October 23, 2017

Primus Gloves, Pvt. Limited
Jose Paul M
Manager QA & RA
Plot No 14-A, Cochin Special Economic Zone, Kakkanad
Cochin, 682037 INDIA

Re: K170612
Trade/Device Name: Sterile Vinyl Examination Gloves, Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: September 25, 2017
Received: September 28, 2017

Dear Jose Paul M:

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 Industry and Consumer Education (DICE) 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 Industry and Consumer Education (DICE) 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,

Michael J. Ryan -S

for 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)*
K170612

Device Name
STERILE VINYL EXAMINATION GLOVES, POWDER FREE

Indications for Use *(Describe)*
The POWDER FREE patient examination gloves is a disposable device intended for medical purposes that is worn on the examiners hand or finger 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)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (K) SUMMARY K170612

1.0 SUBMITTER

1.1	Company Name	:	PRIMUS GLOVES PRIVATE LIMITED
1.2	Address	:	Plot No: 14-A, Cochin Special Economic Zone,
		:	Kakkanad, Cochin, Kerala, India - 682037
1.3	Telephone	:	+ 91 484 2413063
1.4	Fax	:	+91 484 2413089
1.5	Email	:	josepaul@primusgloves.com
1.6	Contact Person	:	Mr. JOSE PAUL M
		:	MANAGER – QA & RA

2.0 OFFICIAL CORRESPONDENT

2.1	Company Name	:	PRIMUS GLOVES PRIVATE LIMITED
2.2	Address	:	Plot No: 14-A, Cochin Special Economic Zone,
		:	Kakkanad, Cochin, Kerala, India - 682037
2.3	Telephone	:	+ 91 484 2413063
2.4	Fax	:	+91 484 2413089
2.5	Email	:	josepaul@primusgloves.com
2.6	Contact Person	:	Mr. JOSE PAUL M
		:	MANAGER – QA & RA

3.0 Preparation date **:** 13th OCTOBER , 2017

4.0 Name of the device **:**

4.1	Device Name	:	STERILE VINYL EXAMINATION GLOVES, POWDER FREE,
4.2	Trade Name	:	PRIMUS VINYL EXAMINATION GLOVES PF
4.3	Common Name	:	PATIENT EXAMINATION GLOVES
4.4	Classification	:	PATIENT EXAMINATION GLOVES
4.5	Class	:	CLASS I
4.6	Product code	:	LYZ
4.7	510(K)Number	:	K 170612

510 (K) SUMMARY K170612

5.0 Identification of the legally marketed predicate device

5.1	Device Name	:	POWDER FREE STERILE VINYL EXAMINATION GLOVE (Clear and Yellow)
5.2	510(k) Number	:	K 053523
5.3	Company	:	Shijiazhuang Hongxiang Plastics Products Co Ltd C/O Ms. Micky Lin, Gloveco , Inc. 3973 Schaefer Ave. Chino , California 97710
5.4	Device Description	:	POWDER FREE STERILE VINYL EXAMINATION GLOVES(Clear and Yellow)
5.5	Classification	:	PATIENT EXAMINATION GLOVES
5.6	Class	:	CLASS I
5.7	Product code	:	LYZ
5.8	Classification Panel	:	General Hospital

6.0 Description of the Device

The subject device is a vinyl examination glove made of synthetic poly vinyl chloride compound. It is sterile, POWDER FREE. The device is ambidextrous. The device meets ASTM D 5250-06: Standard specification for poly vinyl chloride gloves for medical application.

The device is for over-the counter single use.

7.0 Indications for use

The POWDER FREE patient examination gloves is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner

8.0 Summary of performance data

There is no difference in technological characteristics compared to the predicate device. Gloves are made from Poly vinyl chloride compound, sterile, POWDER FREE. The gloves have the same technological characteristics compared to ASTM or equivalent standards as given below,

Characteristics	Standards	Performance of Sterile Vinyl examination gloves, POWDER FREE
Freedom from Holes	ASTM D 5250-06/ ASTM D5151-06	Meets
Dimensions	ASTM D 5250-06	Meets
Physical Properties	ASTM D 5250-06 / ASTM D412-06	Meets
POWDER FREE residue	ASTM D 5250-06	Meets
Bio-compatibility	Primary skin irritation ISO 10993-10	Non-irritant
	Skin/Dermal Sensitization ISO 10993-10	Non-sensitizer
Expiration dating/Shelf life	ASTM D7160-05	Three years
Sterility	ISO 11737-02	Meets

Performance data of gloves based on ASTM D 5250-06and FDA 1000ml water leak test

ASTM D 5250-06and FDA 1000 ml water leak test					
Characteristics	**Test**	**Test standard**	**Sampling plan/Inspection level/AQL**	**sterile, vinyl examination gloves - PRIMUS**	**RESULT**
Freedom from Pin holes	FDA 1000 ml water leak test	ASTM D5151-06 (reap 2011)	ISO 2859-1 / G1/AQL 2.5	PASS	PASS
Dimensions	Length	ASTM D 5250-06	ISO 2859-1 / S2/AQL 4.0	> 230 mm	PASS
	Width	ASTM D 5250-06	ISO 2859-1 / S2/AQL 4.0	85±5 mm to 115±5 mm (sizes S to XL)	PASS
	Thickness	ASTM D 5250-06	ISO 2859-1 / S2/AQL 4.0	> 0.05 in finger & 0.08 in palm	PASS
Physical properties	Before aging	ASTM D 5250-06and ASTM D412-06	ISO 2859-1 / S2/AQL 4.0	Tensile strength : > 11 Mpa	PASS
				Ultimate Elongation : > 300 %	PASS
	After Accelerated aging	ASTM D 5250-06and ASTM D412-06	ISO 2859-1 / S2/AQL 4.0	Tensile strength : > 11 Mpa	PASS
				Ultimate Elongation : > 300 %	PASS
POWDER FREE residue	POWDER FREE residue	ASTM D 5250-06and ASTM D6124-06	N=5	Less than 2 mg per glove	PASS
Bio compatibility	Primary skin irritation	ISO 10993-10	Under the conditions of the study the device is not an irritant		PASS
	Skin/Dermal Sensitization	ISO 10993-10	Under the conditions of the study the device is not a sensitizer		PASS
Sterility		ISO 11737-02	Sterile		Pass

9.0 Predicate comparison chart

Characteristics	PREDICATE – 510(K) : K053523	SUBJECT DEVICE	Acceptance criteria/Standard
Manufacturer	Shijiazhuang Hongxiang Plastics Products Co Ltd C/O Ms. Micky Lin, Gloveco , Inc. 3973 Schaefer Ave. Chino , California 97710	PRIMUS GLOVES PRIVATE LIMITED, Plot No: 14-A, CSEZ, Kakkanad, Cochin, Kerala, India -682037	
Product Name	POWDER FREE STERILE VINYL EXAMINATION GLOVES(Clear and Yellow)	**STERILE VINYL EXAMINTION GLOVES, POWDER FREE**	Similar
Intended Use	The patient examination gloves is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner	The patient examination gloves is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner	Similar
Indication for use	The patient examination gloves is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner	The patient examination gloves is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner	Similar
Description	POWDER FREE sterile Vinyl Examination glove(clear and yellow) is made of poly vinyl chloride The gloves are provided in Sizes Small, Medium, Large and Extra Large	sterile Vinyl Examination gloves POWDER FREE is made of poly vinyl chloride The gloves are provided in Sizes Small, Medium, Large and Extra Large	Similar

Presentation	Sterile gloves are provided in pouches	Sterile gloves are provided in pouches	Similar
Material	Poly Vinyl Chlorid	Poly Vinyl Chlorid	Similar
Non-sterile or sterile	Sterile	Sterile	Similar
Single Use	Yes	Yes	Similar
Ambidextrous	Yes	Yes	Similar
Dimensions	Meets ASTM D 5250-06	Overall length min 230 mm ,width varies from 80 mm for small size to 115 mm for Large size, thickness in finger 0.05 mm min &,Palm 0.08 mm min	Similar
Tensile Strength	Meets ASTM D 5250-06	Tensile strength 11 Mpa min for before & after aging Aging done at 70 ±2 deg C for 72±2 hrs	Similar
Ultimate Elongation	Meets ASTM D 5250-06	Ultimate elongation 300 % min for before & after aging. Aging done at 70 ±2 deg C for 72±2 hrs	Similar

Freedom from pinholes	Meets ASTM D 5151 - 06 and ASTM D 5250-06	Meets ASTM D 5151 - 06 (2011) and ASTM D 5250-06	Similar
Residual Powder	Meets ASTM D 6124-06	Less than 2 mg per glove	Similar
Biocompatibility Tests ISO 10993-10	Non-irritant -Primary Skin Irritation In Rabbits	Under the conditions of the study the device is not an irritant	Similar
	Non-sensitizer - skin Sensitization in Guinea pigs	Under the conditions of the study the device is not a sensitizer	Similar
Labeling	POWDER FREE, Vinyl Examination glove sterile Single use only Ambidextrous Manufactured for Lot No Intended use Quantity Country of origin	*POWDER FREE, * Vinyl Examination glove * sterile *Single use only * Ambidextrous *Manufactured for *Lot No *Intended use *Quantity *Country of origin	Similar
Sterility	Sterile	Sterile	Similar

10.0 CONCLUSION

Based on the intended use, physical properties and technological characteristics, the subject device is as safe, as effective and performs as well as the legally marketed predicate device.