January 8, 2018

Beta Healthcare Products Pvt. Ltd.
% Manoj Zacharias
President
Liberty Management Group Ltd
75 Executive Dr., Ste 114
Aurora, Illinois 60504

Re: K172942
Trade/Device Name: Pristeen (Latex Surgeon's Gloves Powder Free, Polymer coated with protein content labeling claim of 50 ug/dm2 or less per glove of extractable protein)
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO
Dated: November 29, 2017
Received: December 5, 2017

Dear Manoj Zacharias:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172942

Device Name
Pristeen (Latex Surgeon's Gloves Powder Free, Polymer coated with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein)

Indications for Use *(Describe)*

A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510K SUMMARY as required by: 21CFR § 807.92

A. APPLICANT INFORMATION

1.	Submitter Name	Beta Healthcare Products Pvt.Ltd.
	Date Submitted	November 29, 2017
	Address	Plot No 21B, Cochin Special Economic Zone, Kakkanad,Kochi-682037. Kerala, India.
	Phone	+91 484 2413389 , 2413390
	Fax	+91 484 2413341
	E-mail	betahealthcare@gmail.com
	Contact Person	Boney Moolayil
	Designation	Director
	Contact Number	+91 974700797
	Contact Email	betahealthcare@gmail.com

B. US AGENT & CONTACT PERSON INFORMATION

17	US agent & contact person name	Manoj Zacharias
18	Address	Liberty Management Group Ltd. 75 Executive Dr, STE 114, Aurora, IL-60504, USA.
19	Phone	(630) 270-2921
20	Fax	(815) 986-2632
21	E-mail	manoj@libertymanagement.us

C. DEVICE IDENTIFICATION

	Common Name	Surgeon's Glove
	Device Name	Surgeon's Glove powder free
	Product proprietary or trade name	Pristeen (Latex Surgeon's Gloves Powder Free, Polymer coated with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein)
	Classification name	Surgeon's Glove
	Device Classification	1
	Product Code	KGO
	Regulation Number	21 CFR 878.4460
	Review Panel	Gen & Plastic Surgery

D.PREDICATE DEVICE INFORMATION

Sl.No	Name of devices	510k Number	510K Owner
Predicate device-1	Medismart+ Latex Surgeon's Glove powder free-polymer coated with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein	K151114	St.Marys Rubbers Pvt.Ltd, Koovappally P.O, Kanjirappally, Kottayam District, Kerala State, India-686518
Predicate device-2	SURGTEX Latex Surgeon's Glove powder free-polymer coated with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein	K130450	Purna Bina SDN BHD Plo 5, Jalan Mahsuri, 7.5km, Jalan Mersing, Kluang Industrial Area Kluang, Johor 86000

E. DESCRIPTION OF THE DEVICE

The proposed device, Latex Surgeon's Gloves Powder Free, Polymer coated with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein is a sterilized and disposable medical glove intended to be worn by operating room personnel to protect a surgical wound from contamination.

The proposed device is made of' natural rubber latex, as per standard ASTM D35 77 -09

The classification is: Type I - gloves compounded primarily from natural rubber latex".

The proposed device is Powder Free Latex Surgeon's Gloves, and variants of different sizes.

All variants share the same color, creamy, white.

The proposed device is sterilized either using Ethylene Oxide Sterilization or Gamma irradiation method to achieve the Sterility Assurance Level **(SAL) of** $10^{-6}$and place in a sterility maintenance package to ensure a shelf life of 3 years.

F. INDICATIONS FOR USE STATEMENT:

A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

G. NON-CLINICAL TEST CONCLUSION

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate devices. The test results demonstrated that the proposed device complies with the following standards:

ASTM D3577-09:- Standard Specification for Rubber Surgical Gloves.

ASTM D 5151-2011:-Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D6124-2011:- Standard Test Method for Residual Powder on Medical Gloves.

ASTM D5712-10:-Standard Test Method for the Analysis of Aqueous Extractable Protein in NaturalRubber *and* Its Products Using the Modified Lowry Method.

ASTM D6499-12:-Standard Test Method for the Immunological Measurement of Antigenic Proteinin Natural Rubber and Its Products.

ASTM F 1929-2004:- Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.

ISO 10993-10: 2010, Biological evaluation of medical devices **-** Part 10: Tests for irritation and skin sensitization.

1S01137-2: 2013. Sterilization of healthcare products-Radiation-Part2: Establishing the sterilization dose.

ISO 10993-7:2008:-Biological evaluation of medical devices —: Ethylene oxide sterilization residuals

ISO 11135-1:2007:-Sterilization of healthcare products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

H. PRODUCT COMPARISON IN COMPLIANCE WITH ASTM D 3577-09 STANDARD

SIZES AVAILABLE: - 5'/2, 6, 6'/2, 7, 7'/2, 8, 8'/2, 9

SL.NO	CRITERIA	SPECIFICATION AS PER ASTMD3577-09 STANDARD	AVERAGE VALUE OF SUBJECT DEVICE	WHETHER SUBJECT DEVICE COMPLIED WITH THE ASTMD3577 -09 STANDARD
1	**Length**			
	Size 5'/2	Min 265mm	281 mm	Yes
	Size 6	Min 265mm	281mm	Yes
	Size 6'/2	Min 265mm	282mm	Yes
	Size 7	Min 265mm	282mm	Yes
	Size 7'/2	Min 265mm	282mm	Yes
	Size 8	Min 265mm	283mm	Yes
	Size 8'/2	Min 265mm	283mm	Yes
	Size 9	Min 265mm	283mm	Yes
2	**Width**			
	Size 5'/2	70+/-6mm	74mm	Yes
	Size 6	76+/-6mm	78mm	Yes
	Size 6'/2	83+/-6mm	84mm	Yes
	Size 7	89+/-6mm	91mm	Yes
	Size 7'/2	95+/-6mm	97mm	Yes
	Size 8	102+/-6mm	103mm	Yes
	Size 8'/2	108+/-6mm	109mm	Yes
	Size 9	114+/-6mm	115mm	Yes
3	Finger Thickness (All sizes)	Min 0.10mm	0.18mm	Yes
4	Palm Thickness (All sizes)	Min 0.10mm	0.16mm	Yes
5	Cuff Thickness (All sizes)	Min 0.10mm	0.13mm	Yes

SL.NO	CRITERIA	SPECIFICATION AS PER ASTMD3577-09 STANDARD	AVERAGE VALUE OF SUBJECT DEVICE	WHETHER SUBJECT DEVICE COMPLIED WITH THE ASTMD3577 -09 STANDARD
6	**Tensile Strength**			
	Before aging (All sizes)	24Mpa minimum	28.0Mpa	Yes
	After aging@ 70°±2C for 166±2 hr (All sizes)	18Mpa minimum	24.0Mpa	Yes
7	**Ultimate Elongation**			
	Before aging (All sizes)	750% minimum	920%	Yes
	After aging@ 70°±2C for 166±2 hr (All sizes)	560% minimum	750%	Yes
8	Stress at 500% before ageing (All sizes)	5.5 MPa Max	3 Mpa	Yes
9	**Pinhole AQL**			
	Before aging (All sizes)	Max 1.5	1.0	Yes
	After aging@ 70°C for 7 days (All sizes)	Max 1.5	1.0	Yes

I. SUBSTANTIAL EQUIVALENCE COMPARISON

a. General Characteristics Comparison

Characteristic	Subject device K172942	Predicate device-1 K151114	Predicate device-2 K130450	Substantially Equivalent (SE) or Not (NSE)
Product Code	KGO	KGO	KGO	SE
Regulation No.	21 CFR 878.4460	21 CFR 878.4460	21 CFR 878.4460	SE
Class	1	1	1	SE
Intended Use for Latex Surgeon's Gloves Powder Free, Polymer coated with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein.	A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	A latex surgeon Surgeons glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination	A latex surgeon Surgeons glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination -	Substantially equivalent
Powdered or Powder free	powered free	Powdered, and powered free	powered free	SE
Classification per ASTMD3577-99	Type I - gloves compounded primarily from natural rubber latex	Type I - gloves compounded primarily from natural rubber latex	Type I - gloves compounded primarily from natural rubber latex	SE
Sterilization	ETO/as well as Radiation, SAL- 10^{-6}	ETO/as well as Radiation, SAL- 10^{-6}	Radiation SAL: 10^{-6}	SE
Label and Labeling	Meet FDA's Requirements	Meet FDA's Requirements	Meet FDA's Requirements	SE
Special label claim	Protein content labeling claim of 50 µg/dm² or less per glove of extractable protein for Latex Surgeon's Gloves Powder Free, Polymer coated	Same	same	SE
Type of use	Over the counter use	Over the counter use	Over the counter use	SE

b. Technological Characteristics Comparison

Characteristics	**Acceptance criteria of the standard**			Whether the subject device met the acceptance criteria of the standard
	Subject device K172942	Predicate device-1 K151114	Predicate device-2 K130450	
Dimensions	ASTM D3577-09(published date 02/01/2009)	ASTM D3577-09	ASTM D3577-09	Yes
Physical Properties	ASTM D3577-09 (published date 02/01/2009)	ASTM D3577-09	ASTM D3577-09	Yes
Freedom from Holes	ASTM D3577 and AST M D5151,(published date 08/20/2012)	ASTM D3577 and AST M D5151	ASTM D3577 and AST M D5151	Yes
Powder Content for powdered glove	ASTM D3577 and ASTM D6124,(published date 08/20/2012)	ASTM D3577 and ASTM D6124	ASTM D3577 and ASTM D6124	Yes
Powder Content for powder free glove	ASTM D3577 and ASTM D6124,(published date 08/20/2012) Powder content < 2 mg/Glove	ASTM D3577 and ASTM D6124, Powder content < 2 mg/Glove	ASTM D3577 and ASTM D6124, Powder content < 2 mg/Glove	Yes
Protein Content	ASTM D3577, ASTM D5712-10 and ASTM D6499 (published date 02/01/2009)	ASTM D3577, ASTM D5712-10 and ASTM D6499	ASTM D3577, ASTM D5712-10 and ASTM D6499	Yes
Biocompatibility	ISO 10993-10	ISO 10993-10	ISO 10993-10	Yes, Non-irritant and Non-Sensitizer

There is no difference with predicate device.

Substantial equivalence based on non clinical performance data
The performance test data of the non clinical tests are the same as mentioned immediately above.

Substantial equivalence based on clinical performance data.
Clinical data was not required for this submission.

Substantial Equivalence Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices identified in this submission (K151114 and K130450).