Specialty
92358	MicroCool* Breathable High Performance, Surgical Gown, XX-Large, with Secure-Fit
10558	MicroCool* Breathable High Performance, Surgical Gown, Large, Specialty, with Secure-Fit
10550	MicroCool* Breathable High Performance, Surgical Gown, X-Large, Specialty, with Secure-Fit
10566	MicroCool* Breathable High Performance, Surgical Gown, XX-Large, Specialty, with Secure-Fit
92347	MicroCool* Breathable High Performance, Surgical Gown, XXX-Large, with Secure-Fit
13359	MicroCool* Breathable High Performance, Surgical Gown, Small, with Secure-Fit
<b>Non-sterile Codes</b>	
72438	MicroCool* Breathable High Performance, Surgical Gown, Large
72445	MicroCool* Breathable High Performance, Surgical Gown, X-Large
72447	MicroCool* Breathable High Performance, Surgical Gown, XX-Large
72448	MicroCool* Breathable High Performance, Surgical Gown, XX-Large, with Secure-Fit,
72451	MicroCool* Breathable High Performance, Surgical Gown, Large, Specialty
72453	MicroCool* Breathable High Performance, Surgical Gown, X-Large, Specialty
72454	MicroCool* Breathable High Performance, Surgical Gown, Large, with Secure-Fit
72455	MicroCool* Breathable High Performance, Surgical Gown, X-Large, with Secure-Fit
72457	MicroCool* Breathable High Performance, Surgical Gown, XX-Large, Specialty
73038	MicroCool* Breathable High Performance, Surgical Gown, Large, X-Long
73041	MicroCool* Breathable High Performance, Surgical Gown, X-Large, X-Long
79729	MicroCool* Breathable High Performance, Surgical Gown, Large
79739	MicroCool* Breathable High Performance, Surgical Gown, X-Large