

510(k) Summary for the Kimberly-Clark\* Corporation  
KC100 Surgical Drapes and Equipment Covers

MAR 25 2009

**Date Summary was Prepared:** October 31, 2008

**510(k) Submitter:** Thomas Kozma  
Director, Regulatory Affairs  
Kimberly-Clark Health Care  
1400 Holcomb Bridge Road  
Roswell, GA 30076  
Ph: 770.587.8393  
FAX: 920.225.3408  
Email: thomas.kozma@kcc.com

**Primary Contact for this 510(k) Submission:** Lisa Peacock, Consultant to Kimberly-Clark Health Care  
SciMed, Inc.  
Ph: 706.216.3413  
FAX: 800.713.7754  
Email: lisa.peacock@kcc.com

**Device Common Name:** Sterile surgical drapes and surgical equipment covers

**Device Product Codes and Classification Names:** KX Surgical Drapes  
MMP Protective Barrier Covers

**Intended Use:** Kimberly-Clark Corporation intends to market the sterile KC100 Surgical Drapes as devices made of natural or synthetic material intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. Kimberly-Clark intends to market the sterile KC100 Surgical Equipment Covers which are protective barrier covers that are intended to be used to cover surgical equipment and provide a protective barrier for that equipment.

**Predicate Devices:** K080629 proMedical Surgical Drapes and proMedical Surgical Equipment Covers

**Substantial Equivalence:** The surgical drapes and equipment covers described in this 510(k) submission are identical in all specifications to the predicate device models identified in K080629 except for minor variations in the widths and lengths of three models.

**Summary of  
Testing:**

The KC100 Surgical Drapes and Equipment Covers are identical to, and meet the same acceptance testing criteria as, their predicate drapes and covers in K080629. Testing included biocompatibility (i.e., cytotoxicity, irritation, and sensitization) in compliance with the methods of ISO 10993, barrier properties, tensile and tear strength, alcohol repellency, and flammability. All results of testing met acceptance criteria.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 25 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Kimberly-Clark Corporation  
C/o Ms. Lisa Peacock, RAC  
Consultant to Kimberly-Clark Health Care  
SciMed, Incorporated  
172 Conductor Drive  
Dawsonville, Georgia 30534

Re: K083234  
Trade/Device Name: KC100 Surgical Drapes &  
KC100 Surgical Equipment Covers  
Regulation Number: 21 CFR 878.4370  
Regulation Name: Surgical Drape and Drape Accessories  
Regulatory Class: II  
Product Code: KXX  
Dated: February 23, 2009  
Received: February 25, 2009

Dear Ms. Peacock:

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.

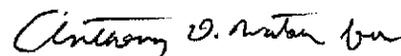
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Ginette Y. Michaud, M.D.

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): K083234

Device Name: KC100 Surgical Equipment Covers

Indications for Use:

Kimberly-Clark\* Corporation intends to market the sterile KC100 Surgical Equipment Covers which are protective barrier covers that are intended to be used to cover surgical equipment and provide a protective barrier for that equipment.

Product Name	Model Code	Cover Materials
Mayo Stand Cover	88656	Blue polyethylene with air-laid reinforcement
Table Cover	88673 88666 89564	Blue polyethylene with air-laid reinforcement

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

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)

  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K083234

**Indications for Use**

510(k) Number (if known): K083234

Device Name: KC100 Surgical Drapes

Indications for Use:

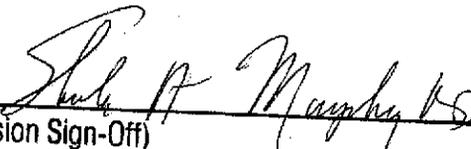
Kimberly-Clark\* Corporation intends to market the sterile KC100 Surgical Drapes as devices made of natural or synthetic material intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. See Page 2 for product list.

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

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

(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 Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K 083 234

## Indications for Use Product List

Product Name	Model Code	Drape Materials
Angiography Surgical Drape	89583	SMS base panel with air-laid pad and polyethylene
Clear Legging Surgical Drape	89195	Polyethylene
Universal Extremity Surgical Drape	89191	SMS base panel with air-laid pad
Legging Surgical Drape	70093855	SMS panel
Head Surgical Drape	70093879	SMS panel
Side Surgical Drape	89556	SMS base panel with air-laid pad
Top Surgical Drape	89554	SMS base panel with air-laid pad
Bottom Surgical Drape	89555	SMS base panel with air-laid pad
Bar Surgical Drape	89533	SMS base panel with air-laid pad
Arthroscopy Surgical Drape	88661	SMS base panel with polyethylene
Under Buttocks Surgical Drape	89584	SMS base panel with air-laid pad and polyethylene
Split EENT Surgical Drape	89197	SMS base panel with air-laid pad
Lithotomy Surgical Drape	89198	SMS base panel with air-laid pad
Laparoscopy T Surgical Drape	89199	SMS base panel with air-laid pad
Thyroid Surgical Drape	89539	SMS base panel with air-laid pad
Minor Procedure Surgical Drape	89531	SMS base panel with air-laid pad
Lap Chole Surgical Drape	89538	SMS base panel with air-laid pad
Cystoscopy T Surgical Drape	89196	SMS base panel with air-laid pad
Chest Surgical Drape	89561	SMS base panel with air-laid pad
Utility Surgical Drape	89536	Air-laid absorbent panel
Split Surgical Drape	89190	Polyethylene
U Surgical Drape	89532	SMS base panel with air-laid pad
Laparotomy Surgical Drape	89537	SMS base panel with air-laid pad
Shoulder Arthroscopy Surgical Drape	89558	SMS base panel with polyethylene
Body Split Surgical Drape	89560	SMS base panel with air-laid pad and polyethylene
Body Split Surgical Drape	89557	SMS base panel with air-laid pad
Half Surgical Drape	89534	SMS panel
Large Surgical Drape	79535	SMS panel
Universal Spine Surgical Drape	89193	SMS base panel with air-laid pad and polyethylene
Dental Surgical Drape	89543	SMS base panel with air-laid pad
Stockinette Surgical Drape	044001-700	Polyethylene stockinette