March 19, 2025

SafeSource Direct LLC
% Grace Powers
Founder/ Principal Consultant
Powers Regulatory Consulting
2451 Cumberland Parkway SE
Suite 3740
Atlanta, Georgia 30339

Re: K250502
Trade/Device Name: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves (AMERI-TUFF Series 4000, AMERI-TOUCH Series 5000)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ
Dated: February 18, 2025
Received: February 20, 2025

Dear Grace Powers:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
DHT4C: Division of Infection
Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250502

Device Name
SafeSource Direct Blue Powder-Free Nitrile Exam Gloves (AMERI-TUFF Series 4000)

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
Warning: 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250502

Device Name
SafeSource Direct Blue Powder-Free Nitrile Exam Gloves (AMERI-TOUCH Series 5000)

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 22.5 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 37.5 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 22.5 Minutes
Thio-Tepa 10.0 mg/ml 37.5 Minutes
Warning: 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.

510(k) Summary
K250502

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 Special 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

Date Prepared: March 19, 2025

Subject Device:

Trade Name: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves (AMERI-TUFF Series 4000, AMERI-TOUCH Series 5000)
Common/Usual Name: Non-Powdered Patient Examination Glove
Classification Name: Polymer Patient Examination Glove, 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: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves
Manufacturer: SafeSource Direct, LLC
510(k): K222898
Common/Usual Name: Non-Powdered Patient Examination Glove
Classification Name: Polymer Patient Examination Glove, 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 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. The purpose of this submission is to add two additional sizes (AMERI-TUFF Series 4000 XS and XXL) and additional series (AMERI-TOUCH Series 5000 XS through XXL) of SafeSource Direct Blue Powder-Free Nitrile Exam Glove

Indications for Use- AMERI-TUFF Series 4000 Gloves
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
Warning: Not recommended for use with these drugs.

Indications for Use- AMERI-TOUCH Series 5000
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 22.5 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 37.5 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 22.5 Minutes
Thio-Tepa 10.0 mg/ml 37.5 Minutes
Warning: Not recommended for use with these drugs.

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

Device Comparison	Subject Device: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves	Predicate Device: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves K222898	Comparison
Name	SafeSource Direct Blue Powder-Free Nitrile Exam Gloves	SafeSource Direct Blue Powder-Free Nitrile Exam Gloves	Identical
Manufacturer	SafeSource Direct, LLC	SafeSource Direct, LLC	Identical
FDA Product Code	LZA, LZC, OPJ	LZA, LZC	Identical
Regulation Name	Polymer Patient Examination Glove, Patient Examination Glove, Specialty	Polymer Patient Examination Glove, 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	A patient examination glove is a disposable device intended for medical	The device name has been updated to

Device Comparison	Subject Device: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves	Predicate Device: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves K222898	Comparison
	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 (Series 4000) or **22.5 Minutes (Series 5000)** 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 43.7 Minutes (Series 4000) or **37.5 Minutes (Series 5000)**	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	differentiate the two lines of gloves. The breakthrough time information is identical with the exception of the Carmustine and Thio-Tepa breakthrough times for the Series 5000 gloves.

Device Comparison	Subject Device: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves	Predicate Device: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves K222898	Comparison
	Vincristine Sulfate (Oncovin) 1.0 mg/ml ≥ 240 Minutes Please note that the following drugs have low permeation times: Carmustine (BCNU) 3.3mg/ml 35.5 Minutes or **25.5 Minutes (Series 5000)** Thio-Tepa 10.0 mg/ml 43.7 Minutes (Series 4000) or **22.5 Minutes (Series 5000)** Warning: Not recommended for use with these drugs.	Thio-Tepa 10.0 mg/ml 43.7 Minutes Not recommended for use with these drugs.	
Sizes	Series 4000: Extra Small, Extra Extra Large Series 5000: Extra Small, Small, Medium, Large, Extra Large, Extra Extra Large	Series 4000: Small, Medium, Large, Extra Large	Similar- the subject device is adding two additional sizes and another line of gloves.
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 (both series) XS: 220mm min S: 220mm min M: 230mm min L: 230mm min XL: 230mm min XXL: 230mm min	Complies with ASTM D6319-19 S: 220mm min M: 230mm min L: 230mm min XL: 230mm min	Similar- both follow the standard
Dimensions-Width	Complies with ASTM D6319-19 (both series) XS: 70±10mm S: 80±10mm M: 95±10mm L: 110±10mm XL: 120±10mm XXL: 130±10mm	Complies with ASTM D6319-19 S: 85±10mm M: 95±10mm L: 105±10mm XL: 115±10mm	Similar- Both comply with the standard.
Dimensions-Thickness	Complies with ASTM D6319-19	Complies with ASTM D6319-19	Identical

Device Comparison	Subject Device: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves	Predicate Device: SafeSource Direct Blue Powder-Free Nitrile Exam Gloves K222898	Comparison
	Palm - 0.05 minimum Finger - 0.05 minimum	Palm - 0.05 minimum Finger - 0.05 minimum	
Physical Properties – Tensile Strength	Complies with ASTM D6319-19 Tensile Strength: Before Aging ≥14 MPa, min After Aging ≥14 MPa, min	Complies with ASTM D6319-19 Tensile Strength: Before Aging ≥14 MPa, min After Aging ≥14 MPa, min	Identical
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	Complies with ASTM D6319-19 and ASTM D5151-06 G-1, AQL 2.5	Identical
Residual Powder	Max. 0.42mg per glove	Max. 0.42mg per glove	Identical
Biocompatibility	ISO 10993-10: Not a skin irritant, not a skin sensitizer ISO 10993-5: Cytotoxic ISO 10993-11: No acute systemic toxicity	ISO 10993-10: Not a skin irritant, not a skin sensitizer ISO 10993-5: Cytotoxic ISO 10993-11: No acute systemic toxicity	Identical
Sterility	Non-sterile	Non-sterile	Identical
Series 5000: Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as Tested per ASTM D 6978	Carmustine (BCNU) 3.3 mg/ml: 22.5 Minutes	Carmustine (BCNU) 3.3 mg/ml: 35.8 Minutes	Different- The breakthrough time was shorter for the Series 5000 subject device.
	Cisplatin 1.0 mg/ml: ≥240 Minutes	Cisplatin 1.0 mg/ml: ≥240 Minutes	Identical
	Cyclophosphamide (Cytoxan) 20.0 mg/ml: ≥240 Minutes	Cyclophosphamide (Cytoxan) 20.0 mg/ml: ≥240 Minutes	Identical
	Dacarbazine (DTIC) 10.0 mg/ml: ≥240 Minutes	Dacarbazine (DTIC) 10.0 mg/ml: ≥240 Minutes	Identical
	Doxorubicin Hydrochloride 2.0 mg/ml: ≥240 Minutes	Doxorubicin Hydrochloride 2.0 mg/ml: ≥240 Minutes	Identical
	Etoposide (Toposar) 20.0 mg/ml: ≥240 Minutes	Etoposide (Toposar) 20.0 mg/ml: ≥240 Minutes	Identical
	Fluorouracil 50.0 mg/ml: ≥240 Minutes	Fluorouracil 50.0 mg/ml: ≥240 Minutes	Identical

	Methotrexate 25 mg/ml: ≥240 Minutes	Methotrexate 25 mg/ml: ≥240 Minutes	Identical
	Mitomycin C 0.5 mg/ml: ≥ 240 Minutes	Mitomycin C 0.5 mg/ml: ≥ 240 Minutes	Identical
	Paclitaxel (Taxol) 6.0 mg/ml: ≥240 Minutes	Paclitaxel (Taxol) 6.0 mg/ml: ≥240 Minutes	Identical
	Thio-Tepa 10.0 mg/ml: 37.5 Minutes	Thio-Tepa 10.0 mg/ml: 87.0 Minutes	Different- The breakthrough time was shorter for the Series 5000 subject device.
	Vincristine Sulfate (Oncovin) 1.0 mg/ml: ≥240 Minutes	Vincristine Sulfate (Oncovin) 1.0 mg/ml: ≥240 Minutes	Identical

Non-Clinical Performance Data

Test Method	Purpose	Acceptance Criteria			Results
ASTM D6319	Physical Dimensions Test	Length (mm): XS/S: ≥ 220 M/L/XL/XXL: ≥ 230 Width (mm): XS: 70 ± 10 S: 80 ± 10 M: 95 ± 10 L: 110 ± 10 XL: 120 ± 10 XXL: 130 ± 10			Length (mm): XS/S: ≥ 220 / Pass M/L/XL/XXL: ≥ 230 / Pass Width (mm): XS: 70 ± 10 / Pass S: 80 ± 10 / Pass M: 95 ± 10 / Pass L: 110 ± 10 / Pass XL: 120 ± 10 / Pass XXL: 130 ± 10 / Pass
		Thickness (mm):			Thickness (mm):
		Finger: ≥ 0.05 Palm: ≥ 0.05			Finger: 0.05 / Pass Palm: 0.05 / Pass
ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5			Complies with ASTM D6319-19 and ASTM D5151-06
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0 mg			0.08-0.44 mg / Pass
ASTM D412	Physical Properties	Meet the requirements of ASTM D412 AQL 4.0			Pass
		Before Aging	Tensile Strength	≥ 14 MPa	14 – 19 MPa
			Ultimate Elongation	≥ 500%	515 – 540%

		Meet the requirements of ASTM D412 AQL 4.0			Pass
		After Aging	Tensile Strength	≥ 14 MPa	Pass
			Ultimate Elongation	≥ 400%	Pass
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

Permeation testing was conducted to support the addition of the labeling claim: Tested for use with chemotherapy drugs. 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).

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device, SafeSource Direct Blue Powder-Free Nitrile Gloves (AMERI-TUFF Series 4000, AMERI-TOUCH Series 5000) is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K222898.