January 9, 2022

Hong Seng Gloves Sdn Bhd
% Michael Van Der Woude
U.S. Agent
Emergo Global Representative LLC
2500 Bee Cave Road, Building 1 Suite 300
Austin, Texas 78746

Re: K212801
Trade/Device Name: Powder free nitrile examination glove- black, non sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: December 2, 2021
Received: December 7, 2021

Dear Michael Van Der Woude:

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,

Clarence W. Murray III, Ph.D.
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212801

Device Name
POWDER FREE NITRILE EXAMINATION GLOVE - BLACK, NON STERILE

Indications for Use *(Describe)*
A patient examination glove is a disposable device made of Nitrile rubber intended for medical purposes that is worn on the examiner's hand 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.

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# 510(k) SUMMARY – K212801

**1.0 Sponsor:**

Company Name: Hong Seng Gloves Sdn Bhd
Company Address: Lot 97, Jalan 10, Kawasan Perusahaan Bakar Arang, 08000 Sungai Petani, Kedah, Malaysia.

**2.0 Submitter:**

Contact Person: Mr. Ho Chia Yao
Company Name: Hong Seng Gloves Sdn Bhd
Company Address: Lot 97, Jalan 10, Kawasan Perusahaan Bakar Arang, 08000 Sungai Petani, Kedah, Malaysia.
Phone No.: +604-4211555
Fax No.: +604-4211555

Date of Summary Prepared: 20th July 2021 **(revised on 8th January 2022)**

**3.0 Identification of the subject device:**

Trade Name : Powder Free Nitrile Examination Glove - Black, Non- Sterile
Common Name : Patient Examination Gloves
Classification Name : Patient Examination Gloves
Device Classification : 1
Regulation Number : 21 CFR 880.6250
Product Code : LZA.

**3.0 Predicate Device:**

**K190942**
Disposable Powder Free Nitrile Examination Glove, Black Color
Company: Ever Growth (Vietnam) Co. Ltd.

**4.0 Description of The Device:**

Powder Free Nitrile Examination Glove - Black, Non-Sterile meet all requirements of ASTM standard D6319 and FDA 21 CFR 880.6250.

The powder free nitrile examination glove is manufactured from Nitrile rubber. Inner surface of gloves undergoes surface treatment process to produce a smooth surface that assists the user in donning the gloves with ease without using any lubricant such as powder on the glove surface. The glove is ambidextrous, i.e., can be worn on right hand or left hand and it is a single use device.

**Design** : Ambidextrous (i.e., fit either hand)
**Finish** : Texture Finger
**Performance** : See Section 7 Summary of Non-Clinical Testing.

**Storage:**
The product is kept away from direct sun and fluorescent lighting and stored in an environment with temperature not exceeding 40-degree C.

# 510(k) SUMMARY – K212801

**Information For "Powder Free" Claim:**

The finished powder free gloves meet ASTM D6319 requirements and are tested in according to ASTM D6124 method for powder measurement (less than 2mg per glove).

**Glove Size and dimension:**
Measurement is done as per ASTM D6319. Length is measured from the tip of the middle finger to the outside edge of the cuff. Width is measured at a level between the base of the index finger and the base of the thumb.

| Size | Palm Width (mm) | Length (mm) |
|---|---|---|
| X-Small | 70±10 | Minimum 230 |
| Small | 80±10 | Minimum 230 |
| Medium | 95±10 | Minimum 230 |
| Large | 110±10 | Minimum 230 |
| X-Large | 120±10 | Minimum 230 |

## 5.0 Indication for use:

A patient examination glove is a disposable device made of Nitrile rubber intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

## 6.0 Technological Characteristics Comparison of the Device:

Provided below is the technological comparison of the subject device vs the predicate device as shown in Table 1.

# 510(k) SUMMARY – K212801

**Table 1**

| CHARACTERISTICS | STANDARDS | DEVICE PERFORMANCE | | COMPARISON ANALYSIS |
|---|---|---|---|---|
| | | PREDICATE | SUBJECT DEVICE | |
| | | BLACK | BLACK | |
| 510(k) Number | - | K190942 | **K212801** | |
| Manufacturer(s) | - | Ever Growth Enterprise Corporation | Hong Seng Gloves Sdn Bhd | Same |
| Material | ASTM D6319 | Nitrile | Nitrile | Same |
| Color | - | Black | Black | Same |
| Physical Properties<br><br><u>Before Aging</u><br>Tensile Strength:<br>Ultimate Elongation:<br><br><u>After Aging</u><br>Tensile Strength:<br>Ultimate Elongation: | ASTM D6319 | <br><br>14Mpa, min<br>500% min<br><br>14Mpa, min<br>400% min | <br><br>29.7Mpa<br>585%<br><br>33.1Mpa<br>554% | <br><br>Different but within the ASTM standard<br><br>Different but within the ASTM standard |
| **Physical Dimensions:**<br><br>**Glove Length:**<br><br>**Glove Thickness:**<br>**- Finger**<br>**- Palm** | **ASTM D6319** | **Complies with ASTM D6319 – 230mm minimum**<br><br>**0.05mm min**<br>**0.05mm min** | **Complies with ASTM D 6319 – 230mm minimum.**<br><br>**0.10mm**<br>**0.07mm** | **Similar**<br><br>**Different but within the ASTM standard** |

| | | | | |
|---|---|---|---|---|
| **Glove Palm Width:**<br><br>**X-Small**<br>**Small**<br>**Medium**<br>**Large**<br>**X-Large** | | **Complies with ASTM D6319**<br><br>**70 ± 10mm**<br>**80 ± 10mm**<br>**95 ± 10mm**<br>**110 ± 10mm**<br>**120 ± 10mm** | **Complies with ASTM D6319**<br><br>**70 ± 10mm**<br>**80 ± 10mm**<br>**95 ± 10mm**<br>**110 ± 10mm**<br>**120 ± 10mm** | **Similar** |
| Powder Free | ASTM D6124 | < 2mg per glove | 0.20 mg/glove | Different but within the ASTM standard |
| Biocompatibility | Primary Skin Irritation – ISO 10993-10:2010 (E) & Consumer Product Safety Commission Title 16. Chapter II, Part 1500 | Passes | The test material did not cause an irritant response. The Primary Irritant Response Category is deemed 'Negligible' | Similar |
| | Dermal Sensitization- ISO 10993-10: 2010 (E) & Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.3 (c) (4) | Passes | The test material did not produce a skin sensitization effect in the guinea pigs. | Similar |
| | Cytotoxicity - MEM Elution, ISO 10993-5: 2009 (E) | Passes | The test material demonstrated a cytotoxic effect under the condition of this study. Additional test i.e. Acute Systemic Toxicity was tested. | Different – but additional test of Acute Systemic Toxicity is conducted. |

# 510(k) SUMMARY – K212801

| CHARACTERISTICS | STANDARDS | DEVICE PERFORMANCE | | COMPARISON ANALYSIS |
|---|---|---|---|---|
| | | PREDICATE | SUBJECT DEVICE | |
| | | BLACK | BLACK | |
| Biocompatibility | Acute Systemic Toxicity, ISO 10993-11:2017 (E) | Not Applicable | The test item did not induce any systemic toxicity in Swiss albino mice. | Different. |
| Watertight (1000ml) | ASTM D5151:2019 | In accordance with ASTM D6319-10 and ASTM D5151-06 (reapproved 2011), G-1, AQL 2.5 | Gloves passed AQL 1.5 | Different, but within the ASTM standard. |
| **Indication for use** | - | The Nitrile Powder Free patient examination glove is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. | A patient examination glove is a disposable device made of nitrile rubber intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. | Same |
| Size | Medical Glove Guidance Manual – Labeling | X Small<br>Small<br>Medium<br>Large<br>X Large | Extra Small<br>Small<br>Medium<br>Large<br>Extra Large | Same |
| Single use | Medical Glove Guidance Manual – Labeling | Yes | Single Use | Same |

There are no significant differences between the two products and they are the same or similar in terms of intended use, materials design, physical properties, thickness and biocompatibility test.

## 7.0 Summary of Non-Clinical Testing

The performance test data of the non-clinical test for this powder free nitrile examination glove is summarized as per below.

# 510(k) SUMMARY – K212801

| Test Method | Standard | Purpose of Testing | Acceptance Criteria | | | Results | | Status |
|---|---|---|---|---|---|---|---|---|
| | | | [redacted] | Before aging | After aging | Before aging | After aging | |
| Physical Properties | ASTM D412 (Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension) | To evaluate the tensile (tension) properties of glove. | Tensile strength | Min 14.0 MPa | Min 14.0 MPa | 29.7Mpa | 33.1Mpa | Pass |
| | | | Ultimate elongation | Min 500% | Min 400% | 585% | 554% | Pass |

# 510(k) SUMMARY – K212801

| Test Method | Standard | Purpose of Testing | Glove Size | Acceptance Criteria | | Results | | Status |
|---|---|---|---|---|---|---|---|---|
| Dimension | ASTM D3767 Standard Practice for Rubber—Measurement of Dimensions | To measure the length, width and thickness of glove | X-Small | Length | Min 240 mm | Length | 250 mm | Pass |
| | | | | Width | 70 ± 10 mm | Width | 78.0 mm | Pass |
| | | | | Thickness | Finger – min 0.05mm<br>Palm – min 0.05mm | Thickness | 0.10 mm<br>0.07 mm | Pass |
| | | | Small | Length | Min 240 mm | Length | 250 mm | Pass |
| | | | | Width | 80 ± 10 mm | Width | 88.0 mm | Pass |
| | | | | Thickness | Finger – min 0.05mm<br>Palm – min 0.05mm | Thickness | 0.10 mm<br>0.07 mm | Pass |
| | | | Medium | Length | Min 240 mm | Length | 250 mm | Pass |
| | | | | Width | 95 ± 10 mm | Width | 98.0 mm | Pass |
| | | | | Thickness | Finger – min 0.05mm<br>Palm – min 0.05mm | Thickness | 0.10 mm<br>0.07 mm | Pass |
| | | | Large | Length | Min 240 mm | Length | 249 mm | Pass |
| | | | | Width | 110 ± 10 mm | Width | 108 mm | Pass |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Thickness | Finger – min 0.05mm<br>Palm – min 0.05mm | Thickness | 0.10 mm<br>0.07 mm | Pass |
| | | | X-Large | Length | Min 240 mm | Length | 250 mm | Pass |
| | | | | Width | 120 ± 10 mm | Width | 118 mm | Pass |
| | | | | Thickness | Finger – min 0.05mm<br>Palm – min 0.05mm | Thickness | 0.10 mm<br>0.07 mm | Pass |

# 510(k) SUMMARY – K212801

| Test Method | Standard | Purpose of Testing | Acceptance Criteria | Results | Status |
|---|---|---|---|---|---|
| Watertight | ASTM D5151 (Standard Test Method for Detection of Holes in Medical Gloves) | To detect holes that leak water and thereby compromise the usefulness of the glove. | Sample size: 500 pcs<br>Inspection level: G1<br>AQL: 1.5, Acceptance No. 10 | The batch size for this sampling is 150,001 to 500,000. Hence, according to the single sampling plan GI, the sample to be drawn is under code M equivalent to 315 pieces with accept 10 and reject 11 to be accepted under AQL 1.5. During the test, 0 piece was found with leaks. Hence it falls within the acceptance criteria. | Pass |

| Test Method | Standard | Purpose of Testing | Acceptance Criteria | Results | Status |
|---|---|---|---|---|---|
| Residual Powder | ASTM D6124 (Standard Test Method for Residual Powder on Medical Gloves) | To determine the amount of residual powder and non-powder solids found on gloves. | Less than 2 mg per glove | Sample size : 5 pcs<br>Requirement : <2mg/glove<br>Result :0.20mg/glove | Pass |

# 510(k) SUMMARY – K212801

| Test Method | Standard | Purpose of Testing | Acceptance Criteria | Results | Status |
|---|---|---|---|---|---|
| Biocompatibility | Primary Skin Irritation – ISO 10993-10:2010 | To assess the potential of the material producing skin irritation and skin sensitization | Non-Irritant | The test material did not cause an irritant response. The Primary Irritant Response Category is deemed 'Negligible' | Pass |
| | Dermal Sensitization- ISO 10993-10: 2010 | | Non-Irritant | The test material did not produce a skin sensitization effect in the guinea pigs. | Pass |
| | Cytotoxicity - MEM Elution, ISO 10993-5: 2009 (E) | To assess the in vitro cytotoxicity of the material | Non-Toxicity | The test material demonstrated a cytotoxic effect under the condition of this study. Additional test i.e. Acute Systemic Toxicity was tested. | Fail |
| | Acute Systemic Toxicity, ISO 10993-11:2017 (E) | To assess the potential of material to cause adverse systemic reactions | Non-Toxicity | The test item did not induce any systemic toxicity in Swiss albino mice. | Pass |

## 8.0 Summary of Clinical Testing:

No clinical study is included in this submission.

## 9.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrate that the subject Powder Free Nitrile Examination Glove - Black, Non-Sterile is as safe, as effective, and performs as well as or better than the legally marketed predicate devices K190942.