

DEC 20 2013

510(K) SUMMARY

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**510(K) OWNER/
APPLICANT** Kimberly-Clark*
1400 Holcomb Bridge Road
Roswell, GA 30076

CONTACT PERSON Monica King, MBA
Associate Director, Regulatory Affairs
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DATE PREPARED: December 20, 2013

TRADE NAME: Kimberly-Clark* KC300 Face Mask

COMMON NAME: Surgical mask

**CLASSIFICATION
NAME:** Surgical mask

**DEVICE
CLASSIFICATION
AND PRODUCT
CODE:** Class II per 21 CFR §878.4040
Product Code – FXX

PREDICATE DEVICES:

The Kimberly-Clark* KC300 face mask, the subject of this submission, is substantially equivalent to the Kimberly-Clark face masks originally cleared in K110455 and K11402.

Component	Predicate Device KC300 (K111402)	Predicate Device (K110455)	KC300 (Proposed Device)
Intended Use	The Kimberly-Clark, K0200 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.	The Kimberly-Clark KC100 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 KC100 face mask(s) is a single use, disposable device(s), provided non-sterile.	The Kimberly-Clark KC300 Face Mask 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile. Product Code 47297, KC300 FLUIDSHIELD* Procedure Mask with SO SOFT* Lining Product Code 47298, KC300 FLUIDSHIELD* Fog-Free Procedure Mask with SO SOFT* Lining Product Code 48297, KC300 FLUIDSHIELD* Surgical Mask with SO SOFT* Lining
Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Single Use	Yes	Yes	Yes

Outer Facing Layer	Polypropylene Spunbond no print	Polypropylene Spunbond no print	Polyethylene/Polyester, with pink and blue ink print
Spunbond Middle Layer	Polypropylene spunbond	N/A (Three layer mask)	Polypropylene spunbond
Meltblown Middle Layer	Polypropylene Meltblown	Polypropylene Meltblown	Polypropylene Meltblown
Inner Facing Layer	Polyester cellulose	Polyethylene/Polyester	Polyethylene/Polyester
Top and Bottom Binding	Polyester Spunlace	Polyester Spunlace	Polyester Spunlace, or Polypropylene spunbond
Earloop	Polyester/Lycra Knitted	Polyester/Lycra Knitted	Polyester/Lycra Knitted
Ties	Polyester Spunlace	Polyester Spunlace	Polypropylene spunbond
Kimberly-Clark Branding	Markem Ink, Blue	Markem Ink, Blue	Markem Ink, Blue
Style	Flat-pleated	Flat-pleated	Flat-pleated
Offered as fog free	Yes	Yes	Yes
Offered with Visor	Yes	Yes	Yes
Product Performance Specifications	Meets ASTM F2100-11, ASTM F1862-07, ASTM F2101-07, ASTM F2299-03, MIL-M369454C 16 CFR 1610 (PSC CS-191-53)	Meets ASTM F2100-11, ASTM F1862-07, ASTM F2101-07, ASTM F2299-03, MIL-M369454C 16 CFR 1610 (PSC CS-191-53)	Meets ASTM F2100-11, ASTM F1862-07, ASTM F2101-07, ASTM F2299-03, MIL-M369454C 16 CFR 1610 (PSC CS-191-53)
Biocompatibility	Biocompatible. Non-cytotoxic, Non-sensitizing, Non-irritating	Biocompatible. Non-cytotoxic, Non-sensitizing, Non-irritating	Biocompatible. Non-cytotoxic, Non-sensitizing, Non-irritating
Dimensions-width	6.5" ± 0.75"	6.5" ± 0.75"	6.5" ± 0.75"
Dimension-length	4" ± 0.75"	4" ± 0.75"	4" ± 0.75"

DEVICE DESCRIPTION: The Kimberly-Clark* KC 300 Face Mask is a four layer mask, constructed of polyester and polypropylene materials. The outer facing layer is currently made of polypropylene spunbond fabric. With the proposed change, the outer facing layer will be made of polyethylene/polyester material used in a predicate device. The inner facing layer is currently made of polyester cellulose. With the proposed change, the inner facing layer will also be made of polyethylene/polyester material used in a predicate device. Kimberly-Clark KC300 Face Mask(s) is a single use, disposable device, provided nonsterile.

INTENDED USE: The Kimberly-Clark KC300 Face Mask 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

Product Code 47297, KC300 FLUIDSHIELD* Procedure Mask with SO SOFT* Lining
Product Code 47298, KC300 FLUIDSHIELD* Fog-Free Procedure Mask with SO SOFT* Lining
Product Code 48297, KC300 FLUIDSHIELD* Surgical Mask with SO SOFT* Lining

TECHNOLOGICAL CHARACTERISTICS: The difference in performance characteristics conform with ASTM 2100-11 and ASTM 2100-07 and raise no new issues of safety and efficacy.

PERFORMANCE TESTING: The KC300 face mask(s) have been tested 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*
- Mil- M36954C Military Specifications
- 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

SUMMARY OF TEST RESULTS: All results of testing met acceptance criteria.

CONCLUSIONS: The conclusions drawn from the non-clinical tests demonstrate that the device is as safe and as effective, and performs as well as the legally marketed device.



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

December 20, 2013

Kimberly-Clark* Corporation
Ms. Monica King
Associate Director of Regulatory Affairs
1400 Holcomb Bridge Road
ROSWELL GA 30076

Re: K131879
Trade/Device Name: Kimberly-Clark KC 300 Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Mask
Regulatory Class: II
Product Code: FXX
Dated: November 19, 2013
Received: November 20, 2013

Dear Ms. King:

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 contact 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K131879

Device Name
Kimberly-Clark KC300 Face Mask

Indications for Use (Describe)

The Kimberly-Clark KC300 Face Mask 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

Product code 47297, KC300 FLUIDSHIELD* Procedure Mask with SO SOFT* Lining
Product code 47298, KC300 FLUIDSHIELD* Fog-Free Procedure Mask with SO SOFT* Lining
Product code 48297 KC300 FLUIDSHIELD* Surgical Mask with SO SOFT* Lining

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Elizabeth F. Claverie -S
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