K080795

510(k) Summary for the ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown

SEP - 3 2008

Intended Use: The Kimberly-Clark* ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gown meets Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gown meets Level 4 of the AAMI Liquid Barrier classifications.

Device Description: The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are full-length, nonwoven SMS polypropylene gowns. They are constructed with raglan sleeves, hook-and-loop neck closures, and tie waist closures. The ULTRA Film-Reinforced Surgical Gown is film-reinforced for higher barrier protection. The ULTRA Surgical Gown fully meets the Association for the Advancement of Medical Instrumentation (AAMI) Level 3 requirements for liquid barrier performance. The ULTRA Film-Reinforced Surgical Gown fully meets the AAMI Level 4 requirements for liquid barrier performance.

Substantial Equivalence: The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are substantially equivalent to the predicate Kimberly-Clark KIMGUARD* and SPUNGUARD* Surgical Gowns in intended use, design, materials, and biocompatibility attributes. The performance attributes of the ULTRA gowns are substantially equivalent to the predicate gowns with the exception that the ULTRA Surgical Gown meets the requirements of AAMI Level 3 liquid barrier requirements and the ULTRA Film-Reinforced Surgical Gown meets the requirements of AAMI Level 4 liquid barrier requirements. The ULTRA gowns and their predicates are provided sterile and for single use.

Summary of Testing: The ULTRA Surgical Gown has been tested in compliance with the requirements of Level 3 liquid barrier performance requirements of ANSI/AAMI PB70: 2003 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities." The ULTRA Film-Reinforced Surgical Gown has been tested in compliance with the requirements of Level 4 liquid barrier performance requirements of ANSI/AAMI PB70: 2003. The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown also meet the requirements of the National Fire Protection Association (NFPA) Test Method 702-1980 for Class I. The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown have been tested in compliance with the biocompatibility requirements of ISO 10993 for surface devices with limited contact with breached or compromised surfaces.

* Registered Trademark or Trademark of Kimberly-Clark Worldwide, Inc. or its affiliates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2008

Mr. David M. Lee
Associate Director of Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K080795
Trade/Device Name: Ultra Surgical Gown
Ultra Film-Reinforced Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: August 15, 2008
Received: August 19, 2008

Dear Mr. Lee:

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

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,

Samuel-Lin, M.D. for //

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

510(k) Number (if known): **K080795**

Device Name: ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns

Indications for Use:

The Kimberly-Clark* ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

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: K080795

Addendum:

The ULTRA Surgical Gowns AAMI Level 3 are available under the following Reference Numbers:

- 95101 ULTRA Surgical Gown, Small
- 95111 ULTRA Surgical Gown, Large
- 95121 ULTRA Surgical Gown, X-Large
- 95055 ULTRA Surgical Gown, Large (2 Pack)
- 95131 ULTRA Surgical Gown, XX-Large

The ULTRA Film-Reinforced Surgical Gowns AAMI Level 4 are available under the following Reference Numbers:

- 95411 ULTRA Film-Reinforced Surgical Gown, Large
- 95421 ULTRA Film-Reinforced Surgical Gown, X-Large
- 95431 ULTRA Film-Reinforced Surgical Gown, XX-Large
- 95511 ULTRA Film-Reinforced Specialty Surgical Gown, Large
- 95521 ULTRA Film-Reinforced Specialty Surgical Gown, X-Large
- 95531 ULTRA Film-Reinforced Specialty Surgical Gown, XX-Large