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

December 11, 2015

ST.MARY'S RUBBERS PVT. LTD
c/o Mr. Manoj Zacharias
Liberty Management Group Ltd
2871 Coastal Dr.
Aurora, IL 60503

Re: K151114
Trade/Device Name: Medismart (Latex Surgeon's Gloves powdered) and Medismart + (Latex Surgeon's Gloves Powder Free, Polymer coated with protein content labeling claim of 50 μg/dm² or less per glove of extractable protein)
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's glove
Regulatory Class: I
Product Code: KGO
Dated: November 7, 2015
Received: November 13, 2015

Dear Mr. 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.

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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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)*
K151114

Device Name
Medismart (Latex Surgeon's Gloves Powdered)

Indications for Use *(Describe)*
A latex surgeon's gloves 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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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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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)*
K151114

Device Name
Medismart + (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 gloves 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)

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510K SUMMARY as required by: 21CFR § 807.92 **K151114**

A. APPLICANT INFORMATION

1.	Submitter Name	ST.MARY'S RUBBERS PVT. LTD.
	Date Submitted	December 10, 2015
	Address	Koovappally P.O, Kanjirappally, Kottayam District, Kerala State, India-686518
	Phone	+91 4828 251533 , 239857,324570
	Fax	+91 4828 251353
	E-mail	info@stmarysrubbers.com
	Contact Person	S.Srinivasan
	Designation	QA Manager
	Contact Number	+91 9497244270
	Contact Email	qa@stmarysrubbers.com

B. US AGENT & CONTACT PERSON INFORMATION

17	US agent & contact person name	Manoj Zacharias
18	Address	Liberty Management Group Ltd. 2871,Coastal Dr. Aurora, IL-60503, USA.
19	Phone	(630) 270-2921
20	Fax	(815) 986-2632
21	E-mail	manoj@libertymanagement.us

C. DEVICE IDENTIFICATION

	Common Name	Surgeon's Gloves
	Device proprietary or trade name	a. Medismart (Latex Surgeon's Gloves powdered), b. Medismart **+** (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 Gloves
	Device Classification	I
	Product Code	KGO
	Regulation Number	21 CFR 878.4460
	Review Panel	Gen & Plastic Surgery

D.PREDICATE DEVICE INFORMATION

Name of device	510k Number	510K Owner
SURGTEX Latex Surgeon's Gloves powdered and SURGTEX Latex Surgeon's Gloves 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 Plot 5, Jalan Mahsuri, 7.5km, Jalan Mersing, Kluang Industrial Area Kluang, Johor 86000
Latex Surgeon's Gloves (powdered and Powder free)	K130301	Elimedical Devices (Eujian) Inc. **1E06,** Wuping Industrial Park, Wuping, Fujian 364300, China

E. DESCRIPTION OF THE DEVICE

The proposed device, Latex Surgeon's Gloves Powdered and 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 D3577-09

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

The proposed device includes Powdered and Powder Free Latex Surgeon's Gloves, and the come in different sizes (5½, 6, 6½, 7, 7½, 8, 8½, 9)

All gloves share the same color, creamy white and all have beaded cuff and textured at the finger tips and palm.

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.INTENDED USE STATEMENT:

A latex surgeon's gloves 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 TESTING

Bench tests were conducted to verify that the proposed device met all design specifications and complies with the following standards-

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

ASTM D5151-2011:- 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 Natural Rubber *and* Its Products Using the Modified Lowry Method.

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

ASTM F1929-2004:- 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.

1ISO 1137-2: 2006. 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: - 5½, 6, 6½, 7, 7½, 8, 8½, 9

SL.NO	CRITERIA	SPECIFICATION AS PER ASTM D3577-09 STANDARD	AVERAGE VALUE OF SUBJECT DEVICE	WHETHER SUBJECT DEVICE COMPLIED WITH THE ASTM D3577 -09 STANDARD
1	**Length**			
	Size 5½	Min 265mm	276 mm	Yes
	Size 6	Min 265mm	278mm	Yes
	Size 6½	Min 265mm	281mm	Yes
	Size 7	Min 265mm	281mm	Yes
	Size 7½	Min 265mm	281mm	Yes
	Size 8	Min 265mm	283mm	Yes
	Size 8½	Min 265mm	283mm	Yes
	Size 9	Min 265mm	284mm	Yes
2	**Width**			
	Size 5½	70+/-6mm	74mm	Yes
	Size 6	76+/-6mm	79mm	Yes
	Size 6½	83+/-6mm	87mm	Yes
	Size 7	89+/-6mm	93mm	Yes
	Size 7½	95+/-6mm	98mm	Yes
	Size 8	102+/-6mm	106mm	Yes
	Size 8½	108+/-6mm	112mm	Yes
	Size 9	114+/-6mm	118mm	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	0.12mm	Yes

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SL.NO	CRITERIA	SPECIFICATION AS PER ASTM D3577-09 STANDARD	AVERAGE VALUE OF SUBJECT DEVICE	WHETHER SUBJECT DEVICE COMPLIED WITH THE ASTM D3577 -09 STANDARD
6	**Tensile Strength**			
	Before aging (All sizes)	24Mpa minimum	28.5Mpa	Yes
	After aging@ 70°±2C for 166±2 hr (All sizes)	18Mpa minimum	24.2Mpa	Yes
7	**Ultimate Elongation**			
	Before aging (All sizes)	750% minimum	934%	Yes
	After aging@ 70°±2C for 166±2 hr (All sizes)	560% minimum	758%	Yes
8	Stress at 500% before aging (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

ST.MARYS RUBBERS PVT.LTD.

SUBMISSION OF PREMARKET NOTIFICATION (510K) FOR LATEX SURGEON'S GLOVES POWDERED & LATEX SURGEON'S GLOVES POWDER FREE (POLYMER COATED)

I. SUBSTANTIALLY EQUIVALENT COMPARISON

a. General Characteristics Comparison

Characteristic	Subject device	Predicate device K130450	Predicate device K130301	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 gloves is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	This 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
Intended Use Latex Surgeon's Gloves Powdered	A latex surgeon's gloves is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	This 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 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	Powdered, and powered free	Powdered, and powered free	Powdered, and 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 SAL- 10^{-6} OR Radiation SAL- 10^{-6}	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	-	SE
Type of use	Over the counter use	Over the counter use	Over the counter use	SE

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b. Technological Characteristics Comparison

Characteristics	Acceptance criteria of the standard			Whether the subject device met the acceptance criteria of the standard
	Subject device	Predicate device K130450	Predicate device K130301	
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 ASTM D5151,(published date 08/20/2012)	ASTM D3577 and ASTM D5151	ASTM D3577 and ASTM D5151	Yes
Powder Content for powdered glove	ASTM D3577 and ASTM D6124,(published date 08/20/2012) (Max 15 mg/ dm^2) Our glove has 10mg/dm^2 on average.	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 D 6499 (published date 02/01/2009) Our glove has Protein Content less than 50 µg/dm^2	ASTM D3577, ASTM D5712-10 and ASTM D6499	ASTM D3577, ASTM D5712-10 and ASTM D6499	Yes
Biocompatibility Skin sensitization Skin irritation	ISO 10993-10 Non- sensitizer under the conditions of the studies. Non -irritant under the conditions of the studies.	ISO 10993-10	ISO 10993-10	Yes, Non-Sensitizer and Non- irritant

***Conformance with ASTM D 6499 was an extra step to corroborate the claim 50 µg/dm^2 or less / glove**

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Substantial Equivalence Discussion

The difference with predicate device is in the sterilization method. The proposed device is sterilized by ETO or Radiation method. Both give a final SAL of $\mathbf{10^{-6}}$ which meets the acceptance level for sterilization.

Clinical data was not required for this submission.

Substantial Equivalence Conclusions

The conclusion drawn from the non-clinical tests demonstrate that the devices Medismart (Latex Surgeon's Gloves Powdered) and Medismart **+** (Latex Surgeon's Gloves Powder Free, Polymer coated with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein), are as safe and as effective and perform as well as the legally marketed predicate devices SURGTEX Latex Surgeon's Gloves powdered and SURGTEX Latex Surgeon's Gloves powder-free-polymer coated with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein (K130450) and Latex Surgeon's Gloves (powdered and Powder free (K130301); therefore, we conclude that the subject device is substantially equivalent to the predicate devices.