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

Re: K190942
Trade/Device Name: Disposable Powder Free Nitrile Examination Glove, Pink/Black Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: October 10, 2019
Received: October 10, 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

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)*
K190942

Device Name
Disposable Powder Free Nitrile Examination Glove, Pink Color

Indications for Use *(Describe)*
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.

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."

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)*
K190942

Device Name
Disposable Powder Free Nitrile Examination Glove, Black Color

Indications for Use *(Describe)*
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.

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
K190942

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:	Dec. 9th , 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, Pink Color Disposable Powder Free Nitrile Examination Glove, Black Color
Common Name:	Nitrile Examination Gloves
510(k) Number	K190942
Classification Name:	Patient Examination Glove
Device Classification:	Class I
Regulation Number:	21 CFR 880.6250
Product Code:	LZA

4.0 Predicate device

Device Name:	Orange Non Sterile Powder Free Nitrile Examination Gloves
Company name:	Central Medicare Sdn. Bhd.
510(K) Number:	K172642

5.0 Device Description:

"Disposable Powder Free Nitrile Examination Glove, Pink Color" and "Disposable Powder Free Nitrile Examination Glove, Black Color" are patient examination gloves 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:

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.

7.0 Summary of the Technological Characteristics of the Device:

"Disposable Powder Free Nitrile Examination Glove, Pink Color" and "Disposable Powder Free Nitrile Examination Glove, Black Color" are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Table 7.1 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, Orange Non Sterile Powder Free Nitrile Examination Gloves made by Central Medicare Sdn Bhd. The subject device "Disposable Powder Free Nitrile Examination Glove, Pink Color" and "Disposable Powder Free Nitrile Examination Glove, Black Color" met with the 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 and ISO 10993-5: Third Edition 2009-06

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 10.1 SE compare

Device Characteristic	**Predicate Device**	**Proposed Device**	Comparison
Product name	Orange Non Sterile Powder Free Nitrile Examination Gloves	Disposable Powder Free Nitrile Examination Glove, Pink Color Disposable Powder Free Nitrile Examination Glove, Black Color	N/A
510(K) No.	K172642	K190942	N/A
Product Owner	Central Medicare Sdn. Bhd.	Ever Growth Enterprise Corporation	Different
Product Code	LZA	LZA	same
Regulation	21 CFR 880.6250	21 CFR 880.6250	same
Class	I	I	same
Intended Use	Orange Non Sterile Powder Free Nitrile Examination Gloves is a disposable device	The Nitrile Powder Free patient examination glove is a non-sterile disposable device	similar

	intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	
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	similar
Dimensions - Thickness	Complies with ASTM D6319-10 Palm - 0.05mm min. Finger - 0.05 mm min.	Complies with ASTM D6319-10 Palm - 0.05mm min. Finger - 0.05 mm min.	Same
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 Max. 0.50 mg 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	ISO 10993-10 Under the conditions of the study, not an irritant and sensitizer	ISO 10993-10 Skin sensitization test & Skin Irritation test: Passes ISO 10993-5 In vitro cytotoxicity test: Passes	similar

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.