APR 8 2005

SUMMARY PREMARKET 510(k) NOTIFICATION
For Lano-E Powder-Free Nitrile Examination Gloves
510(k) Number: K050765

Submission Applicant:

N.S. Uni-Gloves Sdn. Bhd.
Lot 3 & 4/4510 Senawang Industrial Estate,
70450 Seremban, Negeri Sembilan
Malaysia
Telephone No. 60-6-677-2751/2
Fax No. 60-6-677-2755

Registration No. **8040880** Device Listing No. **B 034622**
510(k) Number: K050765

Official Correspondent in the United States:

Kenneth J. Stanton, President
UG Healthcare (USA) Inc.
2420 Carson St., Suite 125
Torrance, CA 90501

Telephone No.: (310) 328-7981
Fax No.: (310) 328-7829

Submitted: March 15, 2005

A. Description of the Device
Trade Name: Lano-E Powder-Free Nitrile Examination Glove
Common Name: Examination Gloves
Classification Name: Patient Examination Glove (per 21 CFR 880.6251)
Class I Powder-Free Nitrile examination glove 80LZA that meets all of the requirements of ASTM Standard D 6319 – 00 Rev A

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.

Summary of Technological Characteristics:

Material: Nitrile **Cuff:** Beaded **Powder Residue:** Maximum 2mg/glove

Quality Assurance: In compliance with ASTM D6319-00 Rev A, EN 455-3 : 2000, EN 455-2 : 2000, EN 455-1 : 2000, ISO 2859-1:1999 and manufactured under ISO9001:2000

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)
Palm Thickness:	0.10 to 0.15 mm (at center of palm)
Finger Thickness:	0.10 to 0.17 mm (at 15mm from tip of center finger)
Cuff Thickness:	0.10 to 0.15 mm (at 40mm from the beaded end)

	BEFORE AGING	AFTER AGING
Tensile Strength:	14.0. Mpa minimum	14.0 Mpa minimum
Ultimate Elongation:	700% minimum	500% minimum
Pinhole AQL	1.5 minimum	1.5 minimum

Special Properties: Processed with pharmaceutical quality lanolin as the emollient and conditioning agent. Also contains Vitamin E which complies with the current USP, Ph.Eur., DAB and BP monographs.

Packaging: 100 pcs per dispenser box, 10 boxes per case, 1,000 gloves per case

Sizes: XXS - XL

Conclusion: The Lano-E Powder-Free Nitrile Examination Glove meets the physical property requirements of ASTM D 6319-00 Rev A and the FDA 1000 ml water test both before and after aging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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N.S. Uni-Gloves Sdn. Bhd.
C/O Mr. Kenneth J. Stanton
President
UG Healthcare (USA) Incorporated
2420 Carson Street Suite 125
Torrance, California 90501

Re: K050765
Trade/Device Name: Lano-E, Powder Free, Nitrile Examination Gloves
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: April 4, 2005
Received: April 5, 2005

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.

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.

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 (240) 276-0115 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/industry/support/index.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

510(k) Number (if known): K050765

Device Name: Lano-E, Powder Free, Nitrile Examination Gloves

Indications For Use: The Lano-E, Powder Free, Nitrile Examination Gloves is a disposable device intended forMedical Purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (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)

Sheila A. Murphy 4/8/05
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K050765