September 26, 2018

ECO Medi Glove Sdn Bhd
Suresh Kumar
Quality Assurance Manager
Lot 23826, Jalan Tembaga Kuning
Kamunting Raya Industrial Estate
Perak, 34600 My

Re: K181066
Trade/Device Name: Powder Free Examination Glove (Blue) with Low Dermatitis claim and with tested for use with Chemotherapy Drugs Claims
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: August 18, 2018
Received: August 27, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Clarence W. Murray Iii III -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)*
K181066

Device Name
Powder Free Nitrile Examination Glove (Blue) With Low Dermatitis Potential Claim and with Tested for use with Chemotherapy Drugs Claims

Indications for Use *(Describe)*
The Nitrile Powder Free 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)	12.9
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)Dacarbazine (DTIC) (10.0 mg/ml)(10,000ppm)	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)	24.7

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 12.9 minutes.
2)Thiotepa (10.0mg/ml)with Permeation time of 24.7 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.

510(K) Summary for K181066
Powder Free Nitrile Examination Glove (Blue) With Low Dermatitis Potential Claim and with Tested for use with Chemotherapy Drugs Claims

1. **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. **Preparation Date** : 12th September 2018

3. **Name of the Device**

Trade Name / Proprietary Name:	Powder Free Nitrile Examination Glove (Blue) With Low Dermatitis Potential Claim and with tested for Use with hemotherapy 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. **Identification of The Legally Marketed Device:**

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

5. **Device Description**

The subject device in this 510(k) Notification is Blue Nitrile Examination gloves, with 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, ASTM D5151-06, ASTM D6124-06, and ASTM D6978-05 and Modified Draize 95 test.

Indication for Use:
The Nitrile Powder Free 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 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.

Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection time in minutes
1)Carmustine (BCNU) (3.3mg/ml)(3,300 ppm)	12.9
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)Dacarbazine (DTIC)(10.0mg/ml)(10,000 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)	24.7

Maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time.
1) Carmustine (BCNU) (3.3mg/ml) with Permeation time of 12.9 minutes.
2) Thiotepa (10mg/ml) with Permeation time of 24.7 minutes

6. Specification for Nitrile gloves:

6.1.1 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

6.1.2 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

6.1.3 Summary of the Technological Characteristics of the Device

Characteristics	Acceptance Criteria	Powder Free Nitrile Examination Gloves(Blue) with Low Dermatitis Potential Claim and with tested for use with chemotherapy drugs Claim, K181066	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
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	Min 230mm	Min 230mm	Same
Physical properties	Before Ageing Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min After Aging at 70°C for 168 hrs @ 100°C for 22 hrs Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Before aging : Tensile strength: Min 14 Mpa Ultimate Elongation : Min 500% After Aging : Tensile strength: Min 14 Mpa Ultimate Elongation : Min 400%	Before aging : Tensile strength: Min 14 Mpa Ultimate Elongation : Min 500% After Aging : Tensile strength: Min 14 Mpa Ultimate Elongation : Min 400%	Same
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-06	Meets ASTM D5151-06	Same
Residual Powder	≤ 2.0 mg/pc	≤ 2.0 mg/pc	≤ 2.0 mg/pc	Same
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		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
ISO 10993-5:2009	Biological Evaluation of Medical Device -Part 5: Test for In Vitro Cytotoxicity	Under the conditions of this study, the test article was not cytotoxic.	No test done	Similar
Resistance against Chemotherapy Drugs		1) Carmustine (3.3mg/ml or 3000ppm), Breakthrough : 12.9 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. 7) Dacarbazine (DTIC) (10mg/ml or 10,000ppm), Breakthrough time: > 240 min. 8) Paclitaxel (6mg/ml or 6,000ppm), Breakthrough time >240 min. 9) Thiotepa (10mg/ml or 10,000ppm), Breakthrough time:24.7 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. 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: 50.6 min.	Difference
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	Same

7. Summary of Non-Clinical Performance data

Testing was performed per ASTM D6319-10 , ASTM D5151-06, ASTM D6124-06,ISO 10993-10:2010 , ISO10993-5 and 16 CFR Part 1500.41. The glove meets standards requirement referenced in section 6.0 above. Biocompatibility test indicates the gloves are not a contact skin sensitizer, not a primary skin irritant, and not cytotoxic.

8. Summary of Clinical Performance Data

Powder Free 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.

9. Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.