



December 23, 2019

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

Re: K190860

Trade/Device Name: Disposable Powder Free Nitrile Examination Glove, Tested For Use With
Chemotherapy Drugs, Disposable Powder Free Nitrile Examination Glove, Tested
For Use With Chemotherapy Drugs, Orange Color

Regulation Number: 21 CFR 880.6250

Regulation Name: Non-Powdered Patient Examination Glove

Regulatory Class: Class I, reserved

Product Code: LZA, LZC

Dated: September 30, 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,

For 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

510(k) Number (if known)
K190860

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

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)
1 Carmustine (BCNU),	3.3 mg/ml	11.8
2 Thiotepa,	10.0 mg/ml	16.9
3 Cyclophosphamide (Cytosan),	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	11.8 minutes
Thiotepa	10.0 mg/ml	16.9 minutes

Warning: Please do not use with Carmustine (BCNU) and Thiotepa

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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Indications for Use

510(k) Number (if known)
K190860

Device Name

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

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)
1 Carmustine (BCNU),	3.3 mg/ml	31.6
2 Thiotepa,	10.0 mg/ml	72.5
3 Cyclophosphamide (Cytosan),	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	31.6 minutes
Thiotepa	10.0 mg/ml	72.5 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)

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510(k) Summary

K190860

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, Tested For Use With Chemotherapy Drugs, White Color

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

Common Name: Nitrile Examination Gloves
510(k) Number K190860
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: Powder-Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs
Company name: Syntex Healthcare Products Co., Ltd
510(K) Number: K182156

5.0 Device Description:

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

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 6.1 Nitrile White color test for 7+2 chemotherapy drugs

	Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min.)
1	Carmustine (BCNU), 3.3 mg/ml	11.8
2	Thiotepa, 10.0 mg/ml	16.9
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	11.8 minutes
Thiotepa, 10.0 mg/ml	16.9 minutes

Warning: Please do not use with Carmustine (BCNU) and Thiotepa

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

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 6.2 Nitrile Orange color test for 7+2 chemotherapy drugs

	Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min.)
1	Carmustine (BCNU), 3.3 mg/ml	31.6
2	Thiotepa, 10.0 mg/ml	72.5
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	31.6 minutes
Thiotepa, 10.0 mg/ml	72.5 minutes

7.0 Summary of the Technological Characteristics of the Device:

Disposable Powder Free Nitrile Examination Glove, Tested For Use With Chemotherapy Drugs, White Color and Disposable Powder Free Nitrile Examination Glove, Tested For Use With Chemotherapy Drugs, Orange Color 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 in 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. Powder-Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs made by Syntex Healthcare Products Co., Ltd. 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	Powder-Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs	Disposable Powder Free Nitrile Examination Glove, Tested For Use With Chemotherapy Drugs, White Color Disposable Powder Free Nitrile Examination Glove, Tested For Use With Chemotherapy Drugs, Orange Color	N/A
510(K) No.	K182156	K190860	N/A
Product Owner	Syntex Healthcare Products Co., Ltd	Ever Growth Enterprise Corporation	Different
Product Code	LZA, LZO	LZA, LZO	same
Regulation	21 CFR 880.6250	21 CFR 880.6250	same
Class	I	I	same
Intended 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.	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	Complies with ASTM D6319-10	Complies with ASTM D6319-10	same

-Palm Width	X Small	70±10	X Small	70±10	
	Small	80 ±10	Small	80 ±10	
	Medium	95±10	Medium	95±10	
	Large	110 ±10	Large	110 ±10	
	X large	120 ±10	X large	120 ±10	
Dimensions -Thickness	Complies with ASTM D6319-10 Palm - 0.05 mm min. Finger - 0.05 mm min.		Complies with ASTM D6319-10 Palm - 0.05mm min. Finger - 0.05 mm min.		similar
Physical Properties	Tensile Strength: Before Aging 14 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		similar
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		same
Chemotherapy drugs tested		Breakthrough Detection Time in Minutes			comparison
Device Characteristic		Predicate device	Proposed Device		
		Blue	White	orange	
Carmustine (BCNU), 3.3 mg/ml		11.4	11.8	31.6	similar
Thiotepa, 10.0 mg/ml		13.6	16.9	72.5	similar
Cyclophosphamide (Cytoxan), 20.0 mg/ml		>240	>240	>240	same
Cisplatin, 1.0 mg/ml		>240	>240	>240	same
Doxorubicin Hydrochloride, 2.0 mg/ml		>240	>240	>240	same
Fluorouracil, 50.0 mg/ml		>240	>240	>240	same
Dacarbazine (DTIC), 10.0 mg/ml		>240	>240	>240	same
Etoposide (Toposar), 20.0 mg/ml		>240	>240	>240	same
Paclitaxel (Taxol), 6.0 mg/ml		>240	>240	>240	same
Methotrexate, 25 mg/ml		>240	-	-	-

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.