December 23, 2019

Ever Growth (Vietnam) Co. Ltd.
% Elizabeth Deng
U.S. Representative
Elizabeth Deng
5748 Eaglewood Place
Ranch Cucamonga, California 91730

Re: K190736
Trade/Device Name: Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: April 2, 2019
Received: September 30, 2019

Dear Elizabeth Deng:

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
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190736

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	Concentration(mg/ml)	Minimum Breakthrough Detection Time (Min)
01 Bleomycin Sulfate	15.0	> 240
02 Busulfan	6.0	> 240
03 Carboplatin	10.0	> 240
04 Carmustine (BCNU)	3.3	59.4
05 Chloroquine	50.0	> 240
06 Cisplatin	1.0	> 240
07 Cyclophosphamide	20.0	> 240
08 Cyclosporin A	100.0	> 240
09 Cytarabine	100.0	> 240
10 Dacarbazine (DTIC)	10.0	> 240
11 Daunorubicin	5.0	> 240
12 Docetaxel	10.0	> 240
13 Doxorubicin Hydrochloride	2.0	> 240
14 Epirubicin	2.0	> 240
15 Etoposide (Toposar)	20.0	> 240
16 Fludarabine	25.0	> 240
17 Fluorouracil	50.0	> 240
18 Gemcitabine	38.0	> 240
19 Idaribicin	1.0	> 240
20 Ifosfamide	50.0	> 240
21 Irinotecan	20.0	> 240
22 Mechlorethamine HCl	1.0	> 240
23 Melphalan	5.0	> 240
24 Methotrexate	25.0	> 240
25 Mitomycin C	0.5	> 240
26 Mitoxantrone	2.0	> 240
27 Oxaliplatin	2.0	> 240
28 Paclitaxel (Taxol)	6.0	> 240
29 Paraplatin	10.0	> 240
30 Retrovir	10.0	> 240
31 Rituximab	10.0	> 240
32 Thiotepa	10.0	118.5
33 Topotecan HCl	1.0	> 240
34 Trisonex	1.0	> 240
35 Velcade (Bortezomib)	1.0	> 240
36 Vincristine	1.0	> 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	59.4 minutes
Thiotepa	10.0 mg/ml	118.5 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.

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510(k) Summary

K190736

1.0 Submitter:

Submitter's name :	Ever Growth (Vietnam) Co. , Ltd.
Submitter's address :	Long Khanh Industrial Zone, Binh Loc Ward, Long Khanh Township, Dong Nai, Vietnam
Phone number :	84-61-3514025
Fax number :	84 -61-3514023
Name of contact person:	Ming Lee
Summary Preparation Date:	Nov. 26th , 2019

2.0 US Agent:

US representative name	Elizabeth Deng
Company address	5748 Eaglewood Place Rancho Cuamonga, California Rancho Cucamonga , CA 91739
Telephone number	909 4659188
Contact email	Baxianunited48@Yahoo.Com

3.0 Name of the Device

Proprietary/Trade name:	Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs
Common Name:	Nitrile Examination Gloves
510(k) Number	K190736
Classification Name:	Patient Examination Glove
Device Classification:	Class I
Regulation Number:	21 CFR 880.6250
Product Code:	LZA, LZC

4.0 Predicate device

Device Name:	Central Medicare Blue Non Sterile Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs
Company name:	Central Medicare Sdn. Bhd
510(K) Number:	K173942

5.0 Device Description:

Disposable Powder Free Nitrile Examination Glove, 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.

6.0 Indications for Use:

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 5.1 Nitrile Blue color test for 36 chemotherapy drugs

	Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min.)
1	Bleomycin Sulfate 15.0 mg/ml	> 240
2	Busulfan 6.0 mg/ml	> 240
3	Carboplatin 10.0 mg/ml	> 240

4	Carmustine (BCNU), 3.3 mg/ml	59.4
5	Chloroquine 50.0 mg/ml	> 240
6	Cisplatin 1 mg/ml	> 240
7	Cyclophosphamide 20 mg/ml	> 240
8	Cyclosporin A 100.0 mg/ml	> 240
9	Cytarabine 100.0 mg/ml	> 240
10	Dacarbazine (DTIC), 10.0 mg/ml	> 240
11	Daunorubicin 5.0 mg/ml	> 240
12	Docetaxel 10.0 mg/ml	> 240
13	Doxorubicin Hydrochloride, 2.0 mg/ml	> 240
14	Epirubicin 2.0 mg/ml	> 240
15	Etoposide (Toposar), 20.0 mg/ml	> 240
1	Fludarabine 25.0 mg/ml	> 240
17	Fluorouracil, 50.0 mg/ml	> 240
18	Gemcitabine 38.0 mg/ml	> 240
19	Idaribicin 1.0 mg/ml	> 240
20	Ifosfamide 50.0 mg/ml	> 240
21	Irinotecan 20.0 mg/ml	> 240
22	Mechlorethamine HCl 1.0 mg/ml	> 240
23	Melphalan 5 mg/ml	> 240
24	Methotrexate 25 mg/ml	> 240
25	Mitomycin C 0.5 mg/ml	> 240
26	Mitoxantrone 2.0 mg/ml	> 240
27	Oxaliplatin 2.0 mg/ml	> 240
28	Paclitaxel (Taxol), 6.0 mg/ml	> 240
29	Paraplatin 10 mg/ml	> 240
30	Retrovir 10 mg/ml	> 240
31	Rituximab 10 mg/ml	> 240
32	Thiotepa, 10.0 mg/ml	118.5
33	Topotecan HCl 1 mg/ml	> 240
34	Trisonex 1 mg/ml	> 240
35	Velcade (Bortezomib) 1 mg/ml	> 240
36	Vincristine 1.0 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	59.4 minutes
Thiotepa, 10.0 mg/ml	118.5 minutes

7.0 Summary of the Technological Characteristics of the Device:

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

summarized with the following technological characteristics compared to ASTM or equivalent standard.

Table 5.3 Summary of the Technological Characteristics

Characteristics	Standard		
Dimension	ASTM standard D 6319-10(Reapproved 2015)		
	Length	≥230mm	
	Width	X Small	70 ± 10 mm
		Small	80 ± 10 mm
		Medium	95 ± 10 mm
		Large	110 ± 10 mm
		X large	120 ± 10 mm
	Thickness	Finger tip	≥0.05mm
		Palm	≥0.05mm
Physical Properties	ASTM standard D 6319-10(Reapproved 2015)		
	Tensile strength (Before aging)		≥14MPa
	Tensile strength (After aging)		≥14MPa
	Elongated rate (Before aging)		≥500%
	Elongated rate (After aging)		≥400%
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.
	In vitro cytotoxicity accordance with ISO 10993-5: Third Edition 2009-06		Passes Under the conditions of the study, the subject device is not cytotoxic.

8.0 Based on Assessment of Non-Clinical Performance Data:

The following bench testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate equivalence to the predicate device. Central Medicare Blue Non Sterile Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs made by Central Medicare Sdn. Bhd. met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing:

- 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.
- Assessment Of Resistance To Permeation By Chemotherapy Drugs per ASTM D6978-05(R 2013)

9.0 Based on Assessment of Clinical Performance Data:

Clinical data was not needed to demonstrate that the subject glove is substantially equivalent to the predicate glove. So determination of substantial equivalence is not based on an assessment of clinical performance data.

10.0 Substantial Equivalence Comparison:

Table 5.4 SE compare

Device Characteristic	**Predicate Device**	**Proposed Device**	Comparison
Product name	Central Medicare Blue Non Sterile Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs	Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs	N/A
510(K) No.	K173942	K190736	N/A
Product Owner	Central Medicare Sdn. Bhd.	Ever Growth 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	Blue Non Sterile Powder-Free Nitrile Examination glove Tested For Use With Chemotherapy Drugs 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. Gloves have been tested for use with chemotherapy drugs using ASTM D6978-05 and will be labeled with a statement of compliance and a summary of the testing result.	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.	similar
Power free	Yes	Yes	same
Size	X Small/Small/ Medium/Large/X Large	X Small/ Small/ Medium/Large/X Large	similar
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 X Small 70±10 Small 80 ±10 Medium 95±10 Large 110 ±10 X large 120 ±10	Complies with ASTM D6319-10 X Small 70±10 Small 80 ±10 Medium 95±10 Large 110 ±10 X large 120 ±10	same
Dimensions -Thickness	Complies with ASTM D6319-10 Palm - 0.08 mm min. Finger - 0.10 mm min.	Complies with ASTM D6319-10 Palm - 0.05mm min. Finger - 0.05 mm min.	similar
Physical Properties	Tensile Strength: Before Aging 15 MPa, min. After Aging 14 MPa, min.	Tensile Strength: Before Aging 14 MPa, min. After Aging 14 MPa, min.	same
	Elongation: Before Aging 500% min. After Aging 400% min.	Elongation: Before Aging 500% min. After Aging 400% min.	same
Residual powder	Complies with ASTM D6319-10 ＜ 2mg per glove	Complies with ASTM D6319-10 ＜ 2mg per glove	same

Freedom from Holes	In accordance with ASTM D6319-10 and ASTM D5151-06(reapproved 2011), G-1, AQL 2.5	In accordance with ASTM D6319-10 and ASTM D5151-06(reapproved 2011), G-1, AQL 2.5	same
Bio-compatibility	AAMI/ANSI/ISO 10993-10 Passes Not a skin irritant & Not a skin sensitizer	AAMI/ANSI/ISO 10993-10 Skin sensitization test & Skin Irritation test: Passes AAMI/ ANSI/ ISO 10993-5 In vitro cytotoxicity test: Passes	Similar

Chemotherapy drugs tested	Breakthrough Detection Time in Minutes		comparison
Device Characteristic	Predicate device	Proposed Device	
	Blue	Blue	
Bleomycin Sulfate 15.0 mg/ml	> 240	> 240	same
Busulfan 6.0 mg/ml	> 240	> 240	same
Carboplatin 10.0 mg/ml	> 240	> 240	same
Carmustine (BCNU), 3.3 mg/ml	12.4	59.4	similar
Chloroquine 50.0 mg/ml	> 240	> 240	same
Cisplatin 1 mg/ml	> 240	> 240	same
Cyclophosphamide 20 mg/ml	> 240	> 240	same
Cyclosporin A 100.0 mg/ml	> 240	> 240	same
Cytarabine 100.0 mg/ml	> 240	> 240	same
Dacarbazine (DTIC), 10.0 mg/ml	> 240	> 240	same
Daunorubicin 5.0 mg/ml	> 240	> 240	same
Docetaxel 10.0 mg/ml	> 240	> 240	same
Doxorubicin Hydrochloride, 2.0 mg/ml	> 240	> 240	same
Epirubicin 2.0 mg/ml	> 240	> 240	same
Etoposide (Toposar), 20.0 mg/ml	> 240	> 240	same
Fludarabine 25.0 mg/ml	> 240	> 240	same
Fluorouracil, 50.0 mg/ml	> 240	> 240	same
Gemcitabine 38.0 mg/ml	> 240	> 240	same
Idaribicin 1.0 mg/ml	> 240	> 240	same
Ifosfamide 50.0 mg/ml	> 240	> 240	same
Irinotecan 20.0 mg/ml	> 240	> 240	same
Mechlorethamine HCl 1.0 mg/ml	> 240	> 240	same
Melphalan 5 mg/ml	> 240	> 240	same
Methotrexate 25 mg/ml	> 240	> 240	same
Mitomycin C 0.5 mg/ml	> 240	> 240	same
Mitoxantrone 2.0 mg/ml	> 240	> 240	same
Oxaliplatin 2.0 mg/ml	> 240	> 240	same
Paclitaxel (Taxol), 6.0 mg/ml	> 240	> 240	same
Paraplatin 10 mg/ml	> 240	> 240	same

Retrovir 10 mg/ml	> 240	> 240	same
Rituximab 10 mg/ml	> 240	> 240	same
Thiotepa, 10.0 mg/ml	24.4	118.5	similar
Topotecan HCl 1 mg/ml	> 240	> 240	same
Trisonex 1 mg/ml	> 240	> 240	same
Velcade (Bortezomib) 1 mg/ml	> 240	> 240	same
Vincristine 1.0 mg/ml	> 240	> 240	same

11.0 Conclusion:

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