Kimberly-Clark

K093115

510(k) Summary for the Kimberly-Clark* Corporation
KC100 Surgical Gowns

MAR 19 2010

Date Summary was Prepared:	March 4, 2010
510(k) Submitter:	Marcia Johnson, RAC Technical Leader, Regulatory Affairs Kimberly-Clark Health Care 1400 Holcomb Bridge Road Roswell, GA 30076 Ph: 770.587.8566 FAX: 920.380.6351 Email: Marcia.johnson@kcc.com
Primary Contact for this 510(k) Submission:	Marcia Johnson, RAC Technical Leader, Regulatory Affairs Kimberly-Clark Health Care 1400 Holcomb Bridge Road Roswell, GA 30076 Ph: 770.587.8566 FAX: 920.380.6351 Email: Marcia.johnson@kcc.com
Device Common Name:	Sterile surgical gowns
Trade Name:	KC100 Surgical Gowns
Device Product Codes and Classification Names:	FYA Surgical Gowns
Predicate Device:	K091097 proMedical Surgical Gowns
Device Description:	Disposable gowns are used in the OR as a protective covering, for operating room staff, from the transfer of microorganisms, body fluids and particulates. Kimberly-Clark's KC100 Surgical Gowns are comprised of a single layer of SMS (spunbond/meltblown/spunbond polypropylene) fabric. The gowns consist of 100% polyester cuffs sewn to the end of the sleeves using polyester thread. The gowns also have a manual closure system.

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Intended Use:	The Kimberly-Clark* KC100 Surgical Gowns are sterile, single use devices intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The Kimberly-Clark* KC100 Surgical Gowns are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.
Technological Characteristics	The Kimberly-Clark* KC100 Surgical Gowns have the same design, material and chemical characteristics of the predicate device.
Summary of Testing:	The KC100 Surgical Gowns are identical to, and meet the same acceptance testing criteria as, their predicate gowns in K091097. 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, flammability, and linting. All results of testing met acceptance criteria
Substantial Equivalence:	The surgical gowns described in this 510(k) submission are identical in all specifications to the predicate device models identified in K091097.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 19 2010

Ms. Marcia Johnson
Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K093115
Trade/Device Name: KC100 Surgical Gowns
Regulation Number: 21CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: March 9, 2010
Received: March 12, 2010

Dear Ms. Johnson:

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,

for 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

510(k) Number (if known): K093115

Device Name: KC100 Surgical Gowns

Indications for Use:

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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)

Gretha Joyce

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093115

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Addendum

The KC100 Surgical Gowns are available under the following Reference Numbers and descriptions.

Sterile Gowns	
99284	KC100 Surgical Gown, Large
99285	KC100 Surgical Gown, X-Large
99294	KC100 Surgical Gown, Large, X-Long
99295	KC100 Surgical Gown, X-Large, X-Long
Non-Sterile Gowns	
79284	KC100 Surgical Gown, Large
79285	KC100 Surgical Gown, X-Large
79294	KC100 Surgical Gown, Large, X-Long
79295	KC100 Surgical Gown, X-Large, X-Long