October 10, 2018

Showa Best Glove, Inc.
Jeffrey Richardson
Director of Operations
579 Edison Street
Menlo, California 30731-6335

Re: K180468
Trade/Device Name: SBG Black Nitrile Powder Free Medical Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: September 4, 2018
Received: September 6, 2018

Dear Jeffrey Richardson:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180468

Device Name
SBG Black Nitrile Powder Free Medical Examination Glove

Indications for Use *(Describe)*
A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers 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."*

# 510(k) Summary

## K180468

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

### 1. SUBMITTER

Showa Best Glove, Inc.
579 Edison Street
Menlo, GA 30731
Tel: 706-862-6740
Fax: 706-862-2660
Date: October 1, 2018

### 2. OFFICIAL CORRESPONDENCE/CONTACT PERSON

Jeffrey Richardson
Showa Best Glove, Inc.
579 Edison Street
Menlo, GA 30731
Tel: 706-862-6740
Fax: 706-862-2660
Email: cmitchell@showagroup.com

### 3. 510(K) PREPARER

Carol Mitchell, Executive Assistant to President/COO
Showa Best Glove, Inc.
579 Edison Street
Menlo, GA 30731
Tel: 706-862-6724
Fax: 706-862-2660
Email: cmitchell@showagroup.com

Margaret Savage, RA/QA Supervisor
Showa Best Glove, Inc.
931 Second Ave. SE
Fayette, AL 35555
Tel: 205-932-3202 134
Fax: 205-932-5904
Email: tsavage@showagroup.com

## 4. DEVICE

Brand Name of Device: SBG Black Nitrile Powder Free Medical Examination Glove
Common or Usual Name: Patient Examination Glove
Classification Name: Non-powdered Patient Examination
Glove Regulation: 21 CFR 880.6250
Device Classification: Class: I
Product Code: LZA

## 5. PREDICATE DEVICE

Trade Name: EMG Black Nitrile Medical Examination Glove Powder Free
Common Name: Patient Examination Glove
510(k) Number: K141579
Manufacturer: ECO MEDI GLOVE SDN. BHD

## 6. INDICATIONS FOR USE

A powder free patient examination gloves is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

## 7. DEVICE DESCRIPTION

The SBG Black Nitrile Powder Free Medical Examination Glove is a single use, disposable device made from a nitrile latex compound, black in color, powder free and non-sterile. The proposed device was tested according to the following standards listed in the table below:

## 8. SUMMARY OF COMPARING TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

There is no difference in the technology characteristics when compared to the predicate device. Both the proposed and predicate devices are made from a nitrile latex compound, black in color, powder free and non-sterile.

| Characteristics | Acceptance Criteria | Proposed Device<br>**SBG Black Nitrile Powder Free Medical Examination Glove**<br>**K180468** | Predicate Device<br>**EMG Black Nitrile Medical Examination Glove Powder Free**<br>**K141579** | Comparison |
|---|---|---|---|---|
| Product Code | LZA | LZA | LZA | Same |
| Intended Use | A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner. The device is for over-the-counter use. | 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. The device is for over-the-counter use. | 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. The device is for over-the-counter use. | Same |
| Material Use | Not made from Natural Rubber Latex | Nitrile latex compound | Nitrile latex compound | Same |
| Color | Black | Black | Black | Same |
| Sterility | Non-Sterile | Non-Sterile | Non-Sterile | Same |
| Dimensions | Overall Length (mm)<br>220 mm = (sizes XS-S)<br>230 mm = (sizes M-XL) | Overall Length (mm)<br>272 mm Minimum<br>All Sizes | Overall Length (mm)<br>300 mm Minimum<br>All Sizes | Similar |
| | Width (± 10 mm)<br>Size S = 80 mm<br>Size M = 95 mm<br>Size L = 110 mm<br>Size XL = 120 mm | Width (± 10 mm)<br>Size S = 70-90 mm<br>Size M = 85-105 mm<br>Size L = 100-120 mm<br>Size XL = 110-130 mm | Width (± 10 mm)<br>Size S = 81-90 mm<br>Size M = 90-100 mm<br>Size L = 100-110 mm<br>Size XL = 110-120 mm | |
| | Thickness at Finger (mm)<br>All Sizes = 0.05 mm | Thickness at Finger (mm)<br>0.16 mm Minimum<br>All Sizes | Thickness at Finger (mm)<br>0.17 mm Minimum<br>All Sizes | |
| | Thickness at Palm<br>All Sizes = 0.05 mm | Thickness at Palm (mm)<br>0.14 mm Minimum<br>All Sizes | Thickness at Palm (mm)<br>0.14 mm Minimum<br>All Sizes | |

| Characteristics | Acceptance Criteria | Proposed Device<br>SBG Black Nitrile Medical Powder Free Examination Glove K180468 | Predicate Device<br>EMG Black Nitrile Medical Examination Glove Powder Free K141579 | Comparison |
|---|---|---|---|---|
| Physical Properties | **Before Aging ASTM 6319-10 (D 412)** | | | |
| | Tensile Strength (MPa) = 14 min. | Tensile Strength (MPa) ≥ 14 | Tensile Strength (MPa) ≥ 14 | Same |
| | Ultimate Elongation (%) = 500 min. | Ultimate Elongation (%) 500 min. | Ultimate Elongation (%) 500 min. | Same |
| | **After Aging ASTM 6319-10 (D573) (70°C ± 2 °C for 166 hrs ± 2 hrs.)** | | | |
| | Tensile Strength (MPa) = 14 min. | Tensile Strength (MPa) ≥ 14 | Tensile Strength (MPa) ≥ 14 | Same |
| | Ultimate Elongation (%) = 500 min. | Ultimate Elongation (%) 500 min. | Ultimate Elongation (%) 500 min. | Similar |
| Freedom from Holes (D 5151) | AQL 2.5 Inspection Level G-1 Accept at 5 failures Reject at 6 failures | AQL 2.5 Inspection Level G-1 Pass | AQL 2.5 Inspection Level G-1 Pass | Same |
| Residual Powder (D 6124) | ≤ 2.0 mg/pc | Contains less than 2.0 mg | Contains less than 2.0 mg | Same |
| Biocompatibility test – Primary Skin Irritation Test (ISO 10993-10:2010 (E) | | Under the conditions of the study, not a primary skin irritant. | Under the conditions of the study, not a primary skin irritant. | Same |
| Biocompatibility test Dermal Sensitization Assay (ISO 10993-10:2010 (E) | | Under conditions of the study, not a contact sensitizer | Under conditions of the study, not a contact sensitizer | Same |
| Safety Assessment (Systemic Toxicity) | | The results from the safety assessment demonstrated the device presents a low potential health risk | / | Different |

## 9. CONCLUSIONS

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