May 6, 2019

Showa Best Glove, Inc.
% Lee Rosebush
Attorney
BakerHostetler
1050 Connecticut Avenue, NW, Suite 1100
Washington, District of Columbia 20036-5304

Re: K190159
Trade/Device Name: Showa® Medical Exam Glove (Green) Powder-free, Disposable Nitrile Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LZC
Dated: January 28, 2019
Received: January 31, 2019

Dear Lee Rosebush:

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,

For David Krause, PhD
Acting Director
Division of Infection Control and Plastic Surgery
Office of Surgical & Infection Control Devices
Office of Product Evaluation & 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)*

K190159

Device Name

Showa® Medical Exam Glove (Green) Powder-free, Disposable Nitrile Glove

Indications for Use *(Describe)*

The Showa® Medical Exam Glove (Green) Powder-free, Disposable Nitrile Glove is a disposable device intended for medical purposes that is worn on the examiner's hand 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:

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*"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**
**K190159**

**Revised 510(k) Date:** March 26, 2019

## General Information

### I. Submitter:

a. Name: Showa Best Glove, Inc.

b. Address: 579 Edison Street, Menlo, GA 30731-6335

c. Telephone Number: 706-862-6712

d. Fax Number: 706-862-6000

e. Contact Person: Jeffrey Richardson

f. FDA Owner/Operator Number: 9041216

### II. Name of Device:

a. Trade or Proprietary Name: Showa® Medical Exam Glove (Green) Powder-free, Disposable Nitrile Gloves

b. Common or Usual Name: Polymer Patient Exam Gloves

c. Classification Name: Patient Examination Glove (LZA, 21 C.F.R. § 880.6250)

d. 510(k) Submission Number: K190159

### III. Predicate Device:

a. Name: N-DEX NightHawk® Black Nitrile Powder-Free Medical Examination Glove (Black), Non-Sterile

b. Submission Number: K082125

### IV. Description of Device:

The Showa® Medical Exam Glove (Green) Powder-free, Disposable Nitrile Glove is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent

contamination between patient and examiner. The gloves are single use only, supplied in a nonsterile state, and come in six (6) sizes: XS, S, M, L, XL, and XXL.

The gloves are made of Nitrile Butadiene Rubber, designed, and manufactured in accordance with ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application.

Their physical and performance characteristics meet all requirements of ASTM D6319-10. The gloves are powder-free and meet the requirements of ASTM D6124-06. No powder is used during any stage of manufacturing. Rather, the gloves are manufactured using online chlorination – a process wherein the examination gloves are dipped in a dilute chlorine solution to reduce surface friction. More specifically, through the chlorination reaction, the compound is stabilized and further cross-linked and the gloves' surface becomes hardened and smooth, thereby providing the gloves with good donning properties. The gloves then are removed from the chlorination solution and neutralized in an aqueous ammonia solution and washed until any residual chlorine is removed, resulting in the gloves' surface pH being similar to that of water. Once the wash process is completed, the reactive material is removed, thus ceasing the chlorination process.

**Technological Characteristic Comparison Table:**

| **Characteristic** | **Predicate Device K082125** N-DEX NightHawk® Black Nitrile Powder-Free Medical Examination Glove (Black), Non-Sterile | **Proposed Device K190159** Showa® Medical Exam Glove (Green) powder-free, disposable nitrile gloves | **Comparison** |
|---|---|---|---|
| Device Description/ Regulation Number | Patient examination glove/ 21 C.F.R. § 880.6250 | Patient examination glove/ 21 C.F.R. § 880.6250 | Identical |
| Product Code | LZA | LZA | Identical |
| Intended Use | Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. | Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. | Identical |

| | | | |
|---|---|---|---|
| Instructions for Use | A disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. | A disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. | Identical |
| Materials | Nitrile | Nitrile | Identical |
| Color | Black | Green | Different |
| Single Use | Yes | Yes | Identical |
| Physical Property | Meets ASTM D6319-00 | Meets ASTM D6319-00 | Identical |
| Powder Residual | Meets ASTM D6124 of <2mg/glove | Meets ASTM D6124 of <2mg/glove | Identical |
| Biocompatibility | Skin irritation Study (ISO 10993-10) | Skin irritation Study (ISO 10993-10) | Identical |
| | Closed Patch Sensitization Study (ISO 10993-10) | Closed Patch Sensitization Study (ISO 10993-10) | Identical |
| | Cytotoxic Study (ISO 10993-5) | / | Different |
| | / | Acute systemic toxicity Study (ISO 10993-11) | Different |
| Shelf Life | N/A | 3 years | Different |
| Biodegradation Properties | None | Biodegradable | Different |

**Summary of Difference and Comparison of Technological Characteristics- The subject device differs from the predicate in that:**

- The subject device has biodegradation property within landfills tested per ASTM D5526 while the predicate device does not have same technological feature. The difference in biodegradation properties does not affect the subject device's safety and effectiveness; subject device met the requirements for Biocompatibility Testing and ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application. The difference in technological feature does not change the performance or affect the intended use of the device.

- Biodegradability is not a medical claim and therefore was not reviewed by FDA.

**Summary of Non-Clinical Testing**

| **Specification** | **Proposed Device K190159**<br>Showa® Medical Exam<br>Glove (Green) Powderfree, Disposable Nitrile Glove |
|---|---|
| Performance Standards (conforms) | ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application;<br>ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves;<br>ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves;<br>ASTM D7160-16 Standard Practice for Determination of Expiration Dating for Medical Gloves;<br>ASTM D412-15a Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension |
| Water Tightness (conforms) | ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves;<br>ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application;<br>ASTM D7160-16 Standard Practice for Determination of Expiration Dating for Medical Gloves |
| **Biocompatibility** | **Proposed Device K190159**<br>Showa® Medical Exam<br>Glove (Green) Powder-free, Disposable Nitrile Glove |
| ISO Skin irritation Study (ISO 10993-10) | Under the conditions of the study, the non-polar and polar device extracts did not elicit a response in the animal model. Therefore, the device is not a skin irritant |
| ISO Closed Patch Sensitization Study (ISO 10993-10) | Under the conditions of the study, the non-polar and polar device extracts did not elicit a response in the animal model. Therefore, the device is not a contact sensitizer |
| Acute Systemic Toxicity Study (ISO 10993-11) | Under conditions of the ISO Acute Systemic Injection Test, the non-polar and polar device extracts did not elicit a response in the animal model. Therefore, the device does not present an acute toxicity potential. |

**Conclusions:**

Based on the Indication for Use, technological characteristics, and non-clinical performance data, Showa® Medical Exam Glove (Green) Powder-free, Disposable Nitrile Glove (K190159) is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K082125).