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510K Summary

Applicant	Kimberly-Clark 1400 Holcomb Bridge Road Roswell, GA 30076
Date of Preparation	November 1, 2013
Official Correspondent	Chris Macauley Technical Leader, Regulatory Affairs Tel: 770.587.8638 Fax: 920.255.4648 email: cmacaul@kcc.com
Trade Name:	KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves
Classification Name:	Patient examination glove.
Device Classification and Product Code	Class I per 21 CFR §880.6250 Product Code - LZA

NOV 07 2013

PREDICATE DEVICES:

K081260 - KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves

K992830 – Safeskin Polymer-Coated Nitrile Examination Gloves

SUBSTANTIAL EQUIVALENCE:

The subject KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves are substantially equivalent to the KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves cleared under K081260 and the Safeskin Polymer-Coated Nitrile Examination Gloves cleared under K992830. The subject KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves and the predicate devices have the same intended use and same fundamental scientific technology. Bench testing has demonstrated that the subject KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Glove performs the same function as the predicate devices and that any minor differences between the subject device and the predicate devices has no adverse impact to safety or efficacy.

<u>SUBSTANTIAL EQUIVALENCY</u>			
<u>Element</u>	<u>Predicate (K081260)</u>	<u>Predicate (K992830)</u>	<u>Subject Device</u>
	<u>KIMBERLY-CLARK* LAVENDER* NITRILE Powder- Free Exam Gloves</u>	<u>Safeskin Polymer- Coated Nitrile Examination Gloves</u>	<u>KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves</u>
INDICATIONS FOR USE	Exam Gloves are disposable Devices, intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.	Same	Same
FDA DEVICE CLASSIFICATION	LZA, Class I Patient Examination Glove	Same	Same
Trade Name	KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves	Safeskin Polymer-Coated Nitrile Examination Gloves	KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves
Construction	Nitrile, chlorinated, powder-free, textured-fingertip, ambidextrous patient examination glove.	Dipped in nitrile latex compound using a former release agent and coated with a polymer on the donning (outer) surface. No donning powder is used.	Nitrile, powder-free, textured-fingertip, ambidextrous patient examination glove with a polymer coating on the donning surface without chlorination.
Applicable Performance Requirements	ASTM D5151-99 ASTM D6319-00a ASTM D6124-06 ISO 10993-10 ISO 10993-11	ASTM D5151-92 ATSM6319-99 ASTM6124-06 ISO 10993-10	ASTM D5151-06 ASTM D6319-10 ASTM D6124-06 ISO 10993-10 ISO 10993-11
Supplied non-Sterile	Yes	Yes	Yes

INTENDED USE:

KIMBERLY-CLARK* LAVENDER* NITRILE 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

TECHNOLOGICAL CHARACTERISTICS			
Summary of technological characteristics compared to predicate device:	There are no different technological characteristics of the Subject Device compared to the predicate devices. They are both powder-free non-sterile nitrile exam gloves with one predicate being chlorinated and the other predicate being non-chlorinated and having a polymer-coating on the donning side.		
Non-Clinical Tests	Dimensions	ASTM D 6319-10	Meets
	Physical Properties	ASTM D 6319-10	Meets
	Freedom from pinholes	ASTM D 6319-10	Meets
	Powder Free	ASTM D 5151-06	Meets
		ASTM D 6124-06	Meets
	ISO Skin Irritation Study	ASTM D 6319-10	Meets
		ISO 10993, Part 10	Meets
		ISO 10993, Part 10	Meets
ISO Systemic Toxicity Study	ISO 10993, Part 1	Meets	
Clinical Tests:	No new clinical tests were required to support this 510(k) notification.		
Conclusions	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.		

Functional test results meet acceptance criteria and demonstrate that the subject device is safe and effective for use in humans and performs as well as the legally marketed predicate devices. The Subject Device meets the FDA recognized consensus standards, or equivalent methods, and acceptable pinhole quality level (AQL) as shown by the data.

CONCLUSION:

Performance testing has demonstrated that the subject KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Glove is substantially equivalent to the predicate K081260, KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves, and to predicate K992830, Safeskin Polymer-Coated Nitrile Examination Gloves.



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

November 7, 2013

Kimberly-Clark Corporation
Ms. Christine Macauley
Technical Leader, Regulatory Affairs
1400 Holcomb Bridge Road
ROSWELL, GA 30076

Re: K131841

Trade/Device Name: Lavender Nitrile Powder-Free Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: August 15, 2013
Received: August 19, 2013

Dear Ms. Macauley:

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

Kwame Ulmer M.S.
Acting Division 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)
K131841

Device Name
KIMBERLY-CLARK LAVENDER NITRILE Powder-Free Exam Gloves

Indications for Use (Describe)
KIMBERLY-CLARK LAVENDER NITRILE 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.

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)

Terrell A.
Cunningham - S

Digitally signed by Terrell A. Cunningham - S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People,
0.9.2342.19200300.100.1.1=1300095968,
cn=Terrell A. Cunningham - S
Date: 2013.10.31 09:41:44 -04'00'