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SUMMARY PREMARKET 510(k) NOTIFICATION

Non-Sterile Powder-Free Natural/Green Lano-E Latex Exam Gloves, with or without Citrus/Peppermint scent plus a protein labeling claim.

510(k) Number (if known): K052666

Submission Applicant/Official Correspondent:

Jarilyn Lim, President
Ascend Eagle Inc.
140-B, Dodd Court
American Canyon, CA 94503
Tel: 707-648-1526
Fax: 707-648-1534

Submitted: September 26, 2005

Description of the Device:

Trade and Proprietary Name: Non-Sterile Powder-Free Natural/Green Lano-E Latex Exam Gloves, with or without Citrus/Peppermint scent plus a protein labeling claim. (Multiple Private Labels)
Common Name: Latex Examination Gloves
Classification Name: Patient Examination Glove (per 21 CFR 880.6251)
Class I: Powder-Free Latex examination glove 80LYY that meets all of the requirements of ASTM Standard D 3578-01aE2.
Predicative Devices: Latex Powder-Free Examination Gloves

Intended Use of the Device:

These patient examination gloves are disposable devices intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between the patient and the examiner.

Substantial Equivalence:

Both in its intended use and/or physical characteristics, this device is equivalent to devices currently marketed by US companies. It is **Substantially Equivalent** to the devices manufactured by SGMP Co., LTD, except by coating, K032293, and by N.S. Uni-Gloves Sdn. Bhd., except by scent, K013163.

Summary of Technological Characteristics:

Material: Latex **Cuff:** Beaded **Powder Residue:** Maximum 2mg/glove
Quality Assurance: In compliance with ASTM D3578-01a, EN 455-1: 2000, EN 455-2: 2000, EN 455-3: 2000, ISO 2859-1:1999 and manufactured under ISO 9001:2000.

K052666

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:	0.13 to 0.18 mm (at center of palm)
Finger Thickness:	0.15 to 0.20 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:	21. Mpa minimum	16.0 Mpa minimum
Ultimate Elongation:	700% minimum	500% minimum
Pinhole AQL	1.5 minimum	1.5 minimum

Biocompatibility:
The biocompatibility test results are as per attached in Appendix B1 and B2 and show that the gloves passed the tests for examination gloves.

Residual Protein Level:
The extractable protein content test result is a per attached in Appendix B5 and show that the gloves meets the protein labeling claim level at < 50ug/g.

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

Conclusion: These Powder-Free Latex Examination Gloves meet the physical property requirements of ASTM D 3578-01 and the FDA 1000 ml water test both before and after aging. It also meets the protein labeling claim level at < 50ug/g.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2006

Ms. Jarilyn Lim
President
Ascend Eagle, Incorporated
140-B, Dodd Court
American Canyon, California 94503

Re: K052666
Trade/Device Name: Non-Sterile, Powder-Free, Latex Examination Gloves, with Lanolin and Vitamin E Coating, Natural or Green Color, with or Without Scent (Combined Citrus Peppermint), and with Protein Labeling Claim (50 Micrograms or Less of total water Soluble Protein Per Gram of Glove)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: January 3, 2006
Received: January 9, 2006

Dear Ms. Lim:

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.

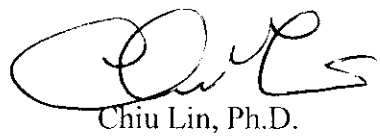
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

APPLICANT: Jarilyn Lim, President
Ascend Eagle Inc.
140-B, Dodd Court
American Canyon, CA 94503

510(k) NUMBER: K052666

DEVICE NAME: Non-Sterile, Powder-Free, Latex Examination Gloves, with Lanolin and Vitamin E Coating, Natural or Green Color, With or Without Scent (combined Citrus-Peppermint), and with Protein Labeling Claim (50 Micrograms or less of total water soluble protein per Gram of glove)

Indications For Use:

The Non-Sterile, Powder-Free, Latex Examination Gloves, with Lanolin and Vitamin E Coating, Natural or Green Color, With or Without Scent (Combined Citrus-Peppermint), and with Protein Labeling Claim (50 micrograms or less total water extractable protein per gram of glove) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use..... AND/ OR Over-The –Counter Use.....X.....
Per 21 CFR 801.109 (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)

4/25/06

..., General Hospital,
...l Control, Dental Devices

...K052666