K112012

MAR 2 1 2012

SUMMARY PREMARKET 510(k) NOTIFICATION
Non-Sterile, Powder-Free, Nitrile Examination Gloves Blue

Submission Applicant: UG Healthcare (USA) Inc.
1565 Sunflower Avenue
Costa Mesa, Ca. 92626

Official Correspondent: Kenneth J. Stanton,President
UG Healthcare (USA) Inc.
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Description of the Device **Trade Name: Non-Sterile, Non-Sterile, Powder-Free, Nitrile Examination Gloves Blue**

A. **Common Name: Examination Gloves**
Classification Name: Patient Examination Glove (per 21 CFR 880.6251)
Class 2: Powder-Free Nitrile examination glove 80LZA that meets all of the requirements of ASTM D6319-10.
Predicative Devices: Nitrile Powder-Free Examination Gloves

Intended Use of the Device: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between the patient and the examiner.

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Summary of Technological Characteristics:
Material: Nitrile **Cuff:** Beaded **Powder Residue:** Maximum 2mg/glove

Quality Assurance: In compliance with ASTM D6319-10, ISO 2859-1, manufactured under ISO9001:2008 and ISO 13485:2003

Inspection Parameters:

Criteria	Inspection Level	AQL
Dimensions	S-2	4.0
Physical Properties	S-2	4.0
Water Tight Test 1000ml	G-1	1.5
Visual Major Defects	G-1	1.5
Visual Minor Defects	G-1	2.5

Physical Properties:

Dimensions:
Overall Length: 240 mm minimum
Width: 95 mm minimum (for medium glove)
Thickness: .05 mm minimum

	BEFORE AGING	AFTER AGING
Tensile Strength:	14.0. Mpa minimum	14.0 Mpa minimum
Ultimate Elongation:	500% minimum	400% minimum

Special Properties: None

Packaging: 150 pcs per dispenser box, 10 boxes per case, 1,500 gloves per case

Sizes: XS – XL

Conclusion: Non-Sterile, Powder-Free, Nitrile Examination Gloves Blue meets the physical property requirements of ASTM D 6319-10, the FDA 1000 ml water test both before and after aging, and the Protein Labeling Claim Level at <50ug/g. This product is as safe, as effective, and performs as well or better than the legally marketed 510 #K000689. It has been supported by results of Biocompatibility Tests, Residual Powder Content tests, Physical Property Tests and the 1000ml Water Tight Test.

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

Mr. Ken Stanton
President
UG Healthcare (USA), Incorporated
1565 Sunflower Avenue
Costa Mesa, California 92626

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Re: K112012
Trade/Device Name: Non-Sterile, Powder-Free Blue, Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: February 28, 2012
Received: March 1, 2012

Dear Mr. Stanton:

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

510k Submission for:
Non-Sterile, Powder-Free, Nitrile Examination Gloves Blue

3.0 Indications for Use:

510K K112012

Device Name: Non-Sterile, Powder-Free, Nitrile Examination Gloves Blue

Indications for Use – Non-Sterile, Powder-Free, Nitrile Examination Gloves Blue is a disposable device intended for Medical Purposes that is worn on the examiners hand to prevent contamination between patient and examiner.

Prescription Use _____ **and/or Over-The-Counter Use** _____X_____
(Part 21 CFR 801 Subpart D) **(Part 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 F. Claxton Williams

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

510(k) Number: K112012