

**510(k) Summary for the Kimberly-Clark* Corporation
Surgical Drapes with AAMI Liquid Barrier Level 4 claim**

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Device Trade Name: Kimberly-Clark* Surgical Drapes

Device Common names: Sterile surgical drapes

Device Product Codes and Classification Names: KKX Class II
Surgical Drapes (21 CFR 878.4370)

Predicate Devices: The predicate device for these Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier Level 4 claim are the Kimberly-Clark* surgical drapes cleared in premarket notification K083234 KC100 Surgical Drapes and Equipment Covers.

Device Description: The Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier Level 4 claim are constructed with various base sheet and reinforcement fabric types, provided in various sizes and shapes, and may contain fluid collection pouches or clear film panels as components. The base sheet fabric is a three layer laminate comprised of polypropylene spunbond/polypropylene meltblown/polypropylene spunbond. Layers are thermally embossed together producing a single layer with various basis weights. Fabric is topically treated to enhance water repellency and to assure static dissipation.

The drape reinforcement fabrics are constructed of various configurations of spunbond, meltblown and film. The reinforcement materials are either CONTROL PLUS*, a spunbond/meltblown/film laminate or SURROUND*, a spunbond/film laminate. The primary component of these materials is polypropylene with surfactant and blue pigment.

Intended Use:

The Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier Level 4 claim are 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. These drapes meet the Level 4 requirements of the AAMI Liquid Barrier Classifications.

The Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier Level 4 claim 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 Kimberly-Clark* Surgical Drape with AAMI Liquid Barrier Level 4 claim, that is subject of this premarket notification is substantially equivalent to the predicate KC100 Surgical Drapes and Equipment Covers (K083234) in intended use, design and biocompatibility. The performance attributes of the Kimberly-Clark* Surgical Drape with AAMI Liquid Barrier Level 4 claim are substantially equivalent to the predicate drape. The key difference is the drapes subject of this submission have been tested for compliance to 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."

Summary of Testing:

In addition to performance testing in accordance with industry recognized test methods, these drapes have been tested for biocompatibility using cytotoxicity, primary skin irritation tests and sensitization testing. Additionally, the Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier Level 4 claim were 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.*"

All results of testing met acceptance criteria.



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

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Re: K102666

Trade/Device Name: Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier
Level 4 claim Model Numbers List Attached

Regulation Number: 21 CFR 878.4370

Regulation Name: Surgical Drape and Drape Accessories

Regulatory Class: II

Product Code: KXX

Dated: September 14, 2010

Received: September 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.

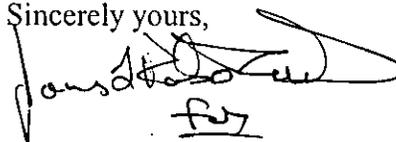
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

A handwritten signature in black ink, appearing to read 'Anthony D. Watson', with a stylized flourish at the end. Below the signature is the handwritten initials 'ADW'.

Anthony D. 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

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510(k) Number (if known): K102666

Device Name: Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier Level 4 claim
 Model Numbers List Attached

Indications for Use:

Kimberly-Clark* Corporation intends to market the sterile Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier Level 4 claim 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. The Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier Level 4 claim meet the Level 4 requirements of the AAMI Liquid Barrier classifications.

The Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier Level 4 claim 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)

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)

Elizabeth P. Clavette-Walker

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102666

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Indications for Use Model Number List

Product Name	Model Number		Drape Materials
	<i>nonsterile</i>	<i>sterile</i>	
Breast Drape	79236	89236	SMS base panel with SF reinforcement
Laparoscopic Abdominal Drape	79233	89233	SMS base panel with SF reinforcement
EENT Split Drape	79351	89352	SMS base panel with SF reinforcement
Laparotomy Drape w/ Arm Board Covers	79228	89228	SMS base panel with SMF reinforcement
Laparotomy Drape w/ Troughs	79234	89234	SMS base panel with SMF reinforcement
Laparotomy Drape	79210	89211	SMS base panel with SMF reinforcement
Cardiovascular Split Drape	79451	89451	SMS base panel with SMF reinforcement
Hip Drape	79341	89341	SMS base panel with SMF reinforcement
CVARTS* CV Incise Drape	79466	89466	SMS base panel with SMF reinforcement
ORTHOARTS* Hip Drape	79346	89346	SMS base panel with SMF reinforcement
ORTHOARTS* Lower Extremity Drape	79278	89278	SMS base panel with SMF reinforcement