September 29, 2023

3A Glove Sdn. Bhd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K230847
Trade/Device Name: Chemotherapy 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: September 7, 2023
Received: September 7, 2023

Dear Boyle Wang:

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)*
K230847

Device Name
Chemotherapy Gloves

Indications for Use *(Describe)*
Chemotherapy Gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs. The proposed device is non-sterile, with fern green, midnight black and sky blue three colors.

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes (minutes)
Carboplatin	10 mg/ml(10,000 ppm)	> 240 min.
Carmustine	3.3 mg/ml (3,300 ppm)	Midnight black:32.6(33.2,32.6,33.0) min. Sky blue:24.5(25.2,24.5,26.1) min Fern Green:24.3(28.1,26.3,24.3) min.
Cisplatin	1.0 mg/ml(1,000 ppm)	> 240 min.
Cyclophosphamide	20.0 mg/ml(20,000 ppm)	> 240 min.
Dacarbazine	10 mg/ml (10,000 ppm)	> 240 min.
Docetaxel	10 mg/ml (10,000 ppm)	> 240 min.
Doxorubicin HCL	2.0 mg/ml(2,000 ppm)	> 240 min.
Epirubicin HCI	2 mg/ml (2,000 ppm)	> 240 min.
Etoposide	20 mg/ml (20,000 ppm)	> 240 min.
Fluorouracil	50.0 mg/ml(50,000 ppm)	> 240 min.
Gemcitabine	38 mg/ml (38,000 ppm)	> 240 min.
Ifosfamice	50 mg/ml (50,000 ppm)	> 240 min.
Ifinotecan	20 mg/ml (20,000 ppm)	> 240 min.
Methotrexate	25 mg/ml (25,000 ppm)	> 240 min.
Mitomycin	0.5 mg/ml (500 ppm)	> 240 min.
Mitoxantrone HCl	2 mg/ml (2,000 ppm)	> 240 min.
Oxaliplatin	5 mg/ml (5,000 ppm)	> 240 min.
Paclitaxel	6.0 mg/ml(6,000 ppm)	> 240 min.
Thio Tepa	10.0 mg/ml(10,000 ppm)	Midnight black: 58.7(87.2,67.8,58.7) Sky blue: 77.3(77.3,85.8,79.8) Fern Green: 67.9(68.4,67.9,79.2)
Vincristine Sulfate	1 mg/ml (1,000 ppm)	> 240 min.

Please note that the following drugs have low permeation times:
Midnight black: Carmustine 3.3 mg/ml 32.6 Minutes (min.); Thio Tepa 10.0 mg/ml 58.7 Minutes (min.).
Sky blue: Carmustine 3.3 mg/ml 24.5 Minutes (min.); Thio Tepa 10.0 mg/ml 77.3 Minutes (min.).
Fern green: Carmustine 3.3 mg/ml 24.3 Minutes (min.); Thio Tepa 10.0 mg/ml 67.9 Minutes (min.).
Warning: Please do not use with Carmustine and Thiotepa.

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

K230847

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

1.0 Submitter's Information

Name: 3A Glove Sdn. Bhd.
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Phone Number: +60127708756
Contact: Poh Seng Ping
Date of Preparation: 2023.09.26

Designated Submission Correspondent

Mr. Boyle Wang
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2.0 Device Information

Trade name: Chemotherapy Gloves
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): S, M, L, XL

3.0 Classification

Product code: LZA,LZC, OPJ
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

4.0 Predicate Device Information

Manufacturer: Ever Growth (Vietnam) Co., Ltd.
Device: Disposable Powder Free Nitrile Examination Glove, Tested For Use With Chemotherapy Drugs, Disposable Powder Free Nitrile Examination Glove, Tested For Use With Chemotherapy

Drugs, Orange Color
510(k) number: K190860

5.0 Device Description

The subject device is single use, disposable gloves intended for medical purposes to be worn on the examiner's hands to prevent contamination between patient and examiner. The gloves are powder-free, ambidextrous with beaded cuff, nitrile, and tested for use with chemotherapy drugs. The gloves are offered in four sizes: small, medium, large, and extra-large and with fern green, midnight black and sky blue three colors for options to each sizes.

6.0 Indication for Use

Chemotherapy Gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 *Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs*. The proposed device is non-sterile, with fern green, midnight black and sky blue three colors.

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes (minutes)
Midnight black		
carboplatin	10 mg/ml(10,000 ppm)	＞ 240 min.
Carmustine	3.3 mg/ml (3,300 ppm)	32.6(33.2,32.6,33.0) min.
Cisplatin	1.0 mg/ml(1,000 ppm)	＞ 240 min.
Cyclophosphamide	20.0 mg/ml(20,000 ppm)	＞ 240 min.
Dacarbazine	10 mg/ml (10,000 ppm)	＞ 240 min.
Docetaxel	10 mg/ml (10,000 ppm)	＞ 240 min.
Doxorubicin HCL	2.0 mg/ml(2,000 ppm)	＞ 240 min.
Epirubicin HCl	2 mg/ml (2,000 ppm)	＞ 240 min.
Etoposide	20 mg/ml (20,000 ppm)	＞ 240 min.
Fluorouracil	50.0 mg/ml(50,000 ppm)	＞ 240 min.
Gemcitabine	38 mg/ml (38,000 ppm)	＞ 240 min.
Ifosfamice	50 mg/ml (50,000 ppm)	＞ 240 min.
Ifinotecan	20 mg/ml (20,000 ppm)	＞ 240 min.
Methotrexate	25 mg/ml (25,000 ppm)	＞ 240 min.
Mitomycin	0.5 mg/ml (500 ppm)	＞ 240 min.
Mitoxantrone HCl	2 mg/ml (2,000 ppm)	＞ 240 min.
Oxaliplatin	5 mg/ml (5,000 ppm)	＞ 240 min.

Paclitaxel	6.0 mg/ml(6,000 ppm)	＞ 240 min.
Thio Tepa	10.0 mg/ml(10,000 ppm)	58.7(87.2,67.8,58.7)
Vincristine Sulfate	1 mg/ml (1,000 ppm)	＞ 240 min.

Please note that the following drugs have low permeation times:
Carmustine 3.3 mg/ml 32.6 Minutes (min.);
Thio Tepa 10.0 mg/ml 58.7 Minutes (min.).
Warning: Please do not use with Carmustine and Thiotepa.

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes (minutes)
Sky blue		
carboplatin	10 mg/ml(10,000 ppm)	＞ 240 min.
Carmustine	3.3 mg/ml (3,300 ppm)	24.5(25.2,24.5,26.1) min.
Cisplatin	1.0 mg/ml(1,000 ppm)	＞ 240 min.
Cyclophosphamide	20.0 mg/ml(20,000 ppm)	＞ 240 min.
Dacarbazine	10 mg/ml (10,000 ppm)	＞ 240 min.
Docetaxel	10 mg/ml (10,000 ppm)	＞ 240 min.
Doxorubicin HCL	2.0 mg/ml(2,000 ppm)	＞ 240 min.
Epirubicin HCl	2 mg/ml (2,000 ppm)	＞ 240 min.
Etoposide	20 mg/ml (20,000 ppm)	＞ 240 min.
Fluorouracil	50.0 mg/ml(50,000 ppm)	＞ 240 min.
Gemcitabine	38 mg/ml (38,000 ppm)	＞ 240 min.
Ifosfamice	50 mg/ml (50,000 ppm)	＞ 240 min.
Ifinotecan	20 mg/ml (20,000 ppm)	＞ 240 min.
Methotrexate	25 mg/ml (25,000 ppm)	＞ 240 min.
Mitomycin	0.5 mg/ml (500 ppm)	＞ 240 min.
Mitoxantrone HCl	2 mg/ml (2,000 ppm)	＞ 240 min.
Oxaliplatin	5 mg/ml (5,000 ppm)	＞ 240 min.
Paclitaxel	6.0 mg/ml(6,000 ppm)	＞ 240 min.
Thio Tepa	10.0 mg/ml(10,000 ppm)	77.3(77.3,85.8,79.8)
Vincristine Sulfate	1 mg/ml (1,000 ppm)	＞ 240 min.

Please note that the following drugs have low permeation times:
Carmustine 3.3 mg/ml 24.5 Minutes (min.);
Thio Tepa 10.0 mg/ml 77.3 Minutes (min.).
Warning: Please do not use with Carmustine and Thiotepa.

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes (minutes)
Fern Green		

carboplatin	10 mg/ml(10,000 ppm)	＞ 240 min.
Carmustine	3.3 mg/ml (3,300 ppm)	24.3(28.1,26.3,24.3) min.
Cisplatin	1.0 mg/ml(1,000 ppm)	＞ 240 min.
Cyclophosphamide	20.0 mg/ml(20,000 ppm)	＞ 240 min.
Dacarbazine	10 mg/ml (10,000 ppm)	＞ 240 min.
Docetaxel	10 mg/ml (10,000 ppm)	＞ 240 min.
Doxorubicin HCL	2.0 mg/ml(2,000 ppm)	＞ 240 min.
Epirubicin HCl	2 mg/ml (2,000 ppm)	＞ 240 min.
Etoposide	20 mg/ml (20,000 ppm)	＞ 240 min.
Fluorouracil	50.0 mg/ml(50,000 ppm)	＞ 240 min.
Gemcitabine	38 mg/ml (38,000 ppm)	＞ 240 min.
Ifosfamice	50 mg/ml (50,000 ppm)	＞ 240 min.
Ifinotecan	20 mg/ml (20,000 ppm)	＞ 240 min.
Methotrexate	25 mg/ml (25,000 ppm)	＞ 240 min.
Mitomycin	0.5 mg/ml (500 ppm)	＞ 240 min.
Mitoxantrone HCl	2 mg/ml (2,000 ppm)	＞ 240 min.
Oxaliplatin	5 mg/ml (5,000 ppm)	＞ 240 min.
Paclitaxel	6.0 mg/ml(6,000 ppm)	＞ 240 min.
Thio Tepa	10.0 mg/ml(10,000 ppm)	67.9(68.4,67.9,79.2)
Vincristine Sulfate	1 mg/ml (1,000 ppm)	＞ 240 min.

Please note that the following drugs have low permeation times:
Carmustine 3.3 mg/ml 24.3 Minutes (min.);
Thio Tepa 10.0 mg/ml 67.9 Minutes (min.).
Warning: Please do not use with Carmustine and Thiotepa.

7.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K230847	Predicate Device (K190860)	Remark
Product Code	LZA,LZC, OPJ	LZA,LZC	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use	Chemotherapy Gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were	Same

	tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs.	tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs.	
Powdered or powder free	Powder free	Powder free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Sterility	Non-Sterile	Non-Sterile	Same
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity,Non-Sterile, a statement of standard ASTM D6978-05 compliance and a summary of the testing results.	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile, a statement of standard ASTM D6978-05 compliance and a summary of the testing results.	Similar

Table2 Device Dimensions Comparison

Predicate Device(K190860)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.05					min
Subject Device	Designation	Size					Tolerance
		S	M	L	XL		
	Length, mm	220	230	230	230		min
	Width, mm	80	95	110	120		±10
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.05					min
Remark	Analysis1						

Analysis1：The sizes and tolerances of proposed device are different with those of the predicate, but they all meet the requirements of ASTM D6319-19, so the differences do not raise any new safety or performance questions.

Table3 Performance Comparison

Item			Subject device	Predicate device (K190860)	Remark
Color			FERN GREEN/ MIDNIGHT BLACK/ SKY BLUE	White, Orange	Analysis 2
Physical Properties	Before Aging	Tensile Strength	14MPa, min	14MPa, min	Same
		Ultimate Elongation	500% min	500% min	Same
	After Aging	Tensile Strength	14MPa, min	14MPa, min	Same
		Ultimate Elongation	400%min	400%min	Same
	Comply with ASTM D6319			Comply with ASTM D6319	Same
Freedom from Holes		Be free from holes when tested in accordance with ASTMD5151 AQL=2.5		Be free from holes when tested in accordance with ASTMD5151 AQL=2.5	Same
Powder Content		Fern Green 0.6 mg/glove Midnight black 1.1 mg/glove Sky blue 1.0 mg/glove		< = 2 mg/glove	Similar
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as Tested per ASTM D 6978		carboplatin 10 mg/ml(10,000 ppm) ＞ 240 min.		NA	Analysis 3
		Carmustine 3.3 mg/ml (3,300 ppm) Fern Green: 24.3(28.1,26.3,24.3) min. Sky blue: 24.5(25.2,24.5,26.1) min. Midnight black: 32.6(33.2,32.6,33.0) min.		Carmustine (BCNU) 3.3 mg/ml: White:11.8 Minutes; Orange:31.6Minutes	Similar
		Cisplatin 1.0 mg/ml(1,000 ppm) ＞ 240 min.		Cisplatin 1.0 mg/ml: ＞240 Minutes	Same
		Cyclophosphamide 20.0 mg/ml(20,000 ppm) ＞ 240 min.		Cyclophosphamide (Cytoxan) 20.0 mg/ml: ＞ 240 Minutes	Same
		Dacarbazine		Dacarbazine (DTIC)	Same

	10 mg/ml (10,000 ppm) ＞ 240 min.	10.0 mg/ml: ＞240 Minutes	
	Docetaxel 10 mg/ml (10,000 ppm) ＞ 240 min.	NA	Analysis 5
	Doxorubicin HCL 2.0 mg/ml(2,000 ppm) ＞ 240 min.	Doxorubicin Hydrochloride 2.0 mg/ml: ＞ 240 Minutes	Similar
	Epirubicin HCl 2 mg/ml (2,000 ppm) ＞ 240 min.	NA	Analysis 5
	Etoposide 20 mg/ml (20,000 ppm) ＞ 240 min.	Etoposide (Toposar) 20.0 mg/ml: ＞ 240 Minutes	Similar
	Fluorouracil 50.0 mg/ml(50,000 ppm) ＞ 240 min.	Fluorouracil 50.0 mg/ml: ＞240 Minutes	Same
	Gemcitabine 38 mg/ml (38,000 ppm) ＞ 240 min.	NA	Analysis 5
	Ifosfamice 50 mg/ml (50,000 ppm) ＞ 240 min.	NA	Analysis 5
	Ifinotecan 20 mg/ml (20,000 ppm) ＞ 240 min.	NA	Analysis 5
	Methotrexate 25 mg/ml (25,000 ppm) ＞ 240 min.	NA	Analysis 5
	Mitomycin 0.5 mg/ml (500 ppm) ＞ 240 min.	NA	Analysis 5
	Mitoxantrone HCl 2 mg/ml (2,000 ppm) ＞ 240 min.	NA	Analysis 5
	Oxaliplatin 5 mg/ml (5,000 ppm) ＞ 240 min.	NA	Analysis 5
	Paclitaxel 6.0 mg/ml(6,000 ppm) ＞ 240 min.	Paclitaxel (Taxol) 6.0 mg/ml: ＞240 Minutes	Same
	Thio Tepa	Thio-Tepa 10.0	Similar

	10.0 mg/ml(10,000 ppm) Fern Green: 67.9(68.4,67.9,79.2)min. Sky blue: 77.3(77.3,85.8,79.8)min. Midnight black: 58.7(87.2,67.8,58.7) min.	mg/ml: White:16.9 Minutes; Orange: 72.5 Minutes	
	Vincristine Sulfate 1 mg/ml (1,000 ppm) ＞ 240 min.	NA	Analysis 5

Analysis 2：The proposed device has different color to the predicate device, but all proposed devices are conducted the performance and biocompatibility tests, the test results shown that the color difference do not effect the safety and performance of proposed device.

Analysis 3: More Chemotherapy Drugs Tested with proposed devices than those with Predicate device. But all proposed devices are conducted the chemo drugs test, the test results shown that they comply with the requirements of standard ASTM D6978, so the differences do not raise any new safety or performance questions.

Table4 Safety Comparison

Item		Proposed device	Predicate device	Remark
Material		Nitrile	Nitrile	SAME
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO10993-10	SAME
	Sensitization	Under conditions of the study, not a sensitizer.		
	Cytotoxicity	Under the conditions of the study, the device is potentially cytotoxic	Comply with ISO10993-5	Analysis 6
	Acute Systemic toxicity	Under the conditions of the study, the device does not elicit acute systemic toxicity response in the model animal.	Complies with ISO 10993-11 Third edition 2017-09	
Label and Labeling		Meet FDA's Requirement	Meet FDA's Requirement	SAME

Analysis 6: The proposed device is potentially cytotoxic, but all proposed devices are conducted the acute systemic toxicity test, the test results show that the proposed device is safe.

8.0 Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for Chemotherapy Gloves was conducted in accordance with the following standards:

ISO 10993-10:2010 *Biological Evaluation of Medical Devices - Part 10: Tests for Irritation And Skin Sensitization.*

ISO 10993-5:2009 *Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity*

ISO 10993-11 Third edition 2017-*09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*

Performance Testing (Bench)

Physical performance qualities of the proposed device were evaluated per *ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.*

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*, in which minimum breakthrough times were determined for a wide range of chemotherapy drugs.

In summary, the performance testing of the subject device was conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

- ASTM D6124-06 (Reapproved 2017), *Standard Test Method for Residual Powder on Medical Gloves*
- ASTM D5151-19, *Standard Test Method for Detection of Holes in Medical Gloves.*
- ASTM D6319-19, *Standard Specification for Nitrile Examination Gloves for Medical Application.*
- ASTM D6978-05 (Reapproved 2019) ,*Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.*

9.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject

device, Chemotherapy Gloves is as safe, as effective, and performs as well as or better than the legally marketed Predicate device under K190860.