November 7, 2022

SafeSource Direct, LLC
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K222898
Trade/Device Name: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ
Dated: October 31, 2022
Received: November 1, 2022

Dear Prithul Bom:

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,

Allan Guan -S

For Bifeng Qian, M.D., 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)*

K222898

Device Name
SafeSource Direct Blue Powder-Free Nitrile Exam Gloves

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs, as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Carmustine (BCNU) 3.3 mg/ml 35.8 Minutes
Cisplatin 1.0 mg/ml ≥ 240 Minutes
Cyclophosphamide (Cytoxan) 20.0 mg/ml ≥ 240 Minutes
Dacarbazine (DTIC) 10.0 mg/ml ≥ 240 Minutes
Doxorubicin Hydrochloride 2.0 mg/ml ≥ 240 Minutes
Etoposide (Toposar) 20.0 mg/ml ≥ 240 Minutes
Fluorouracil 50.0 mg/ml 0.5 mg/ml ≥ 240 Minutes
Methotrexate 25 mg/ml ≥ 240 Minutes
Mitomycin C 0.5 mg/ml ≥ 240 Minutes
Paclitaxel (Taxol) 6.0 mg/ml ≥ 240 Minutes
Thio-Tepa 10.0 mg/ml 87.0 Minutes
Vincristine Sulfate (Oncovin) 1.0 mg/ml ≥ 240 Minutes

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 35.8 Minutes
Thio-Tepa 10.0 mg/ml 87.0 Minutes
Not recommended for use with these drugs.

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.

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510(k) Summary
K222898

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the SafeSource Direct Blue Powder-Free Nitrile Exam Gloves Traditional 510(k) premarket notification.

Sponsor: SafeSource Direct, LLC
200 St Nazaire Rd.
Broussard, LA 70518
Sponsor Contact: Justin Hollingsworth

Submission Contact: Grace Powers, MS, MBA, RAC
Founder/Principal Consultant
Powers Regulatory Consulting
Tel: 404-931-8730

Preparation Date: October 30, 2022

Subject Device:

Trade Name: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves
Common/Usual Name: Non-Powdered Patient Examination Glove
Classification Name: Non-Powdered Patient Examination Glove Specialty
Classification Regulation: 21 CFR 880.6250
Product Code: LZA, LZC, OPJ
Device Class: Class I, Reserved
Classification Panel: General Hospital and Personal Use Devices

Predicate Device: Legally marketed device to which substantial equivalence is claimed:

Trade/Proprietary Name: Medline Powder-Free Light Blue Nitrile Exam Gloves
Manufacturer: Medline Industries, Inc.
510(k): K201390
Common/Usual Name: Non-Powdered Patient Examination Glove
Classification Name: Patient Examination Glove, Specialty
Classification Regulation: 21 CFR 880.6250
Product Code: LZA, LZC
Device Class: Class I, Reserved
Classification Panel: General Hospital and Personal Use Devices

Device Description

The SafeSource Direct Blue Powder-Free Nitrile Exam Gloves are a patient examination glove that is a non-sterile, single use, disposable device intended for medical purposes that is worn on the examiner's hands to prevent

contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs. These gloves are made of synthetic copolymer of acrylonitrile and butadiene (NBR rubber) with a blue dye. The gloves are available in small, medium, large, and extra-large.Physical performance of the proposed device were evaluated per ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application (FR Recognition Number 6-446).

In addition, the proposed device was tested according to ASTM D6978-05 (Reapproved 2019), Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (FR Recognition Number 6-147).

Indications for Use
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs, as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Carmustine (BCNU) 3.3 mg/ml 35.8 Minutes
Cisplatin 1.0 mg/ml ≥ 240 Minutes
Cyclophosphamide (Cytoxan) 20.0 mg/ml ≥ 240 Minutes
Dacarbazine (DTIC) 10.0 mg/ml ≥ 240 Minutes
Doxorubicin Hydrochloride 2.0 mg/ml ≥ 240 Minutes
Etoposide (Toposar) 20.0 mg/ml ≥ 240 Minutes
Fluorouracil 50.0 mg/ml 0.5 mg/ml ≥ 240 Minutes
Methotrexate 25 mg/ml ≥ 240 Minutes
Mitomycin C 0.5 mg/ml ≥ 240 Minutes
Paclitaxel (Taxol) 6.0 mg/ml ≥ 240 Minutes
Thio-Tepa 10.0 mg/ml 87.0 Minutes
Vincristine Sulfate (Oncovin) 1.0 mg/ml ≥ 240 Minutes

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 35.8 Minutes
Thio-Tepa 10.0 mg/ml 87.0 Minutes
Not recommended for use with these drugs.

The gloves are available over the counter.

Technological Characteristics

The SafeSource Direct Blue Powder-Free Nitrile Exam Gloves has similar technological characteristics as the predicate device.

Table 1 – General Comparison

Device Comparison	Subject Device: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves (K222898)	Predicate Device: Medline Powder-Free Light Blue Nitrile Exam Gloves (K201390)	Comparison
Device	SafeSource Direct Blue Powder-Free Nitrile Exam Gloves	Medline Powder-Free Light Blue Nitrile Exam Gloves	Not Applicable
Manufacturer	SafeSource Direct, LLC	Medline Industries, Inc.	Not Applicable
FDA Product Code	LZA, LZC, OPJ	LZA, LZC	Identical
Regulation Name	Non-powdered Patient Examination Glove, Specialty	Non-powdered Patient Examination Glove, Specialty	Identical
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Identical
Intended Use/ Indications for Use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs, as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Carmustine (BCNU) 3.3 mg/ml 35.8 Minutes Cisplatin 1.0 mg/ml ≥ 240 Minutes Cyclophosphamide (Cytoxan) 20.0 mg/ml ≥ 240 Minutes Dacarbazine (DTIC) 10.0 mg/ml ≥ 240 Minutes Doxorubicin Hydrochloride 2.0 mg/ml ≥ 240 Minutes Etoposide (Toposar) 20.0 mg/ml ≥ 240 Minutes	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs, as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Carmustine (BCNU) 3.3 mg/ml 25.3 Minutes Cisplatin 1.0 mg/ml ≥ 240 Minutes Cyclophosphamide (Cytoxan) 20.0 mg/ml ≥ 240 Minutes Dacarbazine (DTIC) 10.0 mg/ml ≥ 240 Minutes Doxorubicin Hydrochloride 2.0 mg/ml ≥ 240 Minutes Etoposide (Toposar) 20.0 mg/ml ≥ 240 Minutes	Identical with the exception of the Carmustine and Thio-Tepa breakthrough times.

Device Comparison	Subject Device: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves	Predicate Device: Medline Powder-Free Light Blue Nitrile Exam Gloves (K201390)	Comparison
	Fluorouracil 50.0 mg/ml 0.5 mg/ml ≥ 240 Minutes Methotrexate 25 mg/ml ≥ 240 Minutes Mitomycin C 0.5 mg/ml ≥ 240 Minutes Paclitaxel (Taxol) 6.0 mg/ml ≥ 240 Minutes Thio-Tepa 10.0 mg/ml 87.0 Minutes Vincristine Sulfate (Oncovin) 43.7 mg/ml ≥ 240 Minutes Please note that the following drugs have low permeation times: Carmustine (BCNU) 3.3 mg/ml 35.8 Minutes Thio-Tepa 10.0 mg/ml 87.0 Minutes Not recommended for use with these drugs.	Fluorouracil 50.0 mg/ml 0.5 mg/ml ≥ 240 Minutes Methotrexate 25 mg/ml ≥ 240 Minutes Mitomycin C 0.5 mg/ml ≥ 240 Minutes Paclitaxel (Taxol) 6.0 mg/ml ≥ 240 Minutes Thio-Tepa 10.0 mg/ml 43.7 Minutes Vincristine Sulfate (Oncovin) 43.7 mg/ml ≥ 240 Minutes Please note that the following drugs have low permeation times: Carmustine (BCNU) 3.3 mg/ml 25.3 Minutes Thio-Tepa 10.0 mg/ml 43.7 Minutes Caution: Testing showed an average breakthrough time of 43.7 minutes with Thio-Tepa WARNING: Do not use with Carmustine	
Sizes	Small, Medium, Large, Extra Large	Extra Small, Small, Medium, Large, Extra Large	Similar- the subject device does not come in extra small.
Materials	Nitrile	Nitrile	Similar
Color	Blue	Blue	Identical
Condition of Use	Single Use (Disposable)	Single Use (Disposable)	Identical
Powder or Powder-Free	Powder free	Powder Free	Identical
Dimensions-Length	Complies with ASTM D6319-19 240mm min.	Complies with ASTM D6319-10 240mm min.	Identical
Dimensions-Width	Complies with ASTM D6319-19 S: 80±10mm M: 95±10mm L: 110±10mm XL: 120±10mm	Complies with ASTM D6319-10 XS: N/A S: 85±10mm M: 95±10mm L: 105±10mm	Similar- Both comply with the standard.

Device Comparison	Subject Device: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves	Predicate Device: Medline Powder-Free Light Blue Nitrile Exam Gloves (K201390)	Comparison
		XL: 115±10mm	
Dimensions-Thickness	Complies with ASTM D6319-19 Palm – 0.05 minimum Finger – 0.05 minimum	Complies with ASTM D6319-10 Palm – 0.14 Finger – 0.16 Cuff – 0.12	Similar- Both comply with the standard. Cuff was not measured on the subject device.
Physical Properties – Tensile Strength	Complies with ASTM D6319-19 Tensile Strength: Before Aging ≥14 Mpa, min After Aging ≥14 Mpa, min	Complies with ASTM D6319-10 Tensile Strength: Before Aging ≥17 Mpa, min After Aging ≥14 Mpa, min	Similar- Both comply with the standard.
Physical Properties – Elongation	Elongation: Before Aging 500% Min After Aging 400% Min	Elongation: Before Aging 500% Min After Aging 400% Min	Identical
Freedom from Holes	Complies with ASTM D6319-19 and ASTM D5151-06 G-1, AQL 2.5	Complies with ASTM D6319-10 and ASTM D5151-06 G-1, AQL 2.5	Identical
Residual Powder	Max. 0.42mg per glove	Max. 0.52mg per glove	Identical
Biocompatibility	ISO 10993-10 ISO 10993-11 Not a skin irritant Not a skin sensitizer No clinical sign of acute systemic toxicity	• ISO 10993-10: Primary Skin Irritation, not a skin irritant • ISO 10993-10: Dermal Sensitization, not a skin sensitizer • ISO 10993-11: No clinical sign of acute systemic toxicity	Identical- Both devices are not a skin irritant or skin sensitizer. Both devices showed no clinical sign of acute systemic toxicity
Sterility	Non-sterile	Non-sterile	Identical

Non-Clinical Performance Data

Table 2 - Summary of Non-Clinical Performance Testing

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319	Physical Dimensions Test	Length (mm): S: ≥ 220 M/L/XL: ≥ 230 Width (mm): S: 80 ± 10 M: 95 ± 10 L: 110 ± 10 XL: 120 ± 10	Length (mm): S: ≥ 220 / Pass M/L/XL: ≥ 230 / Pass Width (mm): S: 82 – 85 / Pass M: 95 – 97 / Pass L: 103 – 107 / Pass XL: 110 – 116 / Pass
		Thickness (mm):	Thickness (mm):

		Finger: ≥ 0.05 Palm: ≥ 0.05			Finger: 0.13 – 0.17 / Pass Palm: 0.09 – 0.11 / Pass
ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5			S: 1/125 / Pass M: 2/125 / Pass L: 2/125 / Pass XL: 4/125 / Pass
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0 mg			0.4 mg / Pass
ASTM D412	Physical Properties	Meet the requirements of ASTM D412 AQL 4.0			1/13 / Pass
		Before Aging	Tensile Strength	≥ 14 MPa	14 – 19 MPa
			Ultimate Elongation	≥ 500%	515 – 540%
		Meet the requirements of ASTM D412 AQL 4.0			1/13 / Pass
		After Aging	Tensile Strength	≥ 14 MPa	15 – 20 / Pass
			Ultimate Elongation	≥ 400%	468 – 525 / Pass
ISO 10993-5	Cytotoxicity	Non-In Vitro Cytotoxicity			Under conditions of the study, device extract is cytotoxic.
ISO 10993-11	Acute Systemic Toxicity	Non-Acute Systemic Toxicity			Under conditions of the study, did not show acute systemic toxicity in vivo. / Pass
ISO 10993-10	Irritation	Non-irritating			Under conditions of the study, not an irritant. / Pass
ISO 10993-10	Sensitization	Non-sensitizing			Under conditions of the study, not a sensitizer. / Pass

Clinical Performance Testing
Clinical testing is not needed for this device.

Conclusion
The conclusions drawn from the nonclinical tests demonstrate that the subject device, SafeSource Direct Blue Powder-Free Nitrile Exam Gloves, is as safe, as effective, and performs as well as or better than the legally marketed predicated device under K201390.