October 26, 2020

Medline Industries Inc
Leontyne Banks
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60061

Re: K200150
Trade/Device Name: Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, QDO
Dated: September 23, 2020
Received: September 23, 2020

Dear Leontyne Banks:

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: CAPT 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)*

K200150

Device Name

Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl)

Indications for Use *(Describe)*

A patient 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.

It has also been tested for use against Fentanyl Citrate, ASTM D6978-05 (Reapproved 2019, Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs).

Drugs Tested:	Breakthrough Time (Minutes)
Fentanyl Citrate, 100mcg/2mL	>240 min

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

K200150

[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor

Medline Industries, Inc. Three Lakes Drive Northfield, IL 60093
Registration Number: 1417592
Applicant Contact: Leontyne Banks, Regulatory Affairs Specialist

Summary Preparation Date

October 18, 2020

Type of 510(k) Submission

Traditional

Device Name / Classification

Device Name: Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl)

Proprietary Name: Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl)
Common Name: Patient Examination Glove, Specialty

Classification Name: Polymer Patient Exam Glove, Fentanyl and other Opioid Protection Glove
Product Code: LZA, QDO Classification Panel: General Hospital Regulation #: 21 CFR 880.6250

Predicate Device

Shen Wei (USA), Inc.: Powder-Free Nitrile Examination Gloves (Orange), K120890

Device Description

The Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl) are non-sterile, single use, disposable gloves intended for medical purposes to be worn on the hands of examiners to prevent contamination between a patient and an examiner. The gloves are nitrile, powder-free, ambidextrous, and orange-colored with a beaded cuff. The proposed device is offered in in the following sizes:

TABLE 1: The Medline Powder-Free Orange Nitrile Patient Examination Gloves

Model Number	Size
CR911S	Small
CR911M	Medium
CR911L	Large
CR911XL	Extra-Large
CR911XXL	Extra Extra-Large

The subject gloves are designed and manufactured in accordance with the ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application and are tested for use with Fentanyl per ASTM D6978-05 (Reapproved 2019).

Indications for Use

A patient 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. It has also been tested for use against Fentanyl Citrate, ASTM D6978-05 (Reapproved 2019, Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs).

Drugs Tested:	Breakthrough Time (Minutes)
Fentanyl Citrate, 100mcg/2mL	>240

Comparison of Technological Characteristics for the subject and Predicate Devices

Characteristic	Subject Device K200150	Predicate Device K120890	Remarks
Product Name	Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl)	Powder-Free Nitrile Examination Gloves (Orange)	N/A
510(k) Number	K200150	K120890	N/A
Manufacture	Medline Industries, Inc.	Shen Wei (USA), Inc	N/A
Product Code	LZA, QDO	LZA	Similar
Intended Use	A patient 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. These gloves were Tested for use with Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019)	A disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is single use only.	Similar
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Materials	Powder-Free Nitrile	Powder-Free Nitrile	Same
Color	Orange	Orange	Same
Sizes	Small, Medium, Large, X- large, XX-large	Small, Medium, Large	Similar
Biocompatibility	AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer	AAMI/ANSI/ISO 10993-1: Not a skin irritant Not a skin sensitizer	Similar
	AAMI/ANSI/ISO 10993-5: Cytotoxic	N/A	Different
	AAMI/ANSI/ISO 10993-11: No Acute systemic toxicity	N/A	Different
Sterility	Non-sterile	Non-sterile	Same
Rx Only or OTC	Over the Counter	Over the Counter	Same

Summary of Non-Clinical Testing

The following performance testing was conducted to demonstrate the safety and effectiveness of the subject device in accordance with the relevant standards cited below:

- ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6124-06 (Reaffirmation 2011) Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-06 (Reapproved 2011) Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Characteristic	Subject Device K200150	Predicate Device K120890	Remarks
Dimensions – Length	Complies with: ASTM D6319-10 minimal: 220mm	Complies with: ASTM D6319-10, minimal: 220mm	Same
Dimensions – Width	Complies with: ASTM D6319-10 minimal: 70mm	Complies with: ASTM D6319-10, minimal: 70mm	Same
Dimensions – Thickness	Complies with: ASTM D6319-10 minimal Palm – 0.05mm. minimal Finger – 0.05mm.	Complies with: ASTM D6319-10, minimal Palm – 0.05mm. minimal Finger – 0.05mm.	Same
Physical Properties	Complies with: ASTM D6319-10 minimum: Tensile Strength: Before Aging ≥14 MPa. After Aging ≥14 MPa. Elongation: Before Aging 500%, min. After Aging 400%, min.	Complies with: ASTM D6319-10 minimum: Tensile Strength: Before Aging ≥14 MPa. After Aging ≥14 MPa. Elongation: Before Aging 500% min. After Aging 400% min.	Same
Freedom from Holes	Complies with ASTM D6319-10 and ASTM D5151-06, AQL 2.5	Complies with ASTM D6319-10 and ASTM D5151-06, AQL 2.5	Same
Powder or Powder-Free	Powder-Free	Powder-Free	Same
Residual Powder	Complies with: ASTM D6319-10, <2mg per glove	Complies with: ASTM D6319-05, <2mg per glove	Same
Contact Durations	Limited, <24 hours	Limited, <24 hours	Same
Fentanyl Testing with Minimum Breakthrough Detection Time as tested per ASTM D6978	Fentanyl Citrate, 100.0 mcg/2mL >240 min	N/A	Different

The biocompatibility evaluation for the Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl) was conducted in accordance with ANSI/AAMI/ISO 10993-1:2018 *Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process*, as recognized by FDA.

The following tests were performed to evaluate the biocompatibility of the Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl):

- ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
- ISO 10993-05:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-11: 2017 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity.
- ISO 10993-12: 2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials.

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device, the Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl) are as safe, effective, and performs as well or better as the legally marketed predicate device cleared under K120890.