January 26, 2018

Sanrea Healthcare Products Pvt Ltd
Jose Paul M
Manager QA & RA
Plot#P-56, Pearl Road, Kinfra IIT Park,
Kanjikode, Palakkad, 678 621, Kerala, IN

Re: K171367
Trade/Device Name: SANCARE STERILE LATEX EXAMINATION GLOVES
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LYY
Dated: December 26, 2017
Received: December 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.

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,

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)*
K171367

Device Name
SANCARE STERILE LATEX EXAMINATION GLOVES

Indications for Use *(Describe)*

The Sterile Latex Patient Examination gloves, Powder Free, 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

K171367

1.0 SUBMITTER

1.1	**Company Name**	:	**SANREA HEALTHCARE PRODUCTS PVT LTD**
1.2	**Address**	:	**Plot#P-56, Pearl Road, Kinfra Integrated Industrial & Textile Park, Kanjikode, Palakkad Kerala, India– 678 621**
1.3	**Telephone**	:	**+ 91-491 -2970145**
1.4	**Email**	:	**josepaul@primusgloves.com, sanreaqa@gmail.com, qa@sanrea.com**
1.5	**Contact Person**	:	**Mr. JOSE PAUL M MANAGER QA & RA**

2.0 OFFICIAL CORRESPONDENT

2.1	**Company Name**	:	**SANREA HEALTHCARE PRODUCTS PVT LTD**
2.2	**Address**	:	**Plot#P-56, Pearl Road, Kinfra Integrated Industrial & Textile Park, Kanjikode, Palakkad Kerala, India– 678 621**
2.3	**Telephone**	:	**+ 91-491 -2970145**
2.4	**Email**	:	**josepaul@primusgloves.com, sanreaqa@gmail.com, qa@sanrea.com**
2.5	**Contact Person**	:	**Mr. JOSE PAUL M MANAGER QA & RA**

3.0 PREPARATION DATE : 17 Jan, 2018

510(K) SUMMARY

4.0 NAME OF THE DEVICE

4.1 Device Name : **STERILE LATEX PATIENT EXAMINATION GLOVES, POWDER FREE**

4.2 Trade Name : SANCARE STERILE LATEX EXAMINATION GLOVES (also marketed as GLOVTEK STERILE LATEX EXAMINATION GLOVES)

4.3 Common Name : PATIENT EXAMINATION GLOVES

4.4 Classification : PATIENT EXAMINATION GLOVES

4.5 Class : CLASS I

4.6 Product Code : LYY

5.0 IDENTIFICATION OF LEGALLY MARKETED PREDICATE DEVICE

5.1 Device Name : Powder free Latex Sterile Patient Examination Gloves

5.2 510(k) Number : K052728

5.3 Company : M/S. KANAM LATEX INDUSTRIES PVT. LTD.
Ooppoottil Buildings, K.K. Road,
Kottayam, Kerala, 686001

5.4 Device Description : Powder free Latex Sterile Patient Examination Gloves

5.5 Classification : PATIENT EXAMINATION GLOVES

5.6 Class : CLASS I

5.7 Product Code : LYY

5.8 Classification Panel : General Hospital

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6.0 DESCRIPTION OF THE DEVICE

The subject device is a patient examination glove made of latex compound. It is sterile, Powder Free. The device is ambidextrous and can be worn on either the left or right hand. The device meets ASTM D3578-05: Standard specification for Rubber Examination Gloves. The subject device is substantially equivalent to legally marketed Latex Examination Powder Free gloves identified as Product code LYY.
The device is for over-the counter single use.

7.0 INDICATIONS FOR USE

The Sterile Latex Patient Examination gloves, Powder Free, 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 Latex compound, which is Sterile and Powder Free. The gloves have the same technological characteristics compared to ASTM or equivalent standards as given below,

Characteristics	Standards	Performance of Latex patient examination gloves, Powder Free
Freedom from Holes	ASTM D3578-05/ ASTM D5151-06	Meets
Dimensions	ASTM D3578-05	Meets
Physical Properties	ASTM D3578-05/ ASTM D412-06	Meets
Powder-free residue	ASTM D3578-05/ ASTM D6124-06	Meets
Residual Protein	ASTM D3578-05/ ASTM D5712-15	Meets
Bio-compatibility	Primary skin irritation ISO 10993-10	Non-irritant
	Skin Sensitization	Non-sensitizer

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	ISO 10993-10	
Expiration dating/Shelf life	ASTM D7160-05	Three years
Sterilization	ISO 11135-2014(E) Sterilization of healthcare products - Ethylene Oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	Meets
Sterility	ISO 11737 -2 Sterilization of Medical devices- Microbiological methods Part 2: Test of sterility performed in the definition , validation and maintenance of sterilization process	Sterile

Performance data of gloves based on ASTM D3578-05and FDA 1000ml water leak test

ASTM D3578-05and FDA 1000 ml water leak test					
Characteristics	**Test**	**Test standard**	**Sampling plan / Inspection level / AQL**	**Sterile, Powder Free, Latex Patient Examination Gloves- Sancare / Glovtek**	**Result**
Freedom from Pin holes	FDA 1000 ml water leak test	ASTM D5151 -06 (Re-approved 2011)	ISO 2859-1 / G1/AQL 2.5	PASS	PASS
Dimensions	Length	ASTM D3578-05	ISO 2859-1 / S2/AQL 4.0	> 230 mm	PASS
	Width	ASTM D3578-05	ISO 2859-1 / S2/AQL 4.0	70±10 mm to 120±10 mm (sizes XS to XL)	PASS
		ASTM D3578-05	ISO 2859-1 /	> 0.08 mm	PASS

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	Thickness		S2/AQL 4.0	(Cuff, palm& finger)	
Physical properties	Before aging	ASTM D3578-05and ASTM D412-06	ISO 2859-1 / S2/AQL 4.0	Tensile strength : > 18 Mpa	PASS
				Ultimate Elongation : >650%	PASS
				Stress at 500% elongation : 5.5 Mpa max	PASS
	After Accelerated aging	ASTM D3578-05and ASTM D573-04	ISO 2859-1 / S2/AQL 4.0	Tensile strength : > 14 Mpa	PASS
				Ultimate Elongation : > 500%	PASS
Powder-free residue	Powder-free residue	ASTM D3578-05and ASTM D6124-06	N=5	Less than 2 mg per glove	PASS
Residual Protein	Residual Protein	ASTM D3578-05 and ASTM D 5712 – 15	N=3	Residual Protein : Less than 50µg/dm²	PASS
Biocompatibility	Primary skin irritation	ISO 10993 -10	Under the conditions of the study the device is not an irritant		PASS
	Skin Sensitization	ISO 10993 -10	Under the conditions of the study the device is not a sensitizer		PASS
Sterility	Sterility	ISO-11737-2	Sterile		PASS

9.0 Predicate Comparison Chart

Characteristics	PREDICATE – 510(K) : K052728	SUBJECT DEVICE :	Comparison
Manufacturer	M/S. KANAM LATEX INDUSTRIES PVT. LTD. Ooppoottil Buildings, K.K. Road, Kottayam, Kerala, 686001	SANREA HEALTHCARE PRODUCTS PVT LTD. Plot # P-56, Pearl Road, Kinfra Integrated Industrial & Textile Park, Kanjikode, Palakkad, Kerala, India – 678 621	-
Product Name	Powder free Latex Sterile Patient Examination Gloves	Sterile Latex Patient Examination Gloves, Powder Free	Similar

510(K) SUMMARY

Intended Use	Intended for medical purpose that is worn on the Examiners hand or finger to prevent contamination between patient and examiner	Intended for medical purpose that is worn on the Examiners hand or finger to prevent contamination between patient and examiner	Similar
Indication for use	A Powder Free Patient Examination Glove is a Disposable Device made of Natural Rubber Latex and is intended to be worn on the hands, for medical purposes to provide a barrier against potentially infectious materials and other contaminants.	The Sterile Latex Patient Examination gloves, Powder Free 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	Sterile Powder Free, Patient Examination gloves made of natural rubber latex. The gloves are provided in Sizes Extra Small, Small, Medium, Large and Extra Large	Sterile Powder Free, Patient Examination gloves made of natural rubber latex. The gloves are provided in Sizes Extra Small, Small, Medium, Large and Extra Large	Similar
Presentation	Sterile gloves are provided in pouches	Sterile gloves are provided in pouches	Identical
Material	Natural Rubber Latex	Natural Rubber Latex	Identical
Product code	LYY	LYY	Identical
Non-sterile or sterile	Sterile	Sterile	Identical
Single Use	Yes	Yes	Identical

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Ambidextrous	Yes	Yes	Identical
Dimensions	Meets ASTM D3578	Meets ASTMD3578 - Overall length min 230 mm, width varies from 70 mm for XS size to 120 mm for XL size, thickness in cuff, finger and palm has a minimum 0.08 mm	Identical
Tensile Strength	Meets ASTM D 3578and ASTM D412, D573	Meets ASTM D 3578 and ASTM D412, D573 - Tensile strength 18 Mpa min for before aging and 14 Mpa min for after aging Aging done at 70 ±2 deg C for 166±2 hrs or 100±2deg C for 22±0.3 hrs	Identical
Ultimate Elongation	Meets ASTM D 3578	Meets ASTM D 3578 Ultimate elongation 650 % min for before aging and 500 % min for after aging. Aging done at 70 ±2 deg C for 166±2 hrs or 100±2 deg C for 22±0.3 hrs	Identical
Stress at 500% Elongation	Meets ASTM D 3578	Meets ASTM D3578 - Stress at 500% Elongation for before aging is 5.5Mpa (max)	Identical
Freedom from pinholes	Meets ASTM D 5151 and ASTM D3578	Meets ASTM D 5151 and ASTM D3578	Identical
		Meets ASTM D 6124	Identical

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Residual Powder	Meets ASTM D 6124	Less than 2 mg per glove	
Residual Protein	Meets ASTM D 5712	Meets ASTM D 5712 – Less than 50µg/dm²	Identical
Biocompatibility Tests ISO 10993-10	Non-irritant – Primary Skin Irritation In Rabbits	Under the conditions of the study the device is not an irritant	Identical
	Non-sensitizer – Skin Sensitization in Guinea pigs	Under the conditions of the study the device is not a sensitizer	Identical
Sterility	Ethylene Oxide sterilized	Ethylene Oxide sterilized	Identical
Labeling	* Powder Free * Latex patient exam glove * Sterile * Single use only * Ambidextrous * Manufactured for * Lot No * Intended use * Quantity * Country of origin	*Powder Free *Latex Patient exam glove *Sterile *Single use only *Ambidextrous *Manufactured for *Lot No *Intended use *Quantity *Country of origin	Identical

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.