MAY 2 2006

K052824

Premarket Notification [510(k)] Summary

1. **Submitted by:**

Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, GA 30076

Contact Person: Cheryl M. Sanzare
Associate Director Regulatory Affairs

Telephone: (770) 587-7131
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Date Prepared: April 26, 2006

2. **Device Name**

Trade / Proprietary Name: Kimberly-Clark Procedure Gown

Common / Usual name: Surgical gown
Classification Name: Gown, surgical (per 21CFR 878.4040)

3. **Predicate Device**

The Kimberly-Clark Procedure Gown is substantially equivalent to the Kimberly-Clark Impervious Open Back Gown cleared under K880382.

4. **Intended Use of the Device**

The Kimberly-Clark Procedure Gown is a non-sterile, disposable, single use item of apparel intended to be worn by healthcare professionals during the preparation and administration of selected chemotherapy drugs. The gown is not intended to be worn during surgical procedures.

5. **Description of the Device**

The Kimberly-Clark Comfort Gown is an open back gown manufactured from a non-woven fabric with a film laminate coating. The non-woven fabric is a polypropylene spunbond with a polyethylene coating. The composition of the gown fabric resists tearing and permeation by various chemotherapy drugs for up to four hours of use.

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Premarket Notification [510(k)] Summary *(Continued)*

6. **Summary of the technological characteristics of the device compared to the predicate device**

The Kimberly-Clark Procedure Gown and the Kimberly-Clark Impervious Open Back Gown (K880382) are manufactured with similar materials of construction. Neither gown is intended to be worn during surgical procedures as both gowns are provided as non-sterile. The K-C Procedure Gown is substantially equivalent to the K-C Imperious Open Back Gown in that they both provide the following characteristics: good tear resistance and fluid barrier.

Summary of Testing:

Test	Result
Dermal Irritation & Sensitization	No evidence of dermal irritation or allergic contact sensitization
Flammability	Meets Class I flammability requirements per NFPA Standard #702-1980.
Liquid Chemical Permeation	Permeation testing per ASTM F 739-99a with the following chemotherapy drugs: carmustine, cisplatin, cyclophosphamide, dacarbazine, doxorubicin hydrochloride, etoposide, fluorouracil, paclitaxel, thioTEPA and vincristine sulfate. Results showed no permeation of the drugs for up to 240 minutes.
Fluid Penetration	Penetration testing per ASTM-F 1670-03 with resistance of the gown fabric to penetration by blood under conditions of continuous liquid contact. The '*pass*' determination was based on visual detection of synthetic blood penetration.
Viral Penetration	Penetration testing per ASTM-F 1671-03 with resistance of the gown fabric to penetration by blood-borne pathogens under conditions of continuous liquid contact. The '*pass*' determination was based on detection of viral penetration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 2006

Ms. Cheryl M. Sanzare
Associate Director Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K052824
Trade/Device Name: Kimberly-Clark Procedure Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: April 10, 2006
Received: April 11, 2006

Dear Ms. Sanzare:

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.

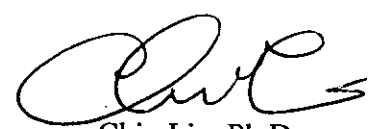
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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

Applicant: Kimberly-Clark Corporation

510(k) Number: K052824

Device Name: Kimberly-Clark Procedure Gown

Indications for Use: Based upon 21CFR§878.4040; Surgical apparel

The Kimberly-Clark Procedure Gown is a non-sterile, disposable, single use item of apparel intended to be worn by healthcare professionals during the preparation and administration of selected chemotherapy drugs. The gown is not intended to be worn during surgical procedures.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter X

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) K052824