DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 19, 2017

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

Re: K171093
Trade/Device Name: Sterile Nitrile Patient Examination Gloves, Powder free
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: July 23, 2017
Received: April 12, 2017

Dear Jose M. Paul:

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" (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 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,

Tara A. Ryan -S

for
Lori Wiggins, MPT, CLT
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)*
K171093

Device Name
STERILE NITRILE PATIENT EXAMINATION GLOVES, POWDER FREE, BLUE COLOUR

Indications for Use *(Describe)*
The Sterile Nitrile Patient Examination gloves, Powder free., Blue color, 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.

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

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510(K) SUMMARY (K171093)

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 : 4TH April 2017

4.0 NAME OF THE DEVICE

4.1 Device Name	:	**STERILE NITRILE PATIENT EXAMINATION GLOVES, POWDER FREE, BLUE COLOUR**
4.2 Trade Name	:	* SANCARE STERILE NITRILE PATIENT EXAMINATION GLOVES POWDER FREE. BLUE COLOUR * GLOVTEK STERILE NITRILE PATIENT EXAMINATION GLOVES POWDER FREE, BLUE COLOUR
4.3 Common Name	:	PATIENT EXAMINATION GLOVES
4.4 Classification	:	PATIENT EXAMINATION GLOVES
4.5 Class	:	CLASS I
4.6 Product Code	:	LZA

5.0 IDENTIFICATION OF LEGALLY MARKETED PREDICATE DEVICE

5.1 Device Name	:	Sterile Nitrile Powder free Examination Glove (VBLU)
5.2 510(k) Number	:	K132006
5.3 Company	:	HARTALEGA SDN BHD, # 7, Kawasan, Perusahaan Suria, Batang Berjuntai, Selangor, Darul Ehsan, MY 45600
5.4 Device Description	:	Sterile Nitrile Powder free Examination Glove(VBLU)
5.5 Classification	:	PATIENT EXAMINATION GLOVES
5.6 Class	:	CLASS I
5.7 Product Code	:	LZA
5.8 Classification Panel	:	General Hospital

6.0 DESCRIPTION OF THE DEVICE

The subject device is a patient examination glove made of synthetic nitrile latex compound. It is sterile, Powder free and is Blue in colour. The device is ambidextrous and can be worn on either the left or right hand. The device meets ASTM D6319-10: Standard specification for Nitrile Examination Gloves for Medical Application.

The subject device is substantially equivalent to legally marketed Nitrile examination gloves identified as Product code LZA. The device is for over-the counter single use.

7.0 INDICATIONS FOR USE

The Sterile Nitrile Patient Examination gloves, Powder free., Blue color, 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 Nitrile latex compound, Sterile, Powder free and Blue in color. The gloves have the same technological characteristics compared to ASTM or equivalent standards as given below,

Characteristics	**Standards**	**Performance of Nitrile patient examination gloves, Powder free, Blue color**
Freedom from Holes	ASTM D6319-10 / ASTM D5151-06	Meets
Dimensions	ASTM D6319-10	Meets
Physical Properties	ASTM D6319-10 / ASTM D412-06	Meets

Powder free residue	ASTM D6319-10	Meets
Bio-compatibility	Primary skin irritation ISO 10993-10	Non-irritant
	Skin Sensitization ISO 10993-10	Non-sensitizer
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 routiene 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 D6319-10 and FDA 1000ml water leak test

ASTM D6319-10 and FDA 1000 ml water leak test					
Characteristics	**Test**	**Test standard**	**Sampling plan / Inspection level / AQL**	**Sterile, Powder free, Nitrile Examination Gloves- SANCARE**	**RESULT**
Freedom from Pin holes	FDA 1000 ml water leak test	ASTM D5151 -06 (Reapproved 2011)	ISO 2859-1 / G1/AQL 2.5	PASS	PASS
Dimensions	Length	ASTM D6319 -10	ISO 2859-1 / S2/AQL 4.0	> 230 mm	PASS
	Width	ASTM D6319 -10	ISO 2859-1 / S2/AQL 4.0	70±10 mm to 120±10 mm	PASS

				(sizes XS to XL)	
	Thickness	ASTM D6319 -10	ISO 2859-1 / S2/AQL 4.0	> 0.05 mm (palm & finger)	PASS
Physical properties	Before aging	ASTM D6319 -10 and ASTM D412-06	ISO 2859-1 / S2/AQL 4.0	Tensile strength : > 14 Mpa	PASS
				Ultimate Elongation : >500%	PASS
	After Accelerated aging	ASTM D6319 -10 and ASTM D412-06	ISO 2859-1 / S2/AQL 4.0	Tensile strength : > 14 Mpa	PASS
				Ultimate Elongation : > 400 %	PASS
Powder free residue	Powder free residue	ASTM D6319 -10 and ASTM D6124-06	N=5	Less than 2 mg per glove	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 Summary of the technological characteristics of device compared to the legally marketed predicate device

Characteristics	**PREDICATE – 510(K) : K132006**	**SUBJECT DEVICE : K171093**	**Acceptance criteria/Standard**
Manufacturer	HARTALEGA SDN BHD, # 7, Kawasan, Perusahaan Suria, Batang Berjuntai, Selangor, Darul Ehsan, MY 45600	SANREA HEALTHCARE PRODUCTS PVT LTD. Plot # P-56, Pearl Road, Kinfra Integrated Industrial & Textile Park, Kanjikode, Palakkad, Kerala, India – 678 621	-

510(K) SUMMARY (K171093)

Product Name	Sterile Nitrile Powder free Examination Glove(VBLU)	Sterile Nitrile Patient Examination Gloves, Powder free, Blue color	Patient examination gloves
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	Medical Glove Guidance Manual
Indication for use	The 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 Sterile Nitrile Patient Examination gloves, Powder free., Blue color, is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between patient and examiner.	Medical Glove Guidance Manual
Description	Sterile Powder free, examination gloves made of nitrile and colored blue. The gloves are provided in Sizes Extra Small, Small, Medium, Large and Extra Large	Sterile Powder free , examination gloves made of nitrile and colored blue. The gloves are provided in Sizes Extra Small, Small, Medium, Large and Extra Large	Medical Glove Guidance Manual
Presentation	Sterile gloves are provided in pouches	Sterile gloves are provided in pouches	Medical Glove Guidance Manual
Material	Nitrile synthetic latex	Nitrile synthetic latex	ASTM D6319-10 LZA product code
Non-sterile or sterile	Sterile	Sterile	Sterility
Single Use	Yes	Yes	Disposable / Single use
Ambidextrous	Yes	Yes	ASTM D 6319-0
		Overall length min 240 mm	Meets ASTM D

Dimensions	Meets ASTM D 6319-10	,width varies from 70 mm for XS size to 120 mm for XL size, thickness in finger and palm has a minimum 0.05 mm	6319-10 - Overall length min 240 mm, width varies from 70 mm for XS size to 120 mm for XL size, thickness in finger and palm has a minimum 0.05 mm
Tensile Strength	Meets ASTM D 6319-10	Tensile strength 14 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	Meets ASTM D 6319-10- Tensile strength 14 Mpa min for before aging and 14 Mpa min for after aging
Ultimate Elongation	Meets ASTM D 6319-10	Ultimate elongation 500 % min for before aging and 400 % min for after aging. Aging done at 70 ±2 deg C for 166±2 hrs or 100±2deg C for 22±0.3 hrs	Meets ASTM D 6319-10 - Ultimate elongation 500 % min for before aging and 400 % min for after aging. Aging done at 70 ±2 deg C for 166±2 hrs or 100±2deg C for 22±0.3 hrs
Freedom from pinholes	Meets ASTM D 5151 -06 and ASTM D6319-10	Meets ASTM D 5151 -06 (2011) and ASTM D6319-10	ASTM D 5151 -06 (2011) and ASTM D6319-10

Residual Powder	Meets ASTM D 6124-06	Less than 2 mg per glove	ASTM D 6124-06(2011) : Less than 2 mg per glove
Biocompatibility Tests ISO 10993-10	Non-irritant -Primary Skin Irritation In Rabbits	Under the conditions of the study the device is not an irritant	Under the conditions of the study the device is not an irritant
	Non-sensitizer - skin Sensitization in Guinea pigs	Under the conditions of the study the device is not a sensitizer	Under the conditions of the study the device is not a sensitizer
Sterility	Sterile	Sterile	Meets ISO 11737-02
Labeling	* Powder free, * Nitrile patient exam glove * Sterile * Single use only * Ambidextrous * Blue color * Manufactured for * Lot No * Intended use * Quantity * Country of origin	*Powder free, *Nitrile Patient exam glove *Sterile *Single use only *Blue color *Ambidextrous *Manufactured for *Lot No *Intended use *Quantity *Country of origin	Chapter 4 - Labeling - Medical Glove Guidance Manual

10.0 CONCLUSION

The conclusions drawn from the non clinical tests of the subject device K171093(Sterile Nitrile Patient Examination Gloves, Powder free., Blue color) demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device identified as Sterile Nitrile Powder free Examination Glove (VBLU), cleared under K132006.