February 17, 2021

ECO Medi Glove Sdn. Bhd
Suresh Kumar
QA Manager
Lot 26910, Lorong Perusahaan 3/3, Kawasan Perusahaan,
Kamunting Raya
Taiping, Perak 34600
Malaysia

Re: K202401
Trade/Device Name: Powder Free NR Latex Surgical Glove (Sterile) with Protein content labelling claims 50ug/dm2 or less per glove of extractable Protein
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: August 1, 2020
Received: August 21, 2020

Dear Suresh Kumar:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ryan Ortega, PhD.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*

K 202401

Device Name

Powder Free NR Latex Surgical Glove (Sterile)with protein content labeling claims 50ug/dm2 or less per glove of extractable protein.

Indications for Use *(Describe)*

Powder Free NR Latex Surgical 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.

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510(K) Summary
Powder Free NR Latex Surgical Glove (Sterile) with Protein content labelling claim 50ug/dm^2 or less per glove of extractable Protein

1.0 Submitter:

Company Name	:	ECO Medi Glove Sdn. Bhd.
Company Address	:	Lot 26910,Lorong Perusahaan 3/3 Kawasan Perusahaan Kamunting Raya, 34600 Taiping, Perak Darul Ridzuan, Malaysia.
Contact Person	:	Mr. Suresh Kumar
Telephone	:	605-8062315
Email	:	qa1@riverstone.com.my

2.0 Preparation Date : 12th February 2021

3.0 Name of the Device

Trade Name / Proprietary Name	:	Powder Free NR Latex Surgical Glove (Sterile) with Protein content labelling claims 50ug/dm^2 or less per glove of extractable Protein
Device Name	:	Surgeon's Glove
Device Classification Name	:	Surgeon's Glove (21 CFR 878.4460)
Device Class	:	Class I
Product Code	:	Surgeon's Glove - KGO

4.0 Predicate Device Information:

Latex Surgeon's Gloves Powder Free with Protein content labelling claims 50ug/dm^2 or less per glove of extractable Protein, 79KGO, which meets all the requirement of ASTM D 3577-09 and FDA 21 CFR 878.4460. It is equivalent to K190632, Latex surgeon's Glove Powder Free with Protein content labeling claim of 50ug/dm^2 or less per glove of extractable protein

5.0 Indication For Use

Powder Free NR Latex Surgical Glove is a device made of Natural Rubber Intended to be worn by operating room personal to protect a surgical wound from contamination

6.0 Device Description

The subject device in this 510(k) Notification is Latex Surgeon's Glove Powder Free with Protein content labelling claims 50ug/dm^2 or less per glove of extractable Protein. The subject device is a Surgeon's glove made from compounded primarily Natural Latex, Yellow, powder free and sterile (Per 21 CFR 878.4460, class I. The device meets all the specifications in ASTM 3577-09, Standard specification for Rubber Surgical Glove. Additionally, the gloves have been tested for biocompatibility.

Latex Surgeon's Gloves Powder Free with Protein content labelling claims 50ug/dm^2 or less per glove of extractable Protein is classification as Type 1: Glove compounded primarily form Natural Rubber Latex
The Proposed device is sterilized using Gamma irradiation method to achieve the sterility Assurance Level (SAL) of 10E^{-6} and place in a sterility maintenance package to ensure a shelf life of 3 years

Powder Free NR Latex Surgical Glove (Sterile), is a disposable device intended for medical purposes that is worn by operating room personal to protect a surgical wound from contamination (product Code KGO).

7.0 Specification for Rubber Surgical gloves:

7.1 Dimension and Thickness of Gloves

Dimension/Size	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Overall Length (mm) (Minimum)	265	265	265	265	265	265	265	265
Width (± 6mm)	70	76	83	89	95	102	108	114
Thickness at Palm (mm) (Minimum)	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
Thickness at Finger Tip (mm) (Minimum)	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
Thickness at cuff (mm) (Minimum)	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10

7.2 Gloves Physical Properties and Holes

Measurement	Before Ageing	After Aging at 70°C for 168 hrs. @ 100°C for 22 hrs.
Tensile Strength (MPa)	24 MPa minimum	18 MPa minimum
Ultimate Elongation (%)	750% minimum	560% minimum
Pin-hole Level	AQL 1.5 Inspection Level G-1	AQL 1.5 Inspection Level G-1

8.0 Technological Characteristics Comparison

Characteristics	Powder Free NR Latex Surgical Glove (Sterile) with Protein content labelling claims 50ug/dm^2 or less per glove of extractable Protein K202401 (Subject Device)	Latex surgeon's Glove Powder Free with Protein content labeling claim of 50ug/dm^2 or less per glove of extractable protein K190632 (Predicate Device)	Comparison
	Eco Medi Glove Sdn. Bhd.	**Lenora Glove Pvt. Ltd**	
	KGO	KGO	Same
Intended use	Powder Free NR latex Surgical Glove is a device made of Natural Rubber intended to be worn by operating room personal to protect a surgical wound from contamination	Surgeons glove is a device made of natural rubber intended to be worn by operating room personal to protect a surgical wound from contamination	Same
Description	Sterile Powder free, surgical gloves are made of natural rubber latex. The gloves are provided in Sizes 5.5 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 5.5,6.0, 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	Same
Anatomic	Yes	Yes	Same
Material use	Natural Rubber Latex	Natural Rubber Latex	Same
Colour	Yellow	Natural (No color is added)	Different
Sterility	Sterile	Sterile	Same
Single used	Single used	Single used	Same
Non-Sterile or Sterile	Sterile	Sterile	Same
Dimensions	Meets ASTM D3577 - 09	Meets ASTM D3577 - 09	Similar
Physical properties	Meets ASTM D3577 -09 and ASTM D412, D573.	Meets ASTM D3577 -09 and ASTM D412, D573.	Similar
Freedom from pinholes	Meets ASTM D 5151 -06 and ASTM D3577- 09	Meets ASTM D 5151 -06 and ASTM D3577- 09	Same

Characteristics	Powder Free NR Latex Surgical Glove (Sterile) with Protein content labelling claims 50ug/dm^2 or less per glove of extractable Protein,K202401	Latex surgeon's Glove Powder Free with Protein content labeling claim of 50ug/dm^2 or less per glove of extractable protein, K190632 (Predicate Device)	Comparison
Residual Powder	Meets ASTM D6124-06, (Reapproved 2017) Powder content < 2 mg/Glove	Meets ASTM D6124-06, (Reapproved 2017) Powder content < 2 mg/Glove	Same
Protein Content	Meets ASTM D 5712, ASTM D 6499-12 & ASTM D3577	Meets ASTM D 5712, ASTM D 6499-12 & ASTM D3577	Same
Mode of Sterilization	Irradiation	EO Sterilization/ Irradiation	Different
Biological Evaluation on Medical Device -Primary Skin Irritation Test	Under the conditions of this study, the test article was a non-irritant.	Under the conditions of this study, the test article was a non-irritant.	Same
Biological Evaluation on Medical Device- Dermal Sensitization Assay Acute Systemic Test	Under the conditions of this study, the test article was a non-sensitizer. Non Toxic	Under the conditions of this study, the test article was a non-sensitizer. Non Toxic	Similar
Labelling	* Powder free * Latex Surgical Glove * Sterile * Single use * Anatomic * Manufactured for * Lot No * Intended use * Quantity * Country of origin	* Powder free * Latex Surgical Glove * Sterile * Single use Anatomic * Manufactured for * Lot No * Intended use * Quantity * Country of origin	similar

The above table shows similarities and differences of the performance between the subject device and the predicate device. There are no major differences in technological characteristics of the subject device compare with the predicate device. There are only minor differences between the subject device and the predicate device. One difference is that the subject device is sterilized by Irradiation whereas the predicate device is sterilized by EO sterilization/Irritation. These minor differences do not impact the intended use, safety and performance of the device. The gloves are made from Natural latex compound, Latex Surgeon's Gloves (Sterile).The gloves met all the specifications in ASTM D3577-09 Standard specification for Rubber Surgical Glove as well Biological Evaluation on medical device.

9.0 SUMMARY OF NON-CLINICAL TESTING

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
Powder Content	ASTM D 5712, ASTM D 6499-12	Meets
Bio-compatibility	Primary skin irritation - ISO 10993-10 Skin Sensitization - ISO 10993-10 Acute Systemic Test	Non-irritant Non-sensitizer Non Toxic
Expiration dating/ Shelf life	ASTM D7160-05	Three years
Sterilization	ISO 11737-Sterilization of medical device-Microbiological method - part 1	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

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 1.5	Meet AQL 1.5	PASS
	Length	ASTM D3577 -09	ISO 2859-1 / S2/AQL 4.0	Min 265	PASS
Dimensions	Width	ASTM D3577-09	ISO 2859-1 / S2/AQL 4.0	70±6 mm to 114±6 mm (sizes 5.5 to 9.0)	PASS
	Thickness	ASTM D3577-09	ISO 2859-1 / S2/AQL 4.0	>0.10mm (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 Ultimate Elongation : >750%	PASS
	After Accelerated aging	ASTM D3577-09 and ASTM D412-06	ISO 2859-1 / S2/AQL 4.0	Tensile strength : > 18 Mpa 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
Powder Content	Powder Residue	ASTM D 5712, ASTM D 6499-12	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 intended uses, technological characteristics and non – clinical performance data, the Latex Surgeon's Gloves Powder Free with Protein content labelling claims 50ug/dm^2 or less per glove of extractable Protein is as safe, as effective, and performs as well as the legally marketed predicate device, Latex surgeon's Glove Powder Free with Protein content labeling claim of 50ug/dm^2 or less per glove of extractable protein, K190632