November 30, 2020

Kimberly Clark Corporation
% Wava Truscott
Consultant
Truscott MedSci Associates, LLC
180 Burkemeade Ct
Roswell, Georgia 30075

Re: K202416
Trade/Device Name: Kimtech Prizm Multi-Layered Exam Glove Tested for use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid, Kimtech Prizm Xtra Multi-Layered Exam Glove Tested for use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid

Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: November 25, 2020
Received: November 30, 2020

Dear Wava Truscott:

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 and Part 809; 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: Elizabeth F. Claverie, MS
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: K202416

Device **1.) Trade Name:** KIMTECH™ PRIZM™ Multi-Layered Exam Glove Tested for use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid

Indications for Use (Describe):

CHEMICAL	CONCENTRATION	STANDARD LENGTH
Cabazitaxel	60 mg/1.5ml (40,000 ppm)	>240 min.
Capecitabine	26 mg/ml (26,000 ppm)	>240 min.
Carmustine	3.3 mg/ml (3,300 ppm)	47.5 min.
Cisplatin	1 mg/ml (1,000 ppm)	>240 min.
Cyclophosphamide	20 mq/ml (20,000 ppm)	>240 min.
Dacarbazine	10 mg/ml (10,000 ppm)	>240 min.
Doxorubicin HCL	2 mq/ml (2,000 ppm)	>240 min.
Eribulin Mesylate	0.5 mg/ml (500 ppm)	>240 min.
Etoposide	20 mq/ml (20,000 ppm)	>240 min.
Floxuridine	100 mg/ml (100,000 ppm)	>240 min.
Fluorouracil	50 mq/ml (50,000 ppm)	>240 min.
Ifosfamide	50 mq/ml (50,000 ppm)	>240 min.
Lenvatinib	20 mg/ml (20,000 ppm)	>240 min.
Mitoxantrone	2 mg/ml (2,000 ppm)	>240 min.
Paclitaxel,	6 mg/ml (6,000 ppm)	>240 min.
Pemetrexed	25 mg/ml (25,000 ppm)	>240 min.
Sorafenib Tosylate	200 mg/ml (200,000 ppm)	>240 min.
Tamoxifen	2 mg/ml (2,000 ppm)	>240 min.
Thiotepa	10 mg/ml (10,000 ppm)	38.2 min.
Vinblastine Sulfate	1 mg/ml (1,000 ppm)	>240 min.
Vincristine Sulfate	1 mg/ml (1,000 ppm)	>240 min.
Vinorelbine	10 mg/ml (10,000 ppm)	>240 min.
Fentanyl Citrate	100mcg/2mL	>240 min.
Simulated Gastric Acid	0.2% (w/v) NaCl in 0.7% (v/v) HCL acid	>240 min.
Fentanyl in Gastric Acid	50/50 mix solution	>240 min.
Caution: Carmustine and Thiotepa have low penetration times of 47.5 min. and 38.2 min. respectively		

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter (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: 06/30/2020 *See PRA Statement below*

510(k) Number: K202416

Device **2.) Trade Name:** KIMTECH™ PRIZM™ Xtra Multi-Layered Exam Glove Tested for use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid

Indications for Use (Describe):

CHEMICAL	CONCENTRATION	XTRA
Cabazitaxel	60 mg/1.5ml (40,000 ppm)	>240 min.
Capecitabine	26 mg/ml (26,000 ppm)	>240 min.
Carmustine	3.3 mg/ml (3,300 ppm)	37.3 min.
Cisplatin	1 mg/ml (1,000 ppm)	>240 min.
Cyclophosphamide	20 mq/ml (20,000 ppm)	>240 min.
Dacarbazine	10 mg/ml (10,000 ppm)	>240 min.
Doxorubicin HCL	2 mq/ml (2,000 ppm)	>240 min.
Eribulin Mesylate	0.5 mg/ml (500 ppm)	>240 min.
Etoposide	20 mq/ml (20,000 ppm)	>240 min.
Floxuridine	100 mg/ml (100,000 ppm)	>240 min.
Fluorouracil	50 mq/ml (50,000 ppm)	>240 min.
Ifosfamide	50 mq/ml (50,000 ppm)	>240 min.
Lenvatinib	20 mg/ml (20,000 ppm)	>240 min.
Mitoxantrone	2 mg/ml (2,000 ppm)	>240 min.
Paclitaxel,	6 mg/ml (6,000 ppm)	>240 min.
Pemetrexed	25 mg/ml (25,000 ppm)	>240 min.
Sorafenib Tosylate	200 mg/ml (200,000 ppm)	>240 min.
Tamoxifen	2 mg/ml (2,000 ppm)	>240 min.
Thiotepa	10 mg/ml (10,000 ppm)	30.1 min.
Vinblastine Sulfate	1 mg/ml (1,000 ppm)	>240 min.
Vincristine Sulfate	1 mg/ml (1,000 ppm)	>240 min.
Vinorelbine	10 mg/ml (10,000 ppm)	>240 min.
Fentanyl Citrate	100mcg/2mL	>240 min.
Simulated Gastric Acid	0.2% (w/v) NaCl in 0.7% (v/v) HCL acid	>240 min.
Fentanyl in Gastric Acid	50/50 mix solution	>240 min.
Caution: Carmustine and Thiotepa have low penetration times of 37.3 min. and 30.1 min. respectively		

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED

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PRAStaff@fda.hhs.gov

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510(k) Number: K202416

510(k) Summary as required by 807.92(c) **Preparation Date:** November 22, 2020
FDA Format: Traditional 510k

Trade Name: KIMTECH™ PRIZM™ Multi-Layered Exam Glove Tested for use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid

Trade Name: KIMTECH™ PRIZM™ Xtra Multi-Layered Exam Glove Tested for use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid

1. Submitter:

Company Name:	Kimberly-Clark Corporation
Address:	1400 Holcomb Bridge Road Roswell, GA 30076
Country:	United States
General phone:	+1 770-587-8000
Contact Person:	Juan M. Marquez Director, Regulatory Affairs Kimberly-Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30076
E-mail:	Juan.M.Marquez@kcc.com
Phone:	+1 678-352-6069
Fax:	+1 920-969-4863

2. Device information:

Device Trade Name: KIMTECH™ PRIZM™ Multi-Layered Exam Glove Tested for use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid

KIMTECH™ PRIZM ™ Xtra Multi-Layered Exam Glove Tested for use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid

Classification name: Per 21 CFR 807.92(a)2(2): Patient Examination Glove

General Hospital and Personal Use Devices

Common name:	Synthetic Non-powdered Exam Glove
Class:	Class I (general controls)
Product Codes:	LZA, LZC, QDO

Indications for use:

Intended Use: The examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Testing was performed to determine Break-through times for the Chemotherapy drugs listed below, plus the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid.

Trade Name: KIMTECH™ PRIZM™ Multi-Layered Exam Glove Tested for use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid

KIMTECH™ PRIZM™ Multi-Layered Gloves: ASTM D6978-05 (2019): "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs"

CHEMICAL	CONCENTRATION	STANDARD Length
Cabazitaxel	60 mg/1.5ml (40,000 ppm)	>240 min.
Capecitabine	26 mg/ml (26,000 ppm)	>240 min.
Carmustine	3.3 mg/ml (3,300 ppm)	47.5 min.
Cisplatin,	1 mg/ml (1,000 ppm)	>240 min.
Cyclophosphamide	20 mq/ml (20,000 ppm)	>240 min.
Dacarbazine	10 mg/ml (10,000 ppm)	>240 min.
Doxorubicin HCL	2 mq/ml (2,000 ppm)	>240 min.
Eribulin Mesylate	0.5 mg/ml (500 ppm)	>240 min.
Etoposide	20 mq/ml (20,000 ppm)	>240 min.
Floxuridine	100 mg/ml (100,000 ppm)	>240 min.
Fluorouracil	50 mq/ml (50,000 ppm)	>240 min.
Ifosfamide,	50 mq/ml (50,000 ppm)	>240 min.
Lenvatinib	20 mg/ml (20,000 ppm)	>240 min.
Mitoxantrone	2 mg/ml (2,000 ppm)	>240 min.
Paclitaxel,	6 mg/ml (6,000 ppm)	>240 min.
Permetrexed	25 mg/ml (25,000 ppm)	>240 min.
Sorafenib Tosylate	200 mg/ml (200,000 ppm)	>240 min.
Tamoxifen	2 mg/ml (2,000 ppm)	>240 min.
Thiotepa	10 mg/ml (10,000 ppm)	38.2 min.
Vinblastine Sulfate	1 mg/ml (1,000 ppm)	>240 min.
Vincristine Sulfate	1 mg/ml (1,000 ppm)	>240 min.
Vinorelbine	10 mg/ml (10,000 ppm)	>240 min.
Fentanyl Citrate	100mcg/2mL	>240 min.
Simulated Gastric Acid	0.2% (w/v) NaCl in 0.7% (v/v) HCL acid	>240 min.
Fentanyl in Gastric Acid	50/50 mix solution	>240 min.
Caution: Carmustine and Thiotepa have low penetration times of 47.5 min. and 38.2 min. respectively		

KIMTECH™ PRIZM™ Multi-Layered Glove:
Caution: Carmustine and Thiotepa have breakthrough times of less than 60 minutes at 47.5 min. and 38.2 min. respectively

Indications for use:

Intended Use: The examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Testing was performed to determine Break-through times for the Chemotherapy drugs listed below, plus the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid.

Trade Name: KIMTECHTM PRIZM TM Xtra Multi-Layered Exam Glove Tested for use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid

CHEMICAL	**CONCENTRATION**	**Xtra**
Cabazitaxel	60 mg/1.5ml (40,000 ppm)	>240 min.
Capecitabine	26 mg/ml (26,000 ppm)	>240 min.
Carmustine	3.3 mg/ml (3,300 ppm)	37.3 min.
Cisplatin,	1 mg/ml (1,000 ppm)	>240 min.
Cyclophosphamide	20 mq/ml (20,000 ppm)	>240 min.
Dacarbazine	10 mg/ml (10,000 ppm)	>240 min.
Doxorubicin HCL	2 mq/ml (2,000 ppm)	>240 min.
Eribulin Mesylate	0.5 mg/ml (500 ppm)	>240 min.
Etoposide	20 mq/ml (20,000 ppm)	>240 min.
Floxuridine	100 mg/ml (100,000 ppm)	>240 min.
Fluorouracil	50 mq/ml (50,000 ppm)	>240 min.
Ifosfamide,	50 mq/ml (50,000 ppm)	>240 min.
Lenvatinib	20 mg/ml (20,000 ppm)	>240 min.
Mitoxantrone	2 mg/ml (2,000 ppm)	>240 min.
Paclitaxel,	6 mg/ml (6,000 ppm)	>240 min.
Permetrexed	25 mg/ml (25,000 ppm)	>240 min.
Sorafenib Tosylate	200 mg/ml (200,000 ppm)	>240 min.
Tamoxifen	2 mg/ml (2,000 ppm)	>240 min.
Thiotepa	10 mg/ml (10,000 ppm)	30.1 min.
Vinblastine Sulfate	1 mg/ml (1,000 ppm)	>240 min.
Vincristine Sulfate	1 mg/ml (1,000 ppm)	>240 min.
Vinorelbine	10 mg/ml (10,000 ppm)	>240 min.
Fentanyl Citrate	100mcg/2mL	>240 min.
Simulated Gastric Acid	0.2% (w/v) NaCl in 0.7% (v/v) HCL acid	>240 min.
Fentanyl in Gastric Acid	50/50 mix solution	>240 min.
Caution: Carmustine and Thiotepa have low penetration times of 37.3 min. and 30.1 min. respectively		

KIMTECH™ PRIZM™ Xtra Multi-Layered Glove:
Caution: Carmustine and Thiotepa have breakthrough times of less than 60 minutes at 37.3 min. and 30.1 min. respectively

Subject Gloves Technological Characteristics Comparison Table

Predicate K200072 & K202416 Subject Gloves: Standard & Xtra Length

Attributes	Standard Test	Predicate Device: K200072	Subject Glove 1 (standard length) K202416	Subject Glove 2 (Xtra-length) K202416	Comparison
Common Name	NA	Synthetic Examination Glove	Synthetic Examination Glove	Synthetic Examination Glove	**Same**
Intended Use	NA	The examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	The examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	The examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	**Same**
Base Material	NA	Synthetic: Nitrile	Synthetic: Nitrile & Polychloroprene	Synthetic: Nitrile & Polychloroprene	**Similar:** Predicate and both Subject gloves are Synthetic Both Predicate and Subject gloves possess nitrile Subject gloves also have polychloroprene in their formulation Does not adversely impact safety or performance
Color	NA	Purple	Dark Violet outer surface Deep Magenta inside surface	Dark Violet outer surface Deep Magenta inside surface	**Different** Subject gloves have different inner & outer surface colors. Does not adversely impact safety or performance
Product code	NA	LZA, LZC, QDO	LZA, LZC, QDO	LZA, LZC, QDO	**Same**

Attributes	Standard Test	Predicate Device: K200072	Subject Glove 1 (standard length) K202416	Subject Glove 2 (Xtra-length) K202416	Comparison
Sterile vs. non-sterile	NA	Non-sterile	Non-sterile	Non-sterile	**Same**
Prescription or OTC	NA	OTC	OTC	OTC	**Same**
Single Use-Disposable	NA	Yes	Yes	Yes	**Same**
Indications for use (summary)	**ASTM D1678-05**	Glove was Tested for use with chemotherapy drugs, the Opioid Fentanyl Citrate, simulated Gastric acid, and Fentanyl in Gastric Acid	Glove was Tested for use with chemotherapy drugs, the Opioid Fentanyl Citrate, simulated Gastric acid, and Fentanyl in Gastric Acid	Glove was Tested for use with chemotherapy drugs, the Opioid Fentanyl Citrate, simulated Gastric acid, and Fentanyl in Gastric Acid	**Same:** Test Method **Same:** Fentanyl Citrate, simulated Gastric Acid and Fentanyl in Gastric Acid **Similar:** Chemotherapy Chemicals tested (see below)
Chemicals Tested	**ASTM D1678-05**	**Chemotherapy drugs tested:** Carmustine (BCNU) Cisplatin, Cyclophosphamide (Cytoxan), Dacarbazine (DTIC) Doxorubicin Hydrochloride, Etoposide (Toposar) Fluorouracil, Methotrexate Paclitaxel (Taxol), Thiotepa Vincristine Sulfate	**Chemotherapy drugs tested**: Cabazitaxel Capecitabine Carmustine Cisplatin, Cyclophosphamide Dacarbazine Doxorubicin HCL Eribulin Mesylate Etoposide Floxuridine Fluorouracil Ifosfamide, Lenvatinib Mitoxantrone Paclitaxel, Permetrexed Sorafenib Tosylate Tamoxifen Thiotepa Vinblastine Sulfate Vincristine Sulfate Vinorelbine	**Chemotherapy drugs tested**: Cabazitaxel Capecitabine Carmustine Cisplatin, Cyclophosphamide Dacarbazine Doxorubicin HCL Eribulin Mesylate Etoposide Floxuridine Fluorouracil Ifosfamide, Lenvatinib Mitoxantrone Paclitaxel, Permetrexed Sorafenib Tosylate Tamoxifen Thiotepa Vinblastine Sulfate Vincristine Sulfate Vinorelbine	**Similar:** Some chemotherapy drugs are different

Attributes	Standard Test	Predicate Device: K200072	Subject Glove 1 (standard length) K202416	Subject Glove 2 (Xtra-length) K202416	Comparison
		In Addition: Fentanyl Citrate simulated Gastric Acid, Fentanyl in Gastric Acid	In Addition: Fentanyl Citrate simulated Gastric Acid, Fentanyl in Gastric Acid	In Addition: Fentanyl Citrate simulated Gastric Acid, Fentanyl in Gastric Acid	**Same**
Caution/ Warning Statements	NA	**Note:** Carmustine and Thiotepa have extremely low permeation times of 3.6 &15.9 min. respectively. **WARNING: Do Not Use With: Carmustine, Thiotepa**	**Caution:** Carmustine and Thiotepa have low permeation times below 60 minutes at 47.5 min and 38.2 min. respectively	**Caution:** Carmustine and Thiotepa have low permeation times below 60 minutes at 37.3 min and 30.1 min. respectively	**Different** The predicate has a Warning while both Subject Glove 1 and 2 have Caution statement
Dimensions: Overall Length	ASTM D6319 Minimum: 230mm	All sizes comply with length dimensions	All sizes comply with length dimensions	All sizes comply with length dimensions	**Same**
Dimensions: Overall Width	ASTM D6319 Minimum: 110 + 10mm	All sizes comply with length dimensions	All sizes comply with length dimensions	All sizes comply with length dimensions	**Same**
Dimensions: Palm & Finger Thickness	ASTM D6319 Minimum: Palm: 0.05mm Finger: 0.05mm	All sizes comply with length dimensions	All sizes comply with length dimensions	All sizes comply with length dimensions	**Same**
Tensile strength: Before & After Aging	ASTM D6319 Minimum Before: 14MPa After: 14Mpa	Complies both before and after accelerated aging	Complies both before and after accelerated aging	Complies both before and after accelerated aging	**Same**
Ultimate elongation Before & After aging	ASTM D6319 Minimum: Before: 500% After: 400%	Complies both before and after accelerated aging	Complies both before and after accelerated aging	Complies both before and after accelerated aging	**Same**

Attributes	Standard Test	Predicate Device: K200072	Subject Glove 1 (standard length) K202416	Subject Glove 2 (Xtra-length) K202416	Comparison
Freedom from holes	ASTM D6319 G1, AQL 2.5 7 Accept 8 Reject	Pass	Pass	Pass	**Same**
Powder Free	ASTM 6319 Maximum <2mg/glove	Pass	Pass	Pass	**Same**
Bio-compatibility	ISO 10993-11 Systemic Toxicity Test	Under conditions of the study, the device extracts did not elicit a systemic response in the model animal.	Under conditions of the study, the device extracts did not elicit a systemic response in the model animal.	Under conditions of the study, the device extracts did not elicit a systemic response in the model animal.	**Same**
	ISO 10993-10 Primary Skin Irritation on Rabbits	Under Conditions of this study, the polar and non-polar device extracts were found not to be an irritant to the animal model.	Under Conditions of this study, the polar and non-polar device extracts were found not to be an irritant to the animal model.	Under Conditions of this study, the polar and non-polar device extracts were found not to be an irritant to the animal model.	**Same**
	ISO 10993-10 Magnusson & Kligman Guinea pig Maximization	Under Conditions of this study, the polar and non-polar device extracts were found not to be sensitizers to the animal model.	Under Conditions of this study, the polar and non-polar device extracts were found not to be sensitizers to the animal model.	Under Conditions of this study, the polar and non-polar device extracts were found not to be sensitizers to the animal model.	**Same**

Non-Clinical Testing was conducted to demonstrate that the two proposed devices met all required design specifications. The test results demonstrated that the proposed devices did meet the performance criteria as specified utilizing the following test method standards and specifications:

Summary of Non-Clinical Performance Tests	
ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application	Pass
ASTM D412-2006a (Reapproved 2013) Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension	Pass
ASTM D573-2004 (Reapproved 2010) Standard Test Method for Rubber-Deterioration in an Air Oven	Pass
ASTM D3767-03 Standard Practice for Rubber Measurement of Dimensions	Pass
ASTM D5151-2006 (Reapproved 2015) Standard Test Method for Detection of holes in Medical Gloves	Pass
ASTM D6124-2006 (Reapproved 2015) Standard Tested Method for Residual Powder on Medical Gloves	Pass
ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Pass
ISO 2859 Sampling Procedures and Tables for Inspection by Attributes	Pass
ISO 10993-10 Biological Evaluation of medical Devices-Part 10: Tests for Irritation and Sensitization	Pass
ISO 10993-11 Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity	Pass

Conclusion: The conclusions drawn from the nonclinical and clinical tests demonstrate that the subject devices are as safe, as effective, and performs as well as or better than the legally marketed device.