K113340

MAY - 4 2012

510K Summary

Date Summary was Prepared:	November 3, 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:	Kimberly-Clark Pediatric/Child Facemask
Device Common names	Mask, surgical
Device Product Codes and Classification Names:	OXZ, Class II Mask, surgical (21 CFR 878.4040)
Predicate Devices	The Kimberly-Clark Pediatric/Child face mask(s) K103150.
Device Description:	The Kimberly-Clark Pediatric/ Child Facemask is a three layer mask, constructed of nonwoven polyester blends and polypropylene materials. Bindings are nonwoven polyester and earloops are knitted polyester/lycra. A malleable nosepiece is placed within the bindings for comfort and individualized fit around the wearer's nose. The Pediatric/ Child Facemask is appropriately sized to the smaller faces of children across a diverse population. The Pediatric/ Child Facemask is a single use, disposable device, provided non-sterile.
Intended Use:	The Kimberly-Clark Pediatric/ Child Facemask, is intended to be worn by the patient/child (recommended ages 4-12) to provide protection for the respiratory tract. It is a single use, disposable device that is provided non-sterile. This Face Mask is recommended for use in a healthcare setting with appropriate adult supervision.

Technological Characteristics and Substantial Equivalence:

The Kimberly-Clark Pediatric/Child face mask is substantially equivalent to the predicate device, Kimberly-Clark Pediatric/Child face mask K103150 in intended use and principles of operation.

Summary of Testing:

The Kimberly-Clark Pediatric/Children's face mask has been tested under the following standards

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
ASTM 2101-07	Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials. Using a Biological Aerosol of *Staphylococcus aureus*
ISO 10993	Standards for evaluating the biocompatibility of a medical device

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
Associate Director of Regulatory Affairs
Kimberly-Clark
1400 Holcomb Bridge Road
Roswell, Georgia 30076

MAY - 4 2012

Re: K113340
Trade/Device Name: Kimberly-Clark Pediatric/Child Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: OXZ
Dated: April 26, 2012
Received: April 27, 2012

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,

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): _____

Device Name: Kimberly-Clark Pediatric/Child Face Mask

Indications for Use:

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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 B. Claverie-Wilson

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

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