October 25, 2021

Bestsafe Glove CO., LTD
Piyawat Chirasakulkarun
Chief Executive Officer
52/43 Wat Khot Hin-Khao Phai Road, Tubma
Muang Rayong, Rayong 21000
Thailand

Re: K210249
Trade/Device Name: Best Glove-Nitrile Powder Free Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: July 30, 2021
Received: September 24, 2021

Dear Piyawat Chirasakulkarun:

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 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)*
K210249

Device Name
BEST GLOVE -NITRILE POWDER FREE EXAMINATION GLOVE

Indications for Use *(Describe)*
Best Glove - Nitrile Powder Free Examination Glove is a disposable device intended for medical purposes that is worn on the examiner's hand 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.***

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# 510(k) SUMMARY
# K210249
# Nitrile Powder Free Examination Gloves

## 1.0 Submitter:

| | |
|---|---|
| Applicant: | BESTSAFE GLOVE CO., LTD<br>52/43 Watkodhin-Kaophai Rd. T.Tubma,<br>A.Muang Rayong Rayong. THAILAND 21000 |
| Phone Number: | +66 (038)-949880 |
| Fax Number: | +66 (038)-949850 |
| Name of Contact Person: | Piyawat Chirasakulkarun |
| Preparation date: | July 30, 2021 |

## 2.0 Identification of the subjected device:

| | |
|---|---|
| Trade/Proprietary Name(s): | BEST GLOVE -NITRILE POWDER FREE EXAMINATION GLOVE |
| Common Name: | Nitrile Powder Free Examination Gloves |
| Classification Name: | Patient Examination Gloves |
| Device Classification: | I |
| Product code | LZA |
| Regulation Number: | 21 CFR 880.6250 |

## 3.0 Predicate Device:

| | |
|---|---|
| Device Name: | Palm Care Blue Nitrile Examination Gloves Powder Free |
| 510(k): | K202384 |
| Common Name: | Patient Examination Gloves |
| Classification Name: | Patient Examination Gloves |
| Device Classification: | I |
| Product Code: | LZA |
| Regulation Number: | 21 CFR 880.6250 |

## 4.0 Description of the Device:

Blue Nitrile Examination Gloves Powder Free are Class I patient examination gloves bearing the product code Nitrile - LZA (21CFR880.6250). The gloves are made from acrylonitrile-butadiene copolymer dispersion. These gloves are blue in color and are powder free.

## 5.0 Indication for Use:

Best Glove Nitrile Powder Free Examination Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

## 6.0 Summary of Technological Characteristics of the Device Compared to the Predicate Device:

| Characteristics | Standards | Device performance | | Comparison |
|---|---|---|---|---|
| | | Predicate | Current | |
| **510(k) Number** | - | K202384 | K210249 | ---- |
| **Manufacturer(s)** | - | Hi-Care Thai Gloves Co. Ltd | BESTSAFE GLOVE CO., LTD | ---- |
| **Indication for Use** | Medical Gloves Guidance Manual - Issued on January 22, 2008 | A powder-free patient Examination Gloves 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 | Best Glove Nitrile Powder Free Examination Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. | Similar |
| **Material** | ASTM D6319-19 | Nitrile (NBR) | Nitrile (NBR) | Same |
| **Color** | - | Blue | Blue | Same |
| **Texture** | - | Finger Textured | Finger Textured | Same |
| **Size** | ASTM D6319-19 | Extra Small<br>Small<br>Medium<br>Large<br>Extra Large | Small<br>Medium<br>Large<br>Extra Large | Different |
| **Single Use** | Medical Gloves Guidance Manual - Issued on January 22, 2008 | Single use | Single use | Same |
| **Dimension** | ASTM D6319-19 | Length 230 mm min.<br><br>Width 95 ± 10 mm min (for Medium size) | Length 230 mm min<br><br>Width 95 ± 10 mm min (for Medium size) | Same |

| Characteristics | Standards | Device performance | | Comparison |
|---|---|---|---|---|
| | | Predicate | Current | |
| **Thickness** | ASTM D6319-19 | Finger: 0.05 mm min<br>Palm: 0.05 mm min | Finger: 0.05 mm min<br>Palm: 0.05 mm min | Same |
| **Physical Properties** | ASTM D6319-19 | **Before aging**<br>Tensile Strength:<br>14 MPa min<br>Ultimate Elongation:<br>500% min<br>**After aging**<br>Tensile Strength<br>14 MPa min<br>Ultimate Elongation:<br>400% min | **Before aging**<br>Tensile Strength:<br>14 MPa min<br>Ultimate Elongation:<br>500% min<br>**After aging**<br>Tensile Strength<br>14 MPa min<br>Ultimate Elongation:<br>400% min | Same |
| **Watertight test (1000 ml)** | ASTM D5151-19 | Pass AQL 1.5 | Pass AQL 1.5 | Similar |
| **Powder Residue** | ASTM D6124-06 (Reapproved 2017) | ≤ 2.0 mg/glove | ≤ 2.0 mg/glove | Similar |
| **Biocompatibility** | Primary Skin Irritation – ISO 10993-10 Third Edition 2010-08-01 | Under the conditions of the study, not an irritant | Under the conditions of the study, not an irritant | Same |
| | Dermal Sensitization – ISO 10993-10 Third Edition 2010-08-01 | Under the conditions of the study, not a sensitizer | Under the conditions of the study, not a sensitizer | Same |
| | In vitro cytotoxicity ISO10993-5 :2009(E) | Under the conditions of the study, noncytotoxic | Under the conditions of the study cytotoxic for undiluted (neat) and 1:2 dilutions but noncytotoxic for 1:4, 1:8 and 1:16 dilutions. Moreover, under the conditions of the study, did not induce any systemic toxicity. | Similar |
| | Acute Systemic Toxicity ISO10993-11:2017(E) | Under the conditions of study, the device extracts do not pose a systemic toxicity concern | Under the conditions of the study, did not induce any systemic toxicity. | Same |

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods. Both devices meet the ASTM standards.

## 7.0 Non-clinical testing summary

Performance Data

| Test Method | Standard | Purpose of testing | Acceptance Criteria | Result | Status |
|---|---|---|---|---|---|
| Dimension | ASTM D6319-19<br>Standard Specification for Nitrile Examination Gloves for Medical Application | To determine the length of the gloves | Min 230 mm for all sizes | Small: 243 mm<br>Medium: 240 mm<br>Large: 240 mm<br>Extra Large: 240 mm | Pass |
| | ASTM D6319-19<br>Standard Specification for Nitrile Examination Gloves for Medical Application | To determine the width of the gloves | Small: 80 ± 10 mm<br>Medium: 95 ± 10 mm<br>Large: 110± 10 mm<br>Extra Large: 120 ± 10 mm | Small: 85 mm<br>Medium: 93 mm<br>Large: 105 mm<br>Extra Large: 115 mm | Pass |
| | ASTM D6319-19<br>Standard Specification for Nitrile Examination Gloves for Medical Application | To determine the thickness of the gloves | Palm 0.05 mm min<br>Finger 0.05 mm min for all sizes | Small: Palm 0.09 mm, Finger: 0.13 mm<br>Medium: Palm: 0.06 mm, Finger: 0.08 mm<br>Large: Palm 0.09 mm, Finger: 0.12 mm<br>Extra Large: Palm 0.09 mm, Finger: 0.12 mm | Pass |
| Watertight test | ASTM D5151-19<br>Standard Test Method for Detection of Holes in Medical Gloves | To determine the holes in the gloves | Sample size: 200 pcs<br>Inspection level : GI<br>AQL 1.5<br>Acceptance Number 7<br>Rejection Number 8 | The batch size for this sampling is 35,001-150,000. Hence, according to the single sampling plan GI, the sample to be drawn is under code L equivalent to 200 pcs with accept 7 and reject 8 to be accept under AQL 1.5...<br><br>Small: 0 (Zero)<br>Medium: 0 (Zero)<br>Large:0 (Zero)<br>Extra Large:0 (Zero). | Pass |

BESTSAFE®
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| Test Method | Standard | Purpose of testing | Acceptance Criteria | Result | Status |
|---|---|---|---|---|---|
| Residual powder | ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves | To determine the residual powder in the gloves | 2 mg per glove or less | Sample size : 5 pcs<br>Requirement: 2 mg per glove or less<br>Result :<br><br>Small:1.42 mg/glove<br>Medium: 0.50 mg/glove<br>Large: 1.34 mg/glove<br>Extra Large:1.36 mg/glove | Pass |
| Physical Properties | ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application | To Determine the physical properties- Tensile strength | **Before Ageing**<br>Tensile Strength 14Mpa<br>Minimal for all sizes<br><br>**After Ageing** Tensile Strength 14Mpa<br>Minimal for all sizes | **Before Ageing**<br>Small: 18.37 MPa<br>Medium: 30.62 MPa<br>Large: 18.30 MPa<br>Extra Large: 18.20 MPa<br><br>**After ageing**:<br>Small: 14.08 MPa<br>Medium: 31.89 MPa<br>Large: 14.00 MPa<br>Extra Large: 14.00 MPa | Pass |
| | | To Determine the physical properties- Ultimate Elongation | **Before Ageing**<br>Ultimate Elongation<br>500% Min for all sizes<br><br>**After Ageing** Ultimate Elongation 400% Min for all sizes | **Before Ageing**:<br>Small: 612%<br>Medium: 500 %<br>Large:620%<br>Extra Large:587%<br><br>**After ageing**:<br>Small:408%<br>Medium: 499%<br>Large:403%<br>Extra Large:416% | Pass |

## 8.0 Clinical Testing Summary

Not applicable - Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

## 9.0 Conclusion:

The conclusions drawn from the non-clinical test demonstrate that the subject device Nitrile Powder Free Examination Glove is as safe, as effective, and performs as well as or better than the legally marketed predicate device K202384

**---END---**