

Traditional 510(k) for Kimberly-Clark* Lavender* Nitrile Powder-Free Exam Gloves
Section 5. 510(k) SUMMARY
K081260
SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Submitter's Name:	Kimberly-Clark Corporation
Submitter's Address:	1400 Holcomb Bridge Road Roswell, GA 30076-2199
Submitter's Phone No:	770-587-8208
Submitter's Fax No.	920-969-5160
Date of Preparation:	May 1, 2008
Name of Device	
Trade Name:	Kimberly-Clark* Lavender* Nitrile Powder-Free Exam Glove
Common Name:	Patient examination glove
Classification Name:	Glove, Patient Examination, Poly - 80 LZA
Legally marketed device to which equivalency is claimed:	Kimberly-Clark* STERLING* Nitrile Powder-Free Exam Glove - K051347
Description of the device:	Lavender colored nitrile, chlorinated, powder-free, textured fingertip, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, <i>Standard Specification for Nitrile Examination Gloves for Medical Application</i> .
Intended use of device:	The Kimberly-Clark* Lavender* Powder-Free Exam Gloves are disposable Devices, intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.
Summary of technological characteristics compared to predicate device:	There are no different technological characteristics compared to the predicate device. They are both powder-free non-sterile nitrile exam gloves, the predicate being a light gray color and the subject of this application being a lavender color.

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

(Continued)

Brief description of Non-Clinical Tests:	<table border="1"> <thead> <tr> <th data-bbox="625 390 1096 425"><u>Non-Clinical Tests</u></th> <th data-bbox="1096 390 1372 425"><u>Standard</u></th> <th data-bbox="1372 390 1588 425"><u>Performance</u></th> </tr> </thead> <tbody> <tr> <td data-bbox="625 425 1096 458">Dimensions</td> <td data-bbox="1096 425 1372 458">ASTM D 6319-00a</td> <td data-bbox="1372 425 1588 458">Meets</td> </tr> <tr> <td data-bbox="625 458 1096 491">Physical Properties</td> <td data-bbox="1096 458 1372 491">ASTM D 6319-00a</td> <td data-bbox="1372 458 1588 491">Meets</td> </tr> <tr> <td data-bbox="625 491 1096 524">Freedom from pinholes</td> <td data-bbox="1096 491 1372 524">ASTM D 6319-00a</td> <td data-bbox="1372 491 1588 524">Meets</td> </tr> <tr> <td data-bbox="625 524 1096 556"></td> <td data-bbox="1096 524 1372 556">ASTM D 5151-06</td> <td data-bbox="1372 524 1588 556">Meets</td> </tr> <tr> <td data-bbox="625 556 1096 589">Powder Free</td> <td data-bbox="1096 556 1372 589">ASTM D 6124-06</td> <td data-bbox="1372 556 1588 589">Meets</td> </tr> <tr> <td data-bbox="625 589 1096 622"></td> <td data-bbox="1096 589 1372 622">ASTM D 6319-00a</td> <td data-bbox="1372 589 1588 622">Meets</td> </tr> <tr> <td data-bbox="625 622 1096 655">ISO Skin Irritation Study</td> <td data-bbox="1096 622 1372 655">ISO 10993, Part 10</td> <td data-bbox="1372 622 1588 655">Meets</td> </tr> <tr> <td data-bbox="625 655 1096 687">Murine Local Lymph Node Assay</td> <td data-bbox="1096 655 1372 687">ISO 10993, Part 10</td> <td data-bbox="1372 655 1588 687">Meets</td> </tr> <tr> <td data-bbox="625 687 1096 738">ISO Systemic Toxicity Study</td> <td data-bbox="1096 687 1372 738">ISO 10993, Part 11</td> <td data-bbox="1372 687 1588 738">Meets</td> </tr> </tbody> </table>	<u>Non-Clinical Tests</u>	<u>Standard</u>	<u>Performance</u>	Dimensions	ASTM D 6319-00a	Meets	Physical Properties	ASTM D 6319-00a	Meets	Freedom from pinholes	ASTM D 6319-00a	Meets		ASTM D 5151-06	Meets	Powder Free	ASTM D 6124-06	Meets		ASTM D 6319-00a	Meets	ISO Skin Irritation Study	ISO 10993, Part 10	Meets	Murine Local Lymph Node Assay	ISO 10993, Part 10	Meets	ISO Systemic Toxicity Study	ISO 10993, Part 11	Meets
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Brief description of Clinical Tests:	No new clinical tests were required to support this 510(k) application.																														
Conclusions drawn from the Non-Clinical and Clinical Tests:	Non-clinical laboratory and animal based biocompatibility test data confirm the Kimberly-Clark* Lavender* Nitrile Powder-Free Exam Gloves meet all applicable exam glove performance and biocompatibility requirements.																														
Other Information deemed necessary by the FDA:	None																														



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2008

Mr. Richard V. Wolfe
Associate Director, Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K081260

Trade/Device Name: Kimberly-Clark* Lavender* Nitrile Powder-Free Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: June 16, 2008
Received: June 18, 2008

Dear Mr. Wolfe:

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.

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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 Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Applicant: Kimberly-Clark Corporation
510(k) Number: K081260
Device Name: Kimberly-Clark* Lavender* Nitrile Powder-Free Exam Gloves
Indications for Use: Based upon 21CFR§880.6250 "Patient examination glove"

A patient examination glove is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter X
Per 21CFR 801.109 Subpart D Per 21CFR 801.109 Subpart C

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

510(k) Number: K 081260