March 20, 2020

ECO Medi Glove SDN BHD
Suresh Kumar
QA Manager
Lot 23826, Jalan Tembaga Kuning,
Kamunting Raya Industrial Estate,
Perak, 34600 My

Re: K193121
Trade/Device Name: GEN 2 Nitrile Examination Glove (Blue) With Low Dermatitis Potential Claim and with tested for use with Chemotherapy Drugs Claims
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: December 14, 2020
Received: December 23, 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); 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,

Elizabeth Claverie-Williams, MS
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
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)*

K193121

Device Name

Gen 2 Nitrile Examination Glove (Blue) With Low Dermatitis Potential Claim and with Tested for use with Chemotherapy Drugs Claims

Indications for Use *(Describe)*

The Gen 2 Nitrile Examination Glove (Blue) with Low Dermatitis Potential Claim is a disposable device intended for Medical purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner. In addition these gloves was tested for use with Chemotherapy drugs in accordance with ASTM D6978-05 standards, Practice for assessment of medical glove to Permeation by Chemotherapy Drugs.

Chemotherapy Drugs and Concentration	Minimum Breakthrough detection time in minutes(μg/cm²/minute)
1)Carmustine (BCNU)(3.3 mg/ml)(3,300ppm)	22
2)Cisplatin (1.0 mg/ml)(1,000ppm)	No breakthrough up to 240 min
3)Cyclophosphamide (Cytoxan)(20 mg/ml)(20,000ppm)	No breakthrough up to 240 min
4)Methotexale (25mg/ml)(25,000ppm)	No breakthrough up to 240 min
5)Doxorubicin Hydrochloride (2.0 mg/ml)(2,000ppm)	No breakthrough up to 240 min
6)Etoposide (Toposar)(20.0 mg/ml)(20,000ppm)	No breakthrough up to 240 min
7)Fluorouracil (50.0 mg/ml)(50,000ppm)	No breakthrough up to 240 min
8)Paclitaxel (Taxol)(6.0 mg/ml)(6,000ppm)	No breakthrough up to 240 min
9)Thiotepa (10.0 mg/ml)(10,000ppm)	47.4

The Maximum testing time is 240 minutes. Please note that the following drugs have low permeation time:
1)Carmustine (BCNU)(3.3mg/ml)with Permeation time of 22 minutes.
2)Thiotepa (10.0mg/ml)with Permeation time of 47.4 minutes.

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
Gen 2 Nitrile Examination Glove (Blue) With Low Dermatitis Potential Claim and Tested for use with Chemotherapy Drugs Claims

1.0 Submitter:

Company Name: ECO Medi Glove Sdn Bhd.

Company Address: Lot 23826,Jalan Tembaga Kuning,
Kamunting Raya Industrial Estate,
34600,Taiping
Perak,Malaysia.

Contact Person: Mr Suresh Kumar

Telephone No: 603-60283033

Email: qa1@riverstone.com.my

2.0 Preparation Date: 16th March 2020

3.0 Device Identification:

Trade Name / Proprietary Name: Gen 2 Nitrile Examination Glove (Blue)
With Low Dermatitis Potential Claim and with
tested for Use with Chemotherapy drugs Claims.

Device Name: Nitrile Patient Examination gloves

Device Classification Name: Patient Examination gloves (21 CFR 880.6250)

Device Class: Class I

Product Code: LZA, LZC

4.0 Predicate Device:

Class I patient Examination glove with claiming, this product contain Low Dermatitis Potential Claim and tested for use with Chemotherapy Drugs, Powder Free, LZC, which meets all the requirement of ASTM D 6319-10 and FDA 21 CFR 880.6250.

Predicate Device: K152542, Powder Free Nitrile Examination (Blue) with Low Dermatitis Potential Claim with tested for use with Chemotherapy Drugs

5.0 Device Description:

The subject device in this 510(k) Notification is Blue Nitrile Examination gloves, with claiming, this product contains Low Dermatitis Potential Claim and tested for use with Chemotherapy drugs. The subject device is a patient examination glove made from nitrile compound, Blue color, powder free and non-sterile (Per 21 CFR 880.6250, class I). The device meets all the specifications in ASTM D6319-10, Standard specification for Nitrile Examination Gloves.

6.0 Intended use of the Device:

Gen 2 patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 standards, Practice for assessment of Medical Glove to Permeation by chemotherapy Drugs. It is for over- the-counter use.

7.0 Specification for Nitrile gloves:

7.1 Dimension and Thickness of Gloves

Dimension	Size S	Size M	Size L	Size XL
Overall Length (mm)	230min	230min	230min	230min
Width (± 5mm)	85	95	105	115
Thickness at Palm (mm)	0.05min	0.05min	0.05min	0.05min
Thickness at Finger Tip (mm)	0.05min	0.05min	0.05min	0.05min

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)	14min	14 Min
Ultimate Elongation (%)	500min	400min
Pin-hole Level	AQL 2.5 Inspection Level G-1	AQL 2.5 Inspection Level G-1

Gloves meet all the specification listed in ASTM D 6319-10

7.3 Technological Characteristics Comparison Table:

Characteristics	**Acceptance Criteria**	**Subject** Gen 2 Nitrile Examination Gloves (Blue) with Low Dermatitis Potential Claim and with tested for use with chemotherapy drugs Claim, (**K193121**)	**Predicate** Powder Free Nitrile Examination Glove (Blue) with Low Dermatitis Potential Claim and with tested for used with Chemotherapy Drugs, (**K152542**)	**Comparison**
Product Code	LZA, LZC	LZA, LZC	LZA, LZC	same
Intended use	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the- counter use.	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over- the-counter use.	same
Material use	Nitrile compound	Nitrile compound	Nitrile compound	same
Colour	Blue	Blue	Blue	same
Sterility	Non sterile	Non sterile	Non sterile	same
Single used	Single used	Single used	Single used	same
Non Sterile	Non Sterile	Non Sterile	Non Sterile	same

Dimensions	Overall Length (mm) Min 230mm Width (±5mm) **Size S= 85mm** **Size M =95mm** **Size L= 105mm Size** **XL = 115mm** Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm	Meets ASTM D6319- 10	Meets ASTM D6319-10	same
Physical properties	**Before Ageing** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min **After Aging at 70^{O}C for 168 hrs @ 100^{O}C for 22 hrs** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Meets ASTM D6319-10	Meets ASTM D6319-10	same
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-06	Meets ASTM D5151-06	same
Residual Powder	$\leq$ 2.0 mg/glove	Meets ASTM D6124-06	Meets ASTM D6124-06	same

Biological Evaluation on Medical Device – Part 10 -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 – Part 10 -Dermal Sensitization Assay		Under the conditions of this study, the test article was a non- sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.	same
Biological Evaluation on Medical Device – Part 5 -Tests for in vitro Cytotoxicity		Under the conditions of this study, the test article was not cytotoxic.	NA	Different
Resistance against Chemotherapy Drugs		1) Carmustine (3.3mg/ml or 3000ppm), Breakthrough : 22 min. 2) Cyclophosphamide (20mg/ml or 20,000ppm), Breakthrough time : >240 min. 3) Cisplatin (1mg/ml or 1000ppm), Breakthrough time : > 240 min 4)Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Breakthrough time : >240 min. 5) Etoposide (20mg/ml or 20,000ppm), Breakthrough time : >240 min. 6) Flourouracil (50mg/ml or 50,000), Breakthrough time : >240 min.	1) Carmustine (3.3mg/ml or 3000ppm), Breakthrough : 20.1 min. 2)Cyclophosphamide (20mg/ml or 20,000ppm),Breakthrough time : >240 min. 3) Cisplatin (1mg/ml or 1000ppm), Breakthrough time : >240 min 4)Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Breakthrough time : >240 min. 5) Etoposide (20mg/ml or 20,000ppm), Breakthrough time : >240 min. 6) Flourouracil (50mg/ml or 50,000), Breakthrough time : >240 min.	similar

		7) Methotexate (25mg/ml or 25,000ppm), Breakthrough time : > 240 min.	7) Methorexate (25mg/ml or 25,000ppm), Breakthrough time : > 240 min.	
		8) Paclitaxel (6mg/ml or 6,000ppm), Breakthrough time: >240 min. 9) Thiotepa (10mg/ml or 10,000ppm), Breakthrough time: 47.4 min.	8) Paclitaxel (6mg/ml or 6,000ppm), Breakthrough time: >240 min 9) Thiotepa (10mg/ml or 10,000ppm), Breakthrough time: 50.6 min.	
Low Dermatitis Potential Claim	1)Modified Draize 95 test	No Clinical evidence presence of residual chemical additives that may induce Type IV allergy in human subject	No Clinical evidence presence of residual chemical additives that may induce Type IV allergy in human subject	similar

Resistance against Chemotherapy Drugs

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection time (Specimen 1/2/3)(Minutes)
1)Carmustine (BCNU) (3.3mg/ml)(3,300 ppm)	22
2) Cisplatin (1.0mg/ml)(1,000 ppm)	No breakthrough up to 240 min
3)Cyclophosphamide (Cytoxan)(20mg/ml)(20,000 ppm)	No breakthrough up to 240 min
4)Methotexate(25.0mg/ml)(25,000 ppm)	No breakthrough up to 240 min
5)Doxorubicin Hydrochloride (2.0mg/ml)(2,000 ppm)	No breakthrough up to 240 min
6)Etoposide (Toposar)(20.0mg/ml)(20,000 ppm)	No breakthrough up to 240 min
7)Fluorouracil (50.0mg/ml)(50,000 ppm)	No breakthrough up to 240 min
8)Paclitaxel (Taxol)(6.0mg/ml)(6,000 ppm)	No breakthrough up to 240 min
9)Thiotepa(10.0mg/ml)(10,000 ppm)	47.4

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time.
Carmustine (BCNU) (3.3mg/ml)
Thiotepa (10mg/ml)

8.0) Summary of Non-Clinical Testing:

Test Method	Purpose	Acceptance Criteria	Results
ASTM D5151-06	Freedom from Holes	AQL 2.5 Inspection Level G-1	Meets ASTM D6319-10
ASTM D6319-10	Dimensions, Physical Properties	ASTM D6319- 10	Meets ASTM D6319-10
ASTM D6124-06	Powder-free residue	≤ 2.0 mg/glove	Meets ASTM D6319-10
Primary skin irritation - ISO 10993-10 Skin Sensitization - ISO 10993-10 In vitro Cytotoxicity – ISO 10993-5	Bio-compatibility	1) The test article was a non-irritant. 2) The test article was a non-sensitizer 3) The test article was not cytotoxic	Test article is non irritant and Non sensitizer and not cytotoxic
ASTMD 6978-05	Chemotherapy Drug test	As per test report	As labeling claim
Modify Draize 95 Test	Low Dermatitis Potential Claim	Induce Type IV allergy in human	Test article do not induce type IV allergy to human

9.0) Summary of Clinical Testing:

Gen 2 Nitrile Examination Glove (Blue) With Low Dermatitis Potential Claim and tested for Use with Chemotherapy drugs were tested in accordance with Modified Draize -95 test, per FDA's guidance document "Guidance for Industry and FDA Reviewer/Staffs: Premarket Notification [510k] Submissions for testing for skin sensitization to chemical in natural Rubber Products".

The study was conducted in two stages. In the first, a population of 30 human subjects was tested to evaluate the product for the potential to cause irritation or sensitization. The second stage was initiated on a further number of subjects to a total of a minimum 205 individuals after the first stage has shown that the test product does not indicate a potential for inducing dermal irritation and does not shown sensitization capability

The study completed on 205 non sensitized adult human subjects, who reasonably reflect the general user population in the US, gave all negative results. There was no clinical evidence of the presence of residual chemical additives at the level that may induce type IV allergy in the un-sensitized general user population in the tested articles

10.0 Conclusion:

The conclusion drawn from the nonclinical and clinical test demonstrate that the subject device in 510(k) K193121, Gen 2 Nitrile Examination Glove (Blue) with Low Dermatitis Potential Claim and tested for Use with Chemotherapy drugs is as safe, as effective and performs as well as or better than the legally marketed predicate device (K15254)