DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 6, 2016

A1 Glove Sdn. Bhd.
Mr. John Phan
Lot 3726, Kawasan Perindustrian Nilai, Mukim Setul
Nilai, Negeri Sembilan 71900
MALAYSIA

Re: K153744
Trade/Device Name: A1 Brand Powder Free Patient Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient examination glove
Regulatory Class: Class I
Product Code: LYY
Dated: July 13, 2016
Received: July 13, 2016

Dear: John Phan

This letter corrects our substantially equivalent letter of July 13, 2016.

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 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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

Susan Runner DDS, MA

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K 153744

Device Name
A1 Glove Powder Free Latex Patient Examination Gloves with Protein Content Labeling Claim
(Contain 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein)

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

pe 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

A1 GLOVE SDN. BHD.

Date: 8th July 2016

510k number: K 153744

1.01 Submitter:

Name	: A1 Glove Sdn. Bhd.
Address	: Lot 3726, Kawasan Perindustrian Nilai, Mukim Setul, Daerah Seremban, Malaysia
Country	: Malaysia
Phone No.	: +60 6012028

1.02 Contact Person:

Contact	: Mr. John Phan
E-mail	: john_phan@hotmail.com
Telephone No.	: +6019-3544 880
Fax No.	: +60-6 799 6066

1.03 Name of Device:

Trade Name	: A1 Glove Powder Free Latex Patient Examination Gloves with Protein Content Labeling Claim (Contain 50 Micrograms per dm² of glove or Less of Water Extractable Protein)
Common Name	: Patient Examination Gloves
Classification Name	: Patient Examination Glove
Product Code	: LYY

1.04 Identification of The Legally Marketed Device:

Powder Free Latex Patient Examination Gloves, with Protein Content labeling Claim (Contain 50 Micrograms per dm^2 of Glove or Less of Water Extractable Protein), LYY, meets all of the requirements of ASTM D-3578 Standard Specification of Latex Examination Gloves for Medical Application which equivalent to legally marketed device of K112612.

Predicate Device: K112612, Powder Free Latex Patient Examination Glove with Protein Content Labeling Claim (Contains 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein)

1.05 Description of Device

Powder Free Latex Patient Examination Gloves, with Protein Content labeling Claim (Contains 50 Micrograms per dm^2 of Glove or Less of Water Extractable Protein), meets all of the requirements of ASTM D3578:05-2010

1.06 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 to prevent contamination between patient and examiner.

1.07 Summary of the Technological Characteristics of the Device
Powder Free Latex Examination Gloves possesses the following technological characteristic (as compared to ASTM or equivalent standard):

CHARACTERISTICS	STANDARDS	SPECIFICATION	DEVICE PERFORMANCE/ ACTUAL SPECIFICATION
Dimensions	ASTM D3578:05-2010	Thickness Palm : min 0.08mm Finger : min 0.08mm Length (by size) S : min 220 M : min 220 L : min 230	**Meet.** Palm Thickness: **0.09 mm** Finger Thickness : **0.11 mm** Length (by size) S : **240 mm** M : **240 mm** L : **240 mm**
Physical Properties	ASTM D3578:05-2010 ASTM D412:06 ASTM D573:04-2010	Tensile Strength (MPa) Before aging : Min 18 MPa After aging : Min 14 MPa Elongation at Break (%) Before aging : Min 650mm After aging: Min 500mm	**Meet** Tensile Strength (MPa) Before aging : **22.91 MPa** After Aging : **20.98 MPa** Elongation at Break (%) Before aging : **850 mm** After aging : **820 mm**
Freedom from pin-holes	ASTM D5151:06-2011	AQL 1.5	**Meet**
Powder Free Residue	ASTM D6124:06-2011	Below 2mg/glove	**Meet**
Protein Content	ASTM D5712:10-2010	Below 50ug/dm^2	**Meet**
Biocompatibility	Animal Irritation Test (ISO 10993-10:2010)	Under the conditions tested, the subject glove was not an irritant.	**Under the conditions tested, the subject glove was not an irritant.**
	Dermal Sensitization (ISO 10993-10:2010)	Under the condition tested, the subject glove was not a sensitizer.	**Under the condition tested, the subject glove was not a sensitizer.**

1.08 Substantial Equivalent based on Assessment of Non-Clinical Performance Data
The performance test data of non-clinical tests that support a determination of substantial equivalence is the same as shown on the table above.

1.09 Substantial Equivalent based on Assessment of Clinical Performance Data
Clinical data for the subject glove is not needed.

1.10 Substantial Equivalence Comparison

Characteristic & Parameters	Predicate Device	Proposed Device	Specification	Substantial Equivalence SE
	K112612, Powder Free Latex Patient Examination Glove with Protein Content Labeling Claim (Contains 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein)	A1 Glove Powder Free Latex Patient Examination Gloves with Protein Content Labeling Claim (Contain 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein)		
Product Code	LYY	LYY		SE
FDA Device Class	Class I	Class I		SE
Intended Use	A patient examination gloves is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.		SE
Material	Natural Rubber Latex	Natural Rubber Latex		SE
Dimensions	Meets ASTM D3578	Meets ASTM D3578:05-2010	Thickness Palm : min 0.08mm Finger : min 0.08mm Length (by size) S : min 220 M : min 220 L : min 230	SE
Physical Properties	Meets ASTM D3578	Meets ASTM D3578:05-2010	Tensile Strength (MPa) Before aging : Min 18 MPa After aging : Min 14 MPa Elongation at Break (%) Before aging : Min 650mm After aging: Min 500mm	SE
Freedom from Pin Holes - ASTM D5151	Meets ASTM D5151	Meets ASTM D5151:06:2011	AQL 1.5	SE
Protein Content- ASTM D5712	Meets ASTM D5712	Meets ASTM D5712:10-2010	Below 50ug/dm^2	SE
Skin Irritation ISO 10993-10:2002	Under the condition tested, the subject glove was not an irritant.	Under the condition tested, the subject glove was not an irritant.	Under the condition tested, the subject glove was not an irritant.	SE
Dermal sensitization ISO 10993-10:2002	Under the condition tested, the subject glove was not a sensitizer.	Under the condition tested, the subject glove was not a sensitizer.	Under the condition tested, the subject glove was not a sensitizer.	SE

Table 1.10. Substantial Equivalence Comparison

1.11 Conclusion

The conclusion drawn from the non-clinical testing demonstrates that the subject glove is as safe, as effective, and performs as well as the legally marketed predicate device, K112612.