April 10, 2020

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

Re: K200072
Trade/Device Name: KIMTECH Purple Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, Simulated Gastric acid, and Fentanyl in Simulated 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: January 15, 2020
Received: January 16, 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); 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,

David Krause

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200072

Device Name
KIMTECH™ Purple Nitrile™ Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid

Indications for Use *(Describe)*
The Nitrile Powder Free patient examination glove is non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
Test Results Follow:

Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time
Blenoxane	(15mg/mL),(15,000 ppm)	>240
Busulfan	(6mg/mL),(6,000 ppm)	>240
Carmustine (BiCNU)	(3.3mg/mL),(3,300 ppm)	>3.6
Cisplatin	(lmg/mL),(1,000 ppm)	>240
Cyclophosphamide/cytoxan	(20mg/mL),(20,000 ppm)	>240
Cytarabine	(100mg/mL),(100,000 ppm)	>240
Dacarbazine(DTIC)	(10mg/mL),(10,000 ppm)	>240
Daunorubicin	(5mg/mL),(5,000 ppm)	>240
Docetaxel	(10mg/mL),(l 0,000ppm)	>240
Doxorubicin	(2mg/mL),(2,000 ppm)	>240
Ellence	(2mg/mL),(2,000 ppm)	>240
Etoposide/Toposar	(20mg/mL,(20,000 ppm)	>240
Fludarabine	(25mg/mL),(25,000 ppm)	>240
Fluorouracil	(50mg/mL),(50,000 ppm)	>240
Gemcitabine	(38mg/mL),(38,000 ppm)	>240
Idarubicin	(1mg/mL),(1,000 ppm)	>240
Ifosfamide	(50mg/mL),(50,000 ppm)	>240
Irinotecan	(20mg/mL),(20,000 ppm)	>240
Mechlorethamine HCL	(l mg/mL),(1,000 ppm)	>240
Melphalan	(5mg/mL),(5,000 ppm)	>240
Methotrexate	(25mg/mL),(25,000 ppm)	>240
Mitomycin C	(0.5mg/mL),(500 ppm)	>240
Mitoxantrone	(2mg/mL),(2,000 ppm)	>240
Paclitaxel	(6mg/mL),(6,000 ppm)	>240
Paraplatin	(10mg/mL),(10,000 ppm)	>240
Rituximab	(10mg/mL),(10,000 ppm)	>240
Thiotepa	(10mg/mL),(10,000 ppm)	>15.9
Trisenox	(0.l mg/mL),(100 ppm)	>240
Vincristine Sulfate	(l mg/ m),(1,000 ppm)	>240

The Fentanyl Citrate and Gastric acid tested as follows:

Fentanyl Citrate	100mcg/2mL	>240
Gastric Acid (simulated)	0.2% NaCl in 0.7% HCL	>240
Fentanyl in Gastric Acid	50/50 Mix	>240

Note: Carmustine and Thiotepa have extremely low permeation times of 3.6 and 15.9 minutes respectively
Warning: Do Not Use With: Carmustine, 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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The information contained herein is being provided in accordance with the requirements of 21 CFR 807.92(c).

510(k) Number: K200072

510(k) Summary Preparation Date: April 6, 2020

KIMTECH™ Purple Nitrile™ Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid

1. Submitter:

Company Name:	Kimberly-Clark Corporation
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2. Correspondent:

Company Name:	Wava Truscott, PhD.
Address:	Truscott MedSci Associates, LLC 180 Burkemeade Ct. Roswell, GA 30075
Phone:	+1 (678) 860-1550
Fax:	+1 (770) 552-2887
Email:	Wava.Truscott@gmail.com

3. Device information:

Device Trade Name:	KIMTECH™ Purple Nitrile™ Powder free Examination Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid, and Fentanyl in Simulated Gastric Acid
Classification Name:	Patient Examination Glove
Classification:	Class I (general controls)
Regulation Number:	21 CFR 880-6250
Common name:	Powder-free Nitrile Exam Glove for use with Chemotherapy drugs and Fentanyl
Product Code:	LZC, LZA, QDO

4. **Predicate Device**:
K170686: Brightway Non-Powdered Nitrile Examination Glove Tested for use with Chemotherapy gloves: LZA, LZC (Subject Glove is exactly the same glove, but seeking the additional QDO claim)

K182241: Non-Sterile Powder-Free Nitrile Examination Glove Black Tested for use with Chemotherapy gloves: LZA, LZC, QDO

5. **Description of the Device**:
KIMTECH™ Purple Nitrile™ Examination Gloves, Powder Free, Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric acid and Fentanyl in Simulated Gastric acid are single use only, non-sterile, disposable gloves. The powder-free gloves are made of a synthetic copolymer of acrylonitrile and butadiene with a purple color additive. The gloves are available in extra small, small, medium, large, and extra-large sizes.

6. **Indications for Use:**

The Nitrile Powder Free patient examination glove is non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Test Results Follow:

Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time
Blenoxane	(15mg/mL),(15,000 ppm)	>240
Busulfan	(6mg/mL),(6,000 ppm)	>240
Carmustine(BiCNU)	(3.3mg/mL),(3,300 ppm)	>3.6
Cisplatin	(lmg/mL),(1,000 ppm)	>240
Cyclophosphamide/cytoxan	(20mg/mL),(20,000 ppm)	>240
Cytarabine	(100mg/mL),(100,000 ppm)	>240
Dacarbazine(DTIC)	(10mg/mL),(10,000 ppm)	>240
Daunorubicin	(5mg/mL),(5,000 ppm)	>240
Docetaxel	(10mg/mL),(l 0,000ppm)	>240
Doxorubicin	(2mg/mL),(2,000 ppm)	>240
Ellence	(2mg/mL),(2,000 ppm)	>240
Etoposide/Toposar	(20mg/mL,(20,000 ppm)	>240
Fludarabine	(25mg/mL),(25,000 ppm)	>240
Fluorouracil	(50mg/mL),(50,000 ppm)	>240
Gemcitabine	(38mg/mL),(38,000 ppm)	>240
Idarubicin	(1mg/mL),(1,000 ppm)	>240
Ifosfamide	(50mg/mL),(50,000 ppm)	>240
Irinotecan	(20mg/mL),(20,000 ppm)	>240
Mechlorethamine HCL	(l mg/mL),(1,000 ppm)	>240
Melphalan	(5mg/mL),(5,000 ppm)	>240
Methotrexate	(25mg/mL),(25,000 ppm)	>240
Mitomycin C	(0.5mg/mL),(500 ppm)	>240
Mitoxantrone	(2mg/mL),(2,000 ppm)	>240
Paclitaxel	(6mg/mL),(6,000 ppm)	>240
Paraplatin	(10mg/mL),(10,000 ppm)	>240
Rituximab	(10mg/mL),(10,000 ppm)	>240
Thiotepa	(10mg/mL),(10,000 ppm)	>15.9
Trisenox	(0.l mg/mL),(100 ppm)	>240
Vincristine Sulfate	(l mg/ m),(1,000 ppm)	>240
Fentanyl Opioid and Gastric acid tested as follows:		
Fentanyl Citrate	100mcg/2mL	>240
Gastric Acid (simulated)	0.2% NaCl in 0.7% HCL	>240

Fentanyl in Gastric Acid 50/50 Mix >240

Note: Carmustine and Thiotepa have extremely low permeation times of 3.6 and 15.9 minutes respectively

Warning: Do Not Use With: Carmustine, Thiotepa

7. Predicate & Subject Technological Characteristics Comparison Table

Attributes	Standard Where Test Sets Limits	a) Predicate Device: K182241	b) Predicate Device: K170686	Subject Device Glove	How Does Subject Glove Compare to Predicates
Common Name of Device Type	NA	Examination Glove	Examination Glove	Examination Glove	a) Same b) Same
Base Material	NA	Nitrile	Nitrile	Nitrile	c) Same d) Same
Color	NA	Black	Purple	Purple	a) Different than K182241; but, biocompatibility, & physical attributes, show difference in color has not altered glove safety or performance b) Identical to K170686
Glove formulation	NA	Owners own proprietary formula	KC Purple Nitrile 9.5 Chemo Formulation	KC Purple Nitrile 9.5 Chemo Formulation	a) Different than K182241, actual formula unknown b) Identical to K170686
Product Codes	NA	LZA, LZC, QDO	LZA, LZC	LZA, LZC, QDO	a) Same b) Similar-no QDO
Sterile vs Non-Sterile	NA	Non-Sterile	Non-Sterile	Non-Sterile	a) Same b) Same
Prescription or OTC	NA	OTC	OTC	OTC	a) Same b) Same

Attributes	Standard Where Limits Test Limits Set	a) Predicate Device: K182241	b) Predicate Device: K170686	Subject Device Glove	How Does Subject Glove Compare to Predicates
Single Use-Disposable	NA	Yes	Yes	Yes	a) Same b) Same
Intended Use	NA	The device 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 device 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 device 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.	a) Same b) Same
Indications for use (summary)	NA	In addition to routine examination glove's intended use, the Subject Glove was Tested for use with chemotherapy drugs and the opioid Fentanyl SEE Below for specifics	In addition to routine examination glove's intended use, the Subject Glove was Tested for use with Chemotherapy drugs SEE Below for specifics	KIMTECH™ Purple Nitrile™ Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs, the Fentanyl Citrate, Gastric acid, and Fentanyl in Gastric acid SEE Below for specifics	a) Similar: Both tested with Chemotherapy drugs, but some drugs different. Both also tested for Fentanyl, but Subject glove also tested with gastric acid and Fentanyl in gastric acid b) similar: Because they are same glove, same Chemo drugs test breakthrough times identical to K170686; because same test data, but subject glove also tested for Fentanyl citrate, gastric acid, and Fentanyl in gastric acid to be cleared for QDO claims

Attributes	Standard Tests Where Limits Set	a) Predicate Device: K182241 Chemotherapy drugs tested:	b) Predicate Device: K170686 Chemotherapy drugs tested:	Subject Device Glove Chemotherapy drugs tested:	How Does Subject Glove Compare to Predicates
Indications for Use Claims	ASTM D6978 -05 Re - approved 2013	• Carmustine (BCN U) • Cisplatin, • Cyclophosphamide (Cytoxan), • Dacarbazine (DTIC) • Doxorubicin Hydrochloride, • Etoposide (Toposar) • Fluorouracil, • Methotrexate • Paclitazel (Taxol), • Thiotepa • Vincristine Sulfate **Note** Carmustine (BCN U) and Thiotepa have low permeation times In Addition: • Fentanyl	• Blenoxane • Busulfan • Carmustine • Cisplatin • Cyclophosphamide /Cytoxan • Cytarabine • Dacarbazine • Daunorubicin • Docetaxel • Doxorubicin • Ellence • Etoposide/ Toposar • Fluorouracil • Gemcitabine • Idarubicin • Ifosfamide • Mechlorethamine HCL • Melphalan • Methotrexate • Mitomycin C • Mitoxantrone • Paclitaxel • Paraplatin • Rituxmab • Thiotepa • Trisenox • Vincristine Sulfate All >240min except ThioTEPA; Ca1mustine	• Blenoxane • Busulfan • Carmustine • Cisplatin • Cyclophosphamide /Cytoxan • Cytarabine • Dacrabazine • Daunorubicin • Docetaxel • Doxorubicin • Ellence • Etoposide/ Toposar • Fluorouracil • Gemcitabine • Idarubicin • Ifosfamide • Mechlorethamine HCL • Melphalan • Methotrexate • Mitomycin C • Mitoxantrone • Paclitaxel • Paraplatin • Rituximab • Thiotepa • Trisenox • Vincristine Sulfate All >240min except ThioTEPA; Carmustine • Fentanyl Citrate • Gastric acid • Fentanyl Citrate in Gastric acid	a) Similar: both tested CHEMO Drugs for pem1eation, but Subject glove tested more. Both tested Fentanyl, but Subject glove also tested Gastricacid b) Similar: The subject glove has listed the same 29 Chemotherapy dugs as (b) because same glove and the data from Kl70686 used for Subject glove data submission, but the glove has now also be e n tested with additional Fentanyl and Gastric Acid to acquire the QDO code.

Attributes	Standard Where Limits Test Limits Set	a) Predicate Device: K182241	b) Predicate Device: K170686	Subject Device Glove	How Does Subject Glove Compare to Predicates
Caution/ Warning Statements	NA	**Note** Carmustine (BCNU) and Thiotepa have low permeation times	**Note:** Carmustine and Thiotepa have extremely low permeation times of 3.6 and 15.9 minutes respectively. **WARNING: Not for use with: Carmustine, Thiotepa**	**Note:** Carmustine and Thiotepa have extremely low permeation times of 3.6 and 15.9 minutes respectively. **WARNING: Not for Use With: Carmustine, Thiotepa**	a) Similar: Predicate K182241 does not list the breakthrough times in the "Note," nor does it instruct wearer not to use with Carmustine, Thiotepa. Subject Glove is more informative b) Same
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: Width (mean)	ASTM D6319 Minimum: 70 ± 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 Min.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 Min 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

Attributes	Standard Where Limits Test Limits Set	a) Predicate Dev ice: K182241	b) Predicate Device: K170686	Subject Device Glove	How Does Subject Glove Compare to Predicates
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
Freedom from holes:	**ASTM** D6319 G1, AQL 2.5 7 Accept 8 Reject	Pass	Pass	Pass	Same
Powder-Free	**ASTM** D6319 Maximum <2mg/ glove	Less than 2.0mg per glove; Pass	Less than 2.0mg per glove; Pass	Less than 2.0mg per glove; Pass	Same
Biocompatibility	ISO 10993- 11 Systemic Toxicity Test	Under conditions of the study, t he 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 Condit ions of this study, the polar and non-polar device extracts were found not to be an irritant to the animal model.	Under Condit ions of this study, the polar and non-polar device extracts were found not to be an irritant to the animal model.	Under Condit ions 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 Condit ions 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

8. **Summary of Non-Clinical Performance Tests:**

Non-Clinical Testing was conducted to demonstrate that the proposed device met all required design specifications. The test results demonstrated that the proposed device met the performance criteria as specified utilizing the following test methods, standards, and specifications:

ASTM D6319-10 Standard D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application

ASTM D412-2006a (Reapproved 2013) Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension

ASTM D573-2004 (Reapproved 2010) Standard Test Method for Rubber-Deterioration in an Air Oven

ASTM D3767-03 Standard Practice for Rubber Measurement of Dimensions

ASTM D5151-2006 (Reapproved 2015) Standard Test Method for Detection of holes in Medical Gloves

ASTM D6124-2006 (Reapproved 2015) Standard Tested Method for Residual Powder on Medical Gloves

ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes

ISO 10993-10 Biological Evaluation of medical Devices-Part 10: Tests for Irritation and Sensitization

ISO 10993-11 Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity

9. **Conclusion:**

The conclusions drawn is that the physical attributes and the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as, or better than, the legally marketed predicate devices.