K111402

OCT 2 0 2011

510K Summary

Date Summary was Prepared:	May 17, 2011
510(k) Submitter:	Ann Waterhouse, RAC Associate Director of Regulatory Affairs Roswell, GA 30076 678-352-6719 (telephone) 920-225-3108 (facsimile) Ann.waterhouse@kcc.com
Device Trade Name:	KC 200 Face Mask KC 300 Face Mask
Device Common names	Mask, surgical
Device Product Codes and Classification Names:	FXX, Class II Mask, surgical (21 CFR 878.4040)
Predicate Devices	The Kimberly-Clark KC100 face mask(s) subject of K110455.
Device Description:	The Kimberly-Clark Face Mask(s) is a four layer mask, constructed of nonwoven polyester blends and polypropylene materials. Bindings are nonwoven polyester. The mask is provided with earloops or ties in either knitted polyester/lycra or nonwoven polyester. A malleable nosepiece is placed within the bindings for comfort and individualized fit around the wearer's nose. Kimberly-Clark KC200 and KC300 Face Mask(s) will be provided with and without a protective visor. Kimberly-Clark Face Mask(s) is a single use, disposable device, provided non-sterile.
Intended Use:	The Kimberly-Clark, KC200 and KC300 Face Mask(s) is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The Kimberly-Clark, KC200 and

KC300 face mask(s) is a s ingle use, disposable device(s), provided non-sterile.

Technological Characteristics and Substantial Equivalence:

The Kimberly-Clark KC200 and K C300 face mask(s) are substantially equivalent to the predicate device, Kimberly-Clark KC100 face mask(s) of K110455 in intended use and principles of operation. The Kimberly-Clark KC200 and KC300 face mask(s) meet ASTM F1862 s tandards at a higher velocity synthetic blood penetration than the KC100 face mask(s). The difference in performance characteristics comply with ASTM 2100-11 and A STM F2100-07, and r aises no new issues of safety and efficacy.

Summary of Testing:

The KC200 and K C300 face mask(s) have been t ested according to ASTM 2100-11 and standards which comprise ASTM F2100-11, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol, *Staphylococcus Aureus*, such as:

Mil- M369454C	Military Specifications: Surgical Mask, disposable 1992
PSC CS-191- 53	Flammability Test Method (16 CFR 1610) for Flammability of Clothing Textiles
ASTM F 2299	Standard Test Method for Evaluating the Initial Efficiency of Materials Used in Medical Masks to Penetration of Particulates Using Latex Spheres
ISO 10993	Standards for evaluating the biocompatibility of a medical device
ASTM F 1862	Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood

All results of testing met acceptance criteria.

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

Ms. Ann Waterhouse, RAC
Associate Director of Regulatory Affairs
Kimberly-Clark
1400 Holcomb Bridge Road, Bldg. 300
Roswell, Georgia 30076

OCT 2 0 2011

Re: K111402
Trade/Device Name: Kimberly-Clark KC 200 Face Mask(s)
Kimberly-Clark KC 300 Face Mask(s)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: October 6, 2011
Received: October 7, 2011

Dear Ms. Waterhouse:

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,

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): K111402

Device Name: Kimberly-Clark KC 200 Face Mask(s)
Kimberly-Clark KC 300 Face Mask(s)

Indications for Use:

The Kimberly-Clark, KC200 and KC300 Face Mask(s) is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The Kimberly-Clark, KC200 and KC300 face mask(s) is a single use, disposable device(s), provided non-sterile.

KC200 Procedure Mask
KC200 Procedure Mask, fog free with visor
KC200 Surgical Mask, fog free
KC200 Surgical Mask, fog free with visor
KC300 Procedure Mask, Fluidshield*, fog free
KC300 Procedure Mask, Fluidshield*, fog free with visor
KC300 Surgical Mask, Fluidshield*, fog free
KC300 Surgical Mask, Fluidshield*, fog free with visor

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 A. Claverie Wilson

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

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