September 6, 2019

Ever Global (Vietnam) Enterprise Corporation
℅ Albert T.w. Li
Official Third Party Correspondent
Center For Measurement Standards Of Industrial
Bldg. 16, 321 Kuang Fu Rd,sec2
Hsinchu, Tw

Re: K190403
Trade/Device Name: Disposable Powder Free Nitrile Examination Glove, White Color, Tested for Use With Chemotherapy Drugs, Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drug
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: August 27, 2019
Received: September 3, 2019

Dear Albert T.w. Li:

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, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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

Ever Global (Vietnam) Enterprise Corporation

No. 1 Road, Long Thanh Industrial Zone, Taman Village, Long Thanh District, Dong Nai Province, Vietnam
Tel: 84-61-3514022

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)*

K190403

Device Name
Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs

Indications for Use *(Describe)*

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min)
1. Carmustine (BCNU), 3.3 mg/ml	6.2
2. Thiotepa, 10.0 mg/ml	38.8
3. Cyclophosphamide (Cytoxan), 20.0 mg/ml	≥ 240
4. Cisplatin, 1.0 mg/ml	≥ 240
5. Doxorubicin Hydrochloride, 2.0 mg/ml	≥ 240
6. Fluorouracil, 50.0 mg/ml	≥ 240
7. Dacarbazine (DTIC), 10.0 mg/ml	≥ 240
8. Etoposide (Toposar), 20.0 mg/ml	≥ 240
9. Paclitaxel (Taxol), 6.0 mg/ml	≥ 240

The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time:

Carmustine (BCNU), 3.3 mg/ml	6.2 minutes
Thiotepa, 10.0 mg/ml	38.8 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Ever Global (Vietnam) Enterprise Corporation

No. 1 Road, Long Thanh Industrial Zone, Taman Village, Long Thanh District, Dong Nai Province, Vietnam
Tel: 84-61-3514022

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)*

K190403

Device Name
Disposable Powder Free Nitrile Examination Glove, White Color, Tested For Use With Chemotherapy Drugs

Indications for Use *(Describe)*
A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min)
1. Carmustine (BCNU), 3.3 mg/ml	22.8
2. Thiotepa, 10.0 mg/ml	54.6
3. Cyclophosphamide (Cytoxan), 20.0 mg/ml	≥ 240
4. Cisplatin, 1.0 mg/ml	≥ 240
5. Doxorubicin Hydrochloride, 2.0 mg/ml	≥ 240
6. Fluorouracil, 50.0 mg/ml	≥ 240
7. Dacarbazine (DTIC), 10.0 mg/ml	≥ 240
8. Etoposide (Toposar), 20.0 mg/ml	≥ 240
9. Paclitaxel (Taxol), 6.0 mg/ml	≥ 240

The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time:

Carmustine (BCNU), 3.3 mg/ml	22.8 minutes
Thiotepa, 10.0 mg/ml	54.6 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Ever Global (Vietnam) Enterprise Corporation

No. 1 Road, Long Thanh Industrial Zone, Taman Village, Long Thanh District, Dong Nai Province, Vietnam
Tel: 84-61-3514022

510(k) SUMMARY

K190403

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name :	Ever Global (Vietnam) Enterprise Corporation
Submitter's address :	No. 1 Road, Long Thanh Industrial Zone, Taman Village, Long Thanh District, Dong Nai Province, Vietnam
Phone number :	84-61-3514022
Fax number :	84 -61-3514023
Name of contact person:	Jerry Lin
Summary Preparation Date:	September 6, 2019

2.0 Name of the Device

Proprietary/Trade name:	Disposable Powder Free Nitrile Examination Glove, White Color, Tested For Use With Chemotherapy Drugs, Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs
Common Name:	Nitrile Examination Gloves
Classification Name:	Patient Examination Glove
Device Classification:	Class I
Regulation Number:	21 CFR 880.6250
Product Code:	LZA, LZC

3.0 Predicate device

Device Name:	KS Medicare Powder Free Nitrile Examination Gloves, Non-sterile, Tested for Use with Chemotherapy Drugs (Blue, Black)
Company name:	Koon Seng Sdn. Bhd.
510(K) Number:	K171171

4.0 Device Description:

Disposable Powder Free Nitrile Examination Glove, White/Blue Color, Tested For Use With Chemotherapy Drugs is a patient examination glove made from nitrile compound, non-sterile (as per 21 CFR 880.6250, Class I). The principle operation of the medical device to provide single use barrier protection for the wearer and the device meets all the requirement specifications for Barrier Protection, tensile properties as defined in ASTM D6319-10, Standard specification for Nitrile Examination Gloves.

5.0 Indication for use:

Disposable Powder Free Nitrile Examination Glove, White Color, Tested For Use With Chemotherapy Drugs

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

Table 5.1 Nitrile white color test for 9 chemotherapy drugs

	Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min.)
1.	Carmustine (BCNU), 3.3 mg/ml	22.8
2.	Thiotepa, 10.0 mg/ml	54.6
3.	Cyclophosphamide (Cytoxan), 20.0 mg/ml	2 240
4.	Cisplatin, 1.0 mg/ml	2 240
5.	Doxorubicin Hydrochloride, 2.0 mg/ml	2 240
6.	Fluorouracil, 50.0 mg/ml	2 240
7.	Dacarbazine (DTIC), 10.0 mg/ml	2 240
8.	Etoposide (Toposar), 20.0 mg/ml	2 240
9.	Paclitaxel (Taxol), 6.0 mg/ml	2 240

The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time:

Carmustine (BCNU), 3.3 mg/ml	22.8 minutes
Thiotepa, 10.0 mg/ml	54.6 minutes

Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

Table 5.2 Nitrile blue color test for 9 chemotherapy drugs

	Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min.)
1.	Carmustine (BCNU), 3.3 mg/ml	6.2
2.	Thiotepa, 10.0 mg/ml	38.8
3.	Cyclophosphamide (Cytoxan), 20.0 mg/ml	2 240
4.	Dacarbazine (DTIC), 10.0 mg/ml	2 240
5.	Doxorubicin Hydrochloride, 2.0 mg/ml	2 240
6.	Etoposide (Toposar), 20.0 mg/ml	2 240
7.	Fluorouracil, 50.0 mg/ml	2 240
8.	Paclitaxel (Taxol), 6.0 mg/ml	2 240
9.	Cisplatin, 1.0 mg/ml	2 240

The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time:

Carmustine (BCNU), 3.3 mg/ml	6.2 minutes
Thiotepa, 10.0 mg/ml	38.8 minutes

6.0 Technological Characteristics:

Shown below is a technological comparison of the subject device(K190403) with the predicate device (K171171)

Device Characteristic	**Predicate Device (K171171)**	**Proposed Device (K190403)**	Comparison
Product name	KS Medicare Powder Free Nitrile Examination Gloves, Non-sterile, Tested for Use with Chemotherapy Drugs (Blue, Black)	Disposable Powder Free Nitrile Examination Glove, White/Blue Color, Tested For Use With Chemotherapy Drugs	N/A
510(K) No.	K171171	K171422	N/A
Product Owner	Koon Seng Sdn. Bhd.	Ever Global Enterprise Corporation	Different
Product Code	LZA, LZC	LZA, LZC	same
Regulation	21 CFR 880.6250	21 CFR 880.6250	same
Class	I	I	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. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:	The Nitrile Powder Free patient examination glove is a non-sterile disposable device intended for medical purposes 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 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:	similar
Power free	Yes	Yes	same
Size	Small/ Medium/Large/X Large	Small/ Medium/Large/X Large	same
Single Use	YES	YES	same
Non-Sterile	YES	YES	same
Dimensions-Length	Complies with ASTM D6319-10 230 mm min.	Complies with ASTM D6319-10 230 mm min.	same

Dimensions -Palm Width	Complies with ASTM D6319-10 Small 80±10 Medium 95 ±10 Large 110±10 X large 120 ±10	Complies with ASTM D6319-10 Small 80±10 Medium 95 ±10 Large 110±10 X large 120 ±10	same
Dimensions -Thickness	Complies with ASTM D6319-10 Palm - 0.07 mm min. Finger - 0.08 mm min.	Complies with ASTM D6319-10 Palm - 0.05mm min. Finger - 0.05 mm min. *{Additional comparisons a device – K171104, that have been approved by FDA is the same intended use and the thickness is lower than Proposed Device)*	similar

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. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:	The Nitrile Powder Free patient examination glove is a non-sterile disposable device intended for medical purposes 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 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:	similar
Power free	Yes	Yes	same
Size	Small/ Medium/Large/X Large	Small/ Medium/Large/X Large	same
Single Use	YES	YES	same
Non-Sterile	YES	YES	same
Dimensions- Length	Complies with ASTM D6319-10 230 mm min.	Complies with ASTM D6319-10 230 mm min.	same
Dimensions -Palm Width	Complies with ASTM D6319-10 Small 80±10 Medium 95 ±10 Large 110±10 X large 120 ±10	Complies with ASTM D6319-10 Small 80±10 Medium 95 ±10 Large 110±10 X large 120 ±10	same
Dimensions -Thickness	Complies with ASTM D6319-10 Palm - 0.07 mm min. Finger - 0.08 mm min.	Complies with ASTM D6319-10 Palm - 0.05mm min. Finger - 0.05 mm min. *{Additional comparisons a device – K171104, that have been approved by FDA is the same intended use and the thickness is lower than Proposed Device)*	similar
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10 Dermal sensitization in the guinea pig ISO 10993-10 /	Primary Skin Irritation in rabbits ISO 10993-10: Third Edition 2010-08-01 Dermal sensitization in the guinea pig ISO 10993-10: Third Edition 2010-08-01 Minimal Essential Media (MEM) Elution ISO 10993-5	similar

7.0 Summary of Non-Clinical Performance Data:

Shown below are the results from the bench testing performed on the subject devices. The testing was performed to

demonstrate the subject devices met the acceptance criteria for each of the non-clinical test shown below: Disposable Powder Free Nitrile Examination Glove, White/Blue Color, Tested For Use With Chemotherapy Drugs are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Table 7.1 Summary of the Non-Clinical Testing

Characteristics	Standard		
Dimension	ASTM standard D 6319-10(Reapproved 2015)		
	Length	2230mm	
	Width	Small	80 ±10 mm
		Medium	95 ±10 mm
		Large	110 ±10 mm
		X large	120 ±10 mm
	Thickness	Finger tip	20.05mm
		Palm	20.05mm
Physical Properties	ASTM standard D 6319-10(Reapproved 2015)		
	Tensile strength (Before aging)		214MPa
	Tensile strength (After aging)		214MPa
	Elongated rate (Before aging)		2500%
	Elongated rate (After aging)		2400%
Freedom from pinholes	21 CFR 800.20 ASTM standard D 6319-10(Reapproved 2015) Test method in accordance with ASTM D5151-06(Reapproved 2015)		Passed Standard Acceptance Criteria
Powder Residual	ASTM standard D6319-10(Reapproved 2015) Test method in accordance with D6124-06(Reaffirmation 2011)		< 2 mg/glove
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10: Third Edition 2010-08-01	Passes Under the conditions of the study, the subject device is not a primary skin irritant.	
	Dermal sensitization in the guinea pig ISO 10993-10: Third Edition 2010-08-01	Passes Under the conditions of the study, the subject device is not a primary skin sensitizer.	
	Minimal Essential Media (MEM) Elution ISO 10993-5	Passes Under the conditions of the study, the subject device is not cytotoxic.	

- ✡ Dimension per ASTM D6319-10 (Reapproved 2015)
- ✡ Tensile strength (Before aging/After aging) and Elongation (Before aging/After aging) per ASTM D6319-10(Reapproved 2015)
- ✡ Water leak test on pinhole per ASTM D6319-10(Reapproved 2015) and per 21 CFR 800.20.
- ✡ Powder Residual tests per ASTM D6319-10(Reapproved 2015)
- ✡ Biocompatibility test per ISO 10993-10: Third Edition 2010-08-01 and ISO 10993-5
- ✡ Assessment of Resistance To Permeation By Chemotherapy Drugs per ASTM D6978-05(R 2013)

8.0 Summary of Clinical Test:

Clinical data was not needed for this device.

9.0 Conclusion:

Based on the nonclinical tests data, it can be concluded that the Disposable Powder Free Nitrile Examination Glove, White/Blue Color, Tested For Use With Chemotherapy Drugs is as safe, as effective, and performs as well as or better than the predicate device K171171, KS Medicare Powder Free Nitrile Examination Gloves, Non-sterile, Tested for Use with Chemotherapy Drugs (Blue, Black), by Koon Seng Sdn. Bhd.