

**510(k) Summary for the Kimberly-Clark\* MicroCool\* Surgical Gowns,  
Breathable High Performance, KC400**

**Intended Use:** The Kimberly-Clark\* MicroCool\* Surgical Gown, Breathable High Performance, KC 400 (hereinafter referred to as "MicroCool\* Surgical Gown") 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 Gowns meet the Level 4 requirements of the AAMI PB70: 2003 Liquid Barrier classifications.

The 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.

**Device Description** The MicroCool\* Surgical Gown is 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 design and is adhesively laminated. The spunbond layers are comprised of nonwoven polypropylene. The film layer is a multi-layer polypropylene olefin, breathable film. A 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 Spunbond facing layers to the film layer to complete the composite. A new sleeve design was incorporated to meet Level 4 of the AAMI Liquid Barrier classifications.

**Substantial Equivalence:** The MicroCool\* Surgical Gown that is the subject of this 510(k) is substantially equivalent to the predicate Kimberly-Clark\* MicroCool\* Surgical Gown (K981393) in intended use, design, materials, and biocompatibility attributes. The performance attributes of the MicroCool\* Surgical Gown are substantially equivalent to the predicate gown with the exception that this MicroCool\* Surgical Gown meets the AAMI Level 4 liquid barrier requirement.

**Summary of Testing:** The Kimberly-Clark\* MicroCool\* Surgical Gown has been tested in compliance with the requirements of Level 4 liquid barrier performance of ANSI/AAMI PB70: 2003 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities." The MicroCool\* 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\* Surgical Gown meets the requirements of Flame Resistant CPSC 1610 Class 1. The MicroCool\* Surgical Gown has been tested in compliance with the biocompatibility requirements of ISO 10993 for surface devices with limited contact with breached or compromised surfaces.

\* Registered Trademark or Trademark of Kimberly-Clark Worldwide, Inc. or its affiliates.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

AUG 10 2009

Mr. David M. Lee  
Associate Director of Regulatory Affairs  
Kimberly-Clark Corporation  
1400 Holcomb Bridge Road  
Building 300, #1092  
Roswell, Georgia 30076

Re: K091357  
Trade/Device Name: MicroCOOL\* Surgical Gowns, Breathable High Performance,  
KC400  
Regulation Number: 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: II  
Product Code: FYA  
Dated: July 14, 2009  
Received: July 16, 2009

Dear Mr. 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.

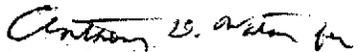
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,

  
Susan Runner, D.D.S., M.A.  
Acting 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**

510(k) Number (if known): \_\_\_\_\_

Device Name: MicroCOOL\* Surgical Gowns, Breathable High Performance, KC400

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shirley A. Murphy MD  
Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K 091357

## 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* Surgical Gown, Breathable High Performance, KC400, Large, X-Long
92042	MicroCool* Surgical Gown, Breathable High Performance, KC400, X-Large, X-Long
92320	MicroCool* Surgical Gown, Breathable High Performance, KC400, Large, with Secure-Fit
92321	MicroCool* Surgical Gown, Breathable High Performance, KC400, X-Large, with Secure-Fit
92323	MicroCool* Surgical Gown, Breathable High Performance, KC400, XX-Large, with Secure-Fit
92330	MicroCool* Surgical Gown, Breathable High Performance, KC400, Large, Specialty, with Secure-Fit
92331	MicroCool* Surgical Gown, Breathable High Performance, KC400, X-Large, Specialty, with Secure-Fit
92333	MicroCool* Surgical Gown, Breathable High Performance, KC400, XX-Large, Specialty, with Secure-Fit
92336	MicroCool* Surgical Gown, Breathable High Performance, KC400, Small
92338	MicroCool* Surgical Gown, Breathable High Performance, KC400, Small, with Secure-Fit
92340	MicroCool* Surgical Gown, Breathable High Performance, KC400, Large
92342	MicroCool* Surgical Gown, Breathable High Performance, KC400, X-Large
92344	MicroCool* Surgical Gown, Breathable High Performance, KC400, XX-Large
92351	MicroCool* Surgical Gown, Breathable High Performance, KC400, Large, Specialty
92353	MicroCool* Surgical Gown, Breathable High Performance, KC400, X-Large, Specialty
92354	MicroCool* Surgical Gown, Breathable High Performance, KC400, Large, with Secure-Fit
92355	MicroCool* Surgical Gown, Breathable High Performance, KC400, X-Large, with Secure-Fit,
92357	MicroCool* Surgical Gown, Breathable High Performance, KC400, XX-Large, Specialty
92358	MicroCool* Surgical Gown, Breathable High Performance, KC400, XX-Large, with Secure-Fit
<b>Non-sterile Codes</b>	
72438	MicroCool* Surgical Gown, Breathable High Performance, KC400, Large
72445	MicroCool* Surgical Gown, Breathable High Performance, KC400, X-Large
72447	MicroCool* Surgical Gown, Breathable High Performance, KC400, XX-Large
72448	MicroCool* Surgical Gown, Breathable High Performance, KC400, XX-Large, with Secure-Fit,
72451	MicroCool* Surgical Gown, Breathable High Performance, KC400, Large, Specialty
72453	MicroCool* Surgical Gown, Breathable High Performance, KC400, X-Large, Specialty
72454	MicroCool* Surgical Gown, Breathable High Performance, KC400, Large, with Secure-Fit
72455	MicroCool* Surgical Gown, Breathable High Performance, KC400, X-Large, with Secure-Fit
72457	MicroCool* Surgical Gown, Breathable High Performance, KC400, XX-Large, Specialty
73038	MicroCool* Surgical Gown, Breathable High Performance, KC400, Large, X-Long
73041	MicroCool* Surgical Gown, Breathable High Performance, KC400, X-Large, X-Long
79729	MicroCool* Surgical Gown, Breathable High Performance, KC400, Large
79739	MicroCool* Surgical Gown, Breathable High Performance, KC400, X-Large