JUL 10 1998

K981393

510(k) Summary of Safety and Effectiveness

Manufacturer:	Kimberly-Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30076
Regulatory Affairs Contact:	Larry R. Kludt Manager Regulatory Affairs 1400 Holcomb Bridge Road Roswell, GA 30076 (770) 587-8279
Summary Date:	July 1, 1998
Product Trade Name:	MicroCool™ Surgical Gown (sterile) MicroCool™ Isolation Gown (nonsterile)
Common Name:	Surgical gown, isolation gown
Classification:	Surgical apparel
Predicate Device:	3M Prevention Fabric Surgical Gown
Description:	The MicroCool 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. This disposable gown is supplied sterile or non-sterile.
Intended Use:	The MicroCool gown is a single use item of surgical apparel intended to be worn by health care professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids and particulate matter. The MicroCool gown was designed to provide a barrier to fluids such as water, blood, sweat and isopropyl alcohol while allowing the wearer to remain comfortable.
Substantial Equivalence:	The MicroCool gown is substantially equivalent to the 3M Prevention Fabric Gown manufactured by 3M Health Care in that they both provide the following characteristics: ■ good tear resistance ■ fluid barrier

Summary of Testing:

Test	Result
Cytotoxicity	No evidence of component sensitizer (met USP XXIII requirements)
Skin Irritation	No evidence of dermal irritation
Sterilant residues	Levels of EO, EC and EG were each within the proposed FDA limits for medical devices that contact skin
Flammability	Meets Class I flammability requirements per 16 CFR Part 1610
Fluid penetration	Resists visual penetration by blood, and viral penetration fluids (met ASTM 1670-97 & ASTM F 903-96 requirements)
Viral penetration	Resists viral penetration (met ASTM F 1671-97a requirements)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 1998

Kimberly-Clark Corporation
C/O Mr. Larry R. Kludt
Manager Regulatory Affaris
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K981393
Trade Name: MicroCool™ Nonsterile Disposable Isolation Gown and MicroCool™ Sterile Disposable Surgical Gown
Regulatory Class: II
Product Code: FYC and FYA
Dated: April 16, 1998
Received: April 17, 1998

Dear Mr. Kludt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to - premarket notification"(21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981393

Device Name: Disposible Sterile MicroCool Surgical Gown, MicroCool Non Sterile Isolation Gown, DISPOSABLE

Indications For Use:

The MicroCool Surgical Gown and the MicroCool Isolation Gown are single use items of surgical apparel intended to be worn by health care professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids and particulate matter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981393

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)