July 13, 2018

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

Re: K171550
Trade/Device Name: Sterile Latex Surgical Gloves, Powderfree
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO
Dated: June 8, 2018
Received: June 12, 2018

Dear Jose 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 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,

Elizabeth F. Claverie -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171550

Device Name

STERILE LATEX SURGICAL GLOVES, POWDER FREE

Indications for Use *(Describe)*

The Sterile Latex Surgical Gloves, Powder free, is a disposable device made of natural rubber; intended for medical purposes that is 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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510(K) SUMMARY

K171550

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 : 05TH July 2018

4.0 IDENTIFICATION OF THE SUBJECT DEVICE

510(K) SUMMARY

4.1 Device Name : **STERILE LATEX SURGICAL GLOVES, POWDER FREE**

4.2 Trade Name : SANCARE STERILE LATEX SURGICAL GLOVES,
GLOVTEK STERILE LATEX SURGICAL GLOVES

4.3 Common Name : SURGEON'S GLOVES

4.4 Classification : SURGEON'S GLOVES

4.5 Class : CLASS I

4.6 CFR Regulation Number : 21 CFR 878.4460

4.7 Product Code : KGO

5.0 IDENTIFICATION OF LEGALLY MARKETED PREDICATE DEVICE

5.1 Device Name : Powder free Sterile Latex Surgical Gloves, Yellow Color

5.2 510(k) Number : K140988

5.3 Company : M/S. Hebei HongSen Plastic Technology Co. Ltd

853 Dorchester Ln Unitb

New Milford, NJ 07646

5.4 Device Description : Powder free Sterile Latex Surgical Gloves, Yellow Color

5.5 Classification : SURGEON'S GLOVES

5.6 Class : CLASS I

5.7 CFR Regulation Number : 21 CFR 878.4460

5.8 Product Code : KGO

5.9 Classification Panel : General Hospital

510(K) SUMMARY

6.0 DESCRIPTION OF THE DEVICE

The subject device is a surgical glove made of natural rubber latex compound. It is sterile, Powder free. The device is anatomic and is hand specific. The device meets ASTM D3577 – 09 : Standard specification for Rubber Surgical Gloves. The device is for over-the counter single use.

7.0 INDICATIONS FOR USE

The Sterile Latex Surgical Gloves, Powder free, is a disposable device made of natural rubber, intended for medical purposes that is worn by operating room personnel to protect a surgical wound from contamination.

8.0 TECHNOLOGICAL CHARACTERISTICS COMPARISON

Characteristics	PREDICATE – 510(K) : K140988	SUBJECT DEVICE :	Comparison
Manufacturer	M/S. Hebei HongSen Plastic Technology Co. Ltd 853 Dorchester Ln Unitb New Milford, NJ 07646	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 Sterile Latex Surgical Gloves, Yellow Color	Sterile Latex Surgical Gloves, Powder free	Similar
Intended Use	Intended to be worn by operating room personnel to protect a surgical wound from contamination.	Intended for medical purposes that is worn by operating room personnel to protect a surgical wound from contamination.	Same
Indication for use	The powder free sterile latex surgical glove, yellow color (Brand Name: Titanfine), is a disposable device made of	The Sterile Latex Surgical Gloves, Powder free, is a disposable device made of natural rubber, intended for	Similar

510(K) SUMMARY

	natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	medical purposes that is worn by operating room personnel to protect a surgical wound from contamination.	
Description	Sterile Powder free, surgical gloves are made of natural rubber latex. The gloves are provided in Sizes 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 and 9.0	Sterile Powder free , surgical gloves are made of natural rubber latex. The gloves are provided in Sizes 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 and 9.0	Same
Presentation	Sterile gloves are provided in pouches	Sterile gloves are provided in pouches	Similar
Material	Natural Rubber Latex	Natural Rubber Latex	Same
Color	Yellow Color	Natural (No color is added)	Different
Non-sterile or sterile	Sterile	Sterile	Same
Single Use	Yes	Yes	Same
Anatomic	Yes	Yes	Same
Dimensions	Meets ASTM D3577-09 - Overall length min 265 mm ,width varies from 76 mm for 6.0 size to 114 mm for 9.0 size, thickness in cuff, finger and palm has a minimum 0.10mm	Meets ASTM D3577 - 09 Dimension for size 7.5 : Length : 300mm Width : 95mm Thickness – Cuff : 0.14mm, Palm : 0.19mm, Finger : 0.22mm	Similar
Tensile Strength	Meets ASTM D3577 -09 and ASTM D412, D573. Tensile strength 24 Mpa min for before aging and 18 Mpa min for after aging. Aging done at 70 ±2 deg C for 166±2 hrs or 100±2deg C	Meets ASTM D3577 -09 and ASTM D412, D573. <u>Results for size 7.5 :</u> Tensile strength (Before Ageing): 31.22 MPa Tensile strength	Similar

	for 22±0.3 hrs	(After Ageing): 24.43 MPa	
Ultimate Elongation	Meets ASTM D 3577-09 - Ultimate elongation 750% min for before aging and 560 % min for after aging. Aging done at 70 ±2 deg C for 166±2 hrs or 100±2deg C for 22±0.3hrs	Meets ASTM D 3577-09 Results for size 7.5 : Ultimate Elongation (Before Ageing) : 843.09 % Ultimate Elongation (After Ageing) : 762.28 %	Similar
Freedom from pinholes	Meets ASTM D 5151 -06 and ASTM D3577 – 09	Meets ASTM D 5151 -06 (2011) and ASTM D3577- 09 Results for size 7.5 : Inspection level/AQL : ISO 2859-1 / G1 / AQL 1.5 Lot Size : 35001 – 150000 pair Sample size : 200 pair Holes found : 0 holes Accept/Reject : 10/11	Similar
Residual Powder Content	Meets ASTM D 6124-06(2011)	Meets ASTM D 6124-06(2011) Result for size 7.5 : Powder content : 0.9mg/glove	Similar
Residual Protein Content	Meets ASTM D 5712	Meets ASTM D 5712 Result for size 7.5 : Protein Content : 25.56 µg/ dm^2	Similar
Biocompatibility Tests - ISO 10993-10	Under the conditions of the study the device is not an irritant	Under the conditions of the study the device is not an irritant	Same
	Under the conditions of the study the device is not a sensitizer	Under the conditions of the study the device is not a sensitizer	Same
Sterility	Sterile	Sterile	Same
Mode of Sterilization	Irradiation	EO Sterilization	Different
Labeling	* Powder free * Latex Surgical Glove * Sterile * Single use only	* Powder free * Latex Surgical Glove * Sterile * Single use only	Identical

	* Anatomic * Manufactured for * Lot No * Intended use * Quantity * Country of origin	* Anatomic * Manufactured for * Lot No * Intended use * Quantity * Country of origin	

The above table shows similarities and differences of the performance between the subject device and the predicate device. There are only two minor differences between the subject device and the predicate device. One of the differences is that the predicate device has yellow color, while our device in submission is natural in color. The second difference is that the subject device is sterilized by EO sterilization where as the predicate device is sterilized by irradiation method. These minor differences do not impact the intended use, safety and performance of the device.

9.0 SUMMARY OF NON-CLINICAL TESTING

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 Sterile Latex Surgical Gloves, Powder free**
Freedom from Holes	ASTM D3577-09 / ASTM D5151-06	Meets
Dimensions	ASTM D3577-09	Meets
Physical Properties	ASTM D3577-09 / ASTM D412-06	Meets
Powder-free residue	ASTM D6124-06	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)	Meets

	Sterilization of healthcare products - Ethylene Oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	
EO Residue	ISO 10993-07:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals Maximum limit of EO Residue : 0.0025mg/device	Meets
ECH Residue	ISO 10993-07:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals Maximum limit of ECH Residue : 0.0025mg/device	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 D3577-09 and FDA 1000ml water leak test

ASTM D3577 - 09 and FDA 1000 ml water leak test					
Characteristics	**Test**	**Test standard**	**Sampling plan /Inspection level / AQL**	**Sterile Latex Surgical Gloves, Powder free**	**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
	Length	ASTM D3577 -09	ISO 2859-1 / S2/AQL 4.0	> 265 mm	PASS

510(K) SUMMARY

Dimensions	Width	ASTM D3577-09	ISO 2859-1 / S2/AQL 4.0	76±6 mm to 114±6 mm (sizes 6.0 to 9.0)	PASS
	Thickness	ASTM D3577-09	ISO 2859-1 / S2/AQL 4.0	> 0.10 mm (Cuff, palm& finger)	PASS
Physical properties	Before aging	ASTM D3577-09 and ASTM D412-06	ISO 2859-1 / S2/AQL 4.0	Tensile strength : > 24 Mpa	PASS
				Ultimate Elongation : >750%	PASS
	After Accelerated aging	ASTM D3577-09 and ASTM D573-04	ISO 2859-1 / S2/AQL 4.0	Tensile strength : > 18 Mpa	PASS
				Ultimate Elongation : > 560%	PASS
Powder-free residue	Powder-free residue	ASTM D3577-09 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

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.