

June 13, 2021

Ansell Healthcare Products LLC Donald Cronk Associate Director 2301 Robb Drive Reno, Nevada 89523

Re: K210401

Trade/Device Name: Microflex Nitrile Patient Examination Gloves Blue Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, Microflex Nitrile Patient Examination Gloves Green Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, Microflex Nitrile Patient Examination Gloves Black Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: February 8, 2021
Received: February 10, 2021

Dear Donald Cronk:

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 <u>https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems</u>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</u>) and CDRH Learn (<u>https://www.fda.gov/training-and-continuing-education/cdrh-learn</u>). 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 (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</u>) for more information or contact DICE by email (<u>DICE@fda.hhs.gov</u>) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Ryan Ortega 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

510(k) Number (if known)

K210401

Device Name

Microflex® Nitrile Patient Examination Gloves Blue Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use (Describe)

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drug has an extremely low permeation time: Carmustine: 47.9 minutes. Warning: Do not use with Carmustine.

Tested chemotherapy drugs are as follows:

Test Chemotherapy drug & Concentration	Average Breakthrough Detection Time (Minutes)
Carmustine - 3.3 mg/ml	47.9
Cyclophosphamide - 20.0 mg/ml	>240
Doxorubicin HCl - 2.0 mg/ml	>240
Etoposide - 20.0 mg/ml	>240
Fentanyl Citrate Injection - 100 mcg/2 ml	>240
Fluorouracil - 50.0 mg/ml	>240
Methotrexate - 25.0 mg/ml	>240
Paclitaxel - 6.0 mg/ml	>240
Thiotepa - 10.0 mg/ml	>240
Vincristine Sulfate - 1.0 mg/ml	>240

Type of Lice	(Select one or both,	as annlinahla)
Type of use		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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

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

Indications for Use

510(k) Number (if known)

K210401

Device Name

Microflex® Nitrile Patient Examination Gloves Green Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use (Describe)

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drug has an extremely low permeation time: Carmustine: 49.6 minutes. Warning: Do not use with Carmustine.

Tested chemotherapy drugs are as follows:

Test Chemotherapy drug & Concentration	Average Breakthrough Detection Time (Minutes)
Carmustine - 3.3 mg/ml	49.6
Cisplatin - 1.0 mg/ml	>240
Cyclophosphamide - 20.0 mg/ml	>240
Dacarbazine - 10.0 mg/ml	>240
Doxorubicin HCl - 2.0 mg/ml	>240
Etoposide - 20.0 mg/ml	>240
Fentanyl Citrate Injection - 100 mcg/2 ml	>240
Fluorouracil - 50.0 mg/ml	>240
Methotrexate - 25.0 mg/ml	>240
Paclitaxel - 6.0 mg/ml	>240
Thiotepa - 10.0 mg/ml	>240
Vincristine Sulfate - 1.0 mg/ml	>240

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)

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

Indications for Use

510(k) Number (if known)

K210401

Device Name

Microflex® Nitrile Patient Examination Gloves Black Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use (Describe)

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drug has an extremely low permeation time: Carmustine: 27.6 minutes. Warning: Do not use with Carmustine.

Tested chemotherapy drugs are as follows:

Test Chemotherapy drug & Concentration	Average Breakthrough Detection Time (Minutes)
Carmustine - 3.3 mg/ml	27.6
Cyclophosphamide - 20.0 mg/ml	>240
Doxorubicin HCl - 2.0 mg/ml	>240
Etoposide - 20.0 mg/ml	>240
Fentanyl Citrate Injection - 100 mcg/2 ml	>240
Fluorouracil - 50.0 mg/ml	>240
Methotrexate - 25.0 mg/ml	>240
Paclitaxel - 6.0 mg/ml	>240
Thiotepa - 10.0 mg/ml	>240
Vincristine Sulfate - 1.0 mg/ml	>240

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)

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510K Summary

Submitter:

Ansell Healthcare Products LLC. 2301 Robb Drive Reno, NV 89523

Contact Person(s):

Don Cronk Associate Director, Regulatory Affairs Phone: (775) 470-7106 Email: <u>don.cronk@ansell.com</u>

Jacob Ramirez Senior Coordinator, Regulatory Affairs Phone: (775) 624-8118 Email: jacob.ramirez@ansell.com

Date Prepared:

5/3/2021

Name of the Device:

Trade Names:	Microflex [®] Nitrile Patient Examination Gloves Blue Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate Microflex [®] Nitrile Patient Examination Gloves Green Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate Microflex [®] Nitrile Patient Examination Gloves Black Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Common Name:	Patient Examination Glove
Classification Name:	Patient Examination Glove
Classification Regulation:	21 CFR 880.6250
Device Class:	1
Product Code:	LZA, LZC, QDO
Classification Panel:	Non-powdered patient examination glove

Legally Marketed Predicate Device:

Company:	Ansell Healthcare Products LLC
Trade Name:	Microflex [®] Nitrile Patient Examination Gloves with Aloe and Chamomile
	Blue Colored Tested for Use with Chemotherapy Drugs
	Microflex [®] Nitrile Patient Examination Gloves with Aloe and Chamomile
	Green Colored Tested for Use with Chemotherapy Drugs
	Microflex [®] Nitrile Patient Examination Gloves with Aloe and Chamomile
	Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl
	Citrate
510(k) Number:	K200671
Device Class:	Class I
Product Code:	LZA, LZC, QDO
Device Name:	Patient Examination Glove (21 CFR 880.6250)

Device Description:

Microflex[®] Nitrile Patient Examination Gloves Blue Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, Microflex[®] Nitrile Patient Examination Gloves Green Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, Microflex[®] Nitrile Patient Examination Gloves Black Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate are non-sterile, single use only, disposable, powder free examination gloves. The gloves are made of nitrile butadiene rubber. A polyacrylic polymer is applied to the inner surface of the gloves to make donning easy.

Characteristics:

- Ambidextrous with beaded cuff and straight fingers
- Finger-textured
- Blue, green, or black colored
- Four (4) sizes small, medium, large, and extra-large
- Tested against chemotherapy drugs and fentanyl citrate

High levels of ozone will degrade rubber material of the gloves; therefore, the gloves should be protected from ozone in particular.

The gloves are designed to meet the specifications of ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application.

Indications for Use Statements:

Microflex[®] Nitrile Patient Examination Gloves Blue Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drug has an extremely low permeation time: Carmustine: 47.9 minutes. Warning: Do not use with Carmustine.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	AVERAGE MINIMUM BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)
Carmustine (3.3 mg/ml)	47.9
Cyclophosphamide (20.0 mg/ml)	>240
Doxorubicin HCl (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fentanyl Citrate Injection (100 mcg/2 ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thieptepa (10.0 mg/ml)	>240
Vincristine Sulfate (1.0 mg/ml)	>240

Tested chemotherapy drugs are as follows:

Microflex[®] Nitrile Patient Examination Gloves Green Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drug has an extremely low permeation time: Carmustine: 49.6 minutes. Warning: Do not use with Carmustine.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	AVERAGE MINIMUM BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)
Carmustine (3.3 mg/ml)	49.6
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (20.0 mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Doxorubicin HCl (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fentanyl Citrate Injection (100 mcg/2 ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thieptepa (10.0 mg/ml)	>240
Vincristine Sulfate (1.0 mg/ml)	>240

Tested chemotherapy drugs are as follows:

Microflex[®] Nitrile Patient Examination Gloves Black Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drug has an extremely low permeation time: Carmustine: 27.6 minutes. Warning: Do not use with Carmustine.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	AVERAGE MINIMUM BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)
Carmustine (3.3 mg/ml)	27.6
Cyclophosphamide (20.0 mg/ml)	>240
Doxorubicin HCl (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fentanyl Citrate Injection (100 mcg/2 ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thieptepa (10.0 mg/ml)	>240
Vincristine Sulfate (1.0 mg/ml)	>240

Tested chemotherapy drugs are as follows:

Technological Characteristics:

Microflex[®] Nitrile Patient Examination Gloves Blue Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, Microflex[®] Nitrile Patient Examination Gloves Green Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, Microflex[®] Nitrile Patient Examination Gloves Black Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate have the following technological characteristics as compared to ASTM or equivalent standards:

Characteristics	Standard/Test/	Result Summary
	FDA Guidance	
Physical Characteristics:		
Dimensions:	ASTM D6319-10	Meets ASTM D6319-10 requirements for
		length, width and thickness
Length	Minimum 230mm	Minimum 240mm
Palm width (mm)		
Size – S	80 ± 10	85 ± 5
Size – M	95 ± 10	95 ± 5
Size – L	110± 10	105 ± 5
Size - XL	120 ± 10	115 ± 5
Thickness (mm) - single-v	vall	
Finger	minimum 0.05	Finger – min 0.09
Palm	minimum 0.05	Palm – min 0.06
Cuff	-	Cuff – min 0.05
Physical Properties:	ASTM D6319-10	Meets ASTM D6319-10 requirements for tensile
		strength and ultimate elongation before and
		after accelerated aging:
Tensile Strength		
Before Aging	minimum 14 MPa	minimum 16 MPa
After Aging	minimum 14 MPa	minimum 14 MPa
Ultimate Elongation		

Before Aging	minimum 500%	minimum 500%
After Aging	minimum 400%	minimum 400%
Freedom from holes	ASTM D6319-10	Meets or exceeds ASTM D6319-10 and ASTM
	ASTM D5151-06	D5151-06 requirements of AQL 2.5
Powder Residual	ASTM D6319-10	Meets applicable requirement for powder free;
	ASTM D6124-06	≤ 2 mg per glove
Biocompatibility:		
ISO In Vitro Cytotoxicity	ISO 10993-5:2009	Under the conditions of the study, undiluted,
		1:2, 1:4, 1:8, 1:16 dilution was cytotoxic., 1:32
		and 1:64 are not cytotoxic
ISO Skin Irritation Study	ISO10993-10:2010	Under the conditions of the study, not an irritant
ISO Maximization	ISO 10993-10:2010	Under the conditions of the study, not a
Sensitization Study		sensitizer
ISO acute systemic toxicity	ISO 10993-11: 2006	Under the conditions of the study, no evidence of systemic toxicity

Substantial Equivalence:

	Predicate Device	Proposed Subject Device	Substantial Equivalence to Predicate	
Trade name	Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Blue Colored Tested for Use with Chemotherapy Drugs Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Green Colored Tested for Use with Chemotherapy Drugs Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Microflex® Nitrile Patient Examination Gloves Blue Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate Microflex® Nitrile Patient Examination Gloves Green Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate Microflex® Nitrile Patient Examination Gloves Black Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Not applicable	
510k Number	K200671	K210401	Not Applicable	
Product Owner	Ansell Healthcare	Ansell Healthcare	Yes	
Product Code	LZA, LZC, QDO	LZA, LZC, QDO	Yes	
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Yes	
Regulatory Class	I	I	Yes	
Regulation Name	Patient Examination Glove	Patient Examination Glove	Yes	
Indications for use	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	Yes	
Material Composition	Synthetic nitrile rubber	Synthetic nitrile rubber	Yes	
Coating	Polyacrylic polymer inner coating to aid donning	Polyacrylic polymer inner coating to aid donning	Yes	

Noe and Aloe and Chamomile coated on		N/A	As noted	
Chamomile	the donning surface			
Design	Non-sterile	Non-sterile	Yes	
	Single use	Single use	Yes	
	Powder-free	Powder-free	Yes	
	Ambidextrous	Ambidextrous	Yes	
	Beaded cuff	Beaded cuff	Yes	
Color	Blue, Green, and Pink	Blue, Green, and Black	As noted	
Performance	Meets ASTM D6319-10	Meets ASTM D6319-10	Yes	
a. Dimensions	requirements	requirements		
b. Physical	Meets ASTM D6319-10	Meets ASTM D6319-10	Yes	
Properties	requirements	requirements		
c. Freedom from	Meets ASTM D6319-10	Meets ASTM D6319-10	Yes	
holes	requirements of GI, AQL 2.5	requirements of GI, AQL 2.5		
d. Powder Residual	Meets ASTM D6319-10	Meets ASTM D6319-10	Yes	
	requirements; Not more than	requirements; Not more than		
	2.0mg/glove	2.0mg/glove		
e. Sterility	Non-sterile	Non-sterile	Yes	
Biocompatibility	Passes Primary Skin Irritation Test	Passes Primary Skin Irritation Test	Yes	
	and Dermal Sensitization Test	and Dermal Sensitization Test and		

Chemotherapy	Microflex [®] Nitrile Patient Examination		Microflex [®] Nitrile Patient Examination		As Noted
Claim	Gloves with Aloe and Chamomile Blue Colored Tested for Use with		Gloves Blue Colored Tested for Use with		(Fentanyl Citrate)
	Colored Tested for Use with Chemotherapy Drugs		Chemotherapy Drugs and Fentanyl Citrate		, , , ,
	Significantly blugs		A powder-free patient examination glove is		
	The Nitrile Patient Examination Glove		a disposable device int		
	with Aloe and Chamor		purposes that is worn		
		intended to be worn by operating room personnel to protect a surgical wound		mination between The glove was tested	
	from contamination. T	-	for use with Chemothe	-	
	for use with Chemothe		Fentanyl Citrate as per	r ASTM D6978-05	
		ASTM D6978-05 Standard Practice for		Assessment for	
	Assessment for Medic		Medical Gloves to Peri	,	
	Permeation by Chemotherapy Drugs. Please note that the following drugs have		Chemotherapy Drugs. following drug has an		
	extremely low permea		permeation time: Carr	-	
	Carmustine (BCNU): 1		minutes. Warning; Do	not use with	
	Thiotepa: 67.1 minute	s. Warning: Do not	Carmustine.		
	use with Carmustine.		T		
	Tested chemotherapy drugs are as		Tested chemotherapy drugs are as follows:		
	follows:	5 UE 03	Tost	Average	
			Test Chemotherapy	Average Minimum	
	Test	Average	Drug and	Breakthrough	
	Chemotherapy	Minimum	Concentration	Detection Time	
	Drug and	Breakthrough		(Minutes)	
	Concentration	Detection Time (Minutes)	Carmustine (3.3 mg/ml)	47.9	
	Carmustine (3.3 mg/ml)	17.4	Cyclophosphamide (20.0 mg/ml)	>240	
	Cyclophosphamide (20.0 mg/ml)	>240	Doxorubicin HCl (2.0 mg/ml)	>240	
	Doxorubicin HCl	>240	Etoposide (20.0	>240	
	(2.0 mg/ml)		mg/ml)		
	Etoposide (20.0	>240	Fentanyl Citrate	>240	
	mg/ml)		Injection (100		
	Fluorouracil (50.0 mg/ml)	>240	mcg/2 ml) Fluorouracil (50.0	>240	
	Methotrexate	>240	mg/ml)	>240	
	(25.0 mg/ml)	240	Methotrexate	>240	
	Paclitaxel (6.0	>240	(25.0 mg/ml)		
	mg/ml)		Paclitaxel (6.0	>240	
	Thiotepa (10.0	67.1	mg/ml)		
	mg/ml)	> 240	Thiotepa (10.0	>240	
	Vincristine Sulfate (1.0 mg/ml)	>240	mg/ml) Vincristine Sulfate	>240	
	(1.0 mg/m)	11	(1.0 mg/ml)	7240	
Chemotherapy	Microflex [®] Nitrile Pati		Microflex [®] Nitrile Patient Examination		As Noted
Claim	Gloves with Aloe and Chamomile Green Colored Tested for Use with		Gloves Green Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate		(Fentanyl Citrate)
	Chemotherapy Drugs	Chemotherapy Drugs			
			A powder-free patient examination glove is		
	The Nitrile Patient Examination Glove with Aloe and Chamomile Green Colored		a disposable device intended for medical purposes that is worn on the examiner's		
	is intended to be worn by operating room personnel to protect a surgical wound from contamination. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drugs have		hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drug has an extremely low		
	extremely low permea		permeation time: Carr		
	Carmustine (BCNU): 27.9 minutes and		minutes. Warning: Do not use with		
	-	Thiotepa: 48.6 minutes. Warning: Do not		Carmustine.	
	LICO with Cormucting	use with Carmustine.			

Tested chemotherapy drugs are as follows:TestAverage Minimum Breakthrough Dug and ConcentrationTestMinimum Breakthrough Dutection Time (Minutes)Carmustine (3.3 (20.0 mg/ml)27.9 mg/ml)TestMinimum Breakthrough Detection Time (Minutes)Carmustine (3.3 (20.0 mg/ml)27.9 mg/ml)Carmustine (3.3 (20.0 mg/ml)49.6 mg/ml)Doxorubicin HCl (2.0 mg/ml)>240 (2.0 mg/ml)>240 (2.0 mg/ml)>240 (2.0 mg/ml)Etoposide (20.0 mg/ml)>240 (2.0 mg/ml)>240 (2.0 mg/ml)Fluorouracil (50.0 mg/ml)>240 (2.0 mg/ml)>240 mg/ml)Paciltaxel (6.0 mg/ml)>240 (25.0 mg/ml)>240 mg/ml)Thiotepa (10.0 mg/ml)48.6 mg/ml)>240 Fluorouracil (50.0 mg/ml)Thiotepa (10.0 mg/ml)48.6 mg/ml)>240 Fluorouracil (50.0 pacitaxel (5.0 pacitaxel (6.0 pacitaxel (6.0Vincristine Sulfate (1.0 mg/ml)>240>240 Pacitaxel (6.0 pacitaxel (6.0	
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mg/ml)	
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Chemotherapy Microflex® Nitrile Patient Examination Microflex® Nitrile Patient Examination Yes	S
Claim Gloves with Aloe and Chamomile Pink Gloves Black Colored Tested for Use with	-
Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	
Chemotherapy Drugs and Fentanyl Citrate	
A powder-free patient examination glove is	
The Nitrile Patient Examination Glove a disposable device intended for medical with Aloe and Chamomile Pink Colored is purposes that is worn on the examiner's	
intended to be worn by operating room hand to prevent contamination between	
personnel to protect a surgical wound patient and examiner. The glove was tested	
from contamination. The glove was tested for use with Chemotherapy Drugs and	
for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05	
Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for	
Standard Practice for Assessment for Medical Gloves to Permeation by	
Medical Gloves to Permeation byChemotherapy Drugs. Please note that theChemotherapy Drugs. Please note thatfollowing drug has an extremely low	
Chemotherapy Drugs. Please note that following drug has an extremely low permeation time: Carmustine: 27.6	
permeation times: Carmustine (BCNU): minutes. Warning: Do not use with	
23.4 minutes and Thiotepa: 64.9 minutes. Carmustine.	
Warning: Do not use with Carmustine.	
Tested chemotherapy drugs are as follows:	
Tested chemotherapy drugs are as	
follows: Test Minimum	
Chemotherapy Breakthrough	
Test Average Drug and Detection Time	
Chemotherapy Minimum Concentration	
Drug and Breakthrough Concentration Detection Time Carmustine (3.3 27.6	
Concentration Detection Time Carmustine (3.3 27.6 (Minutes) mg/ml)	
Carmustine (3.3 23.4 Cyclophosphamide >240	
mg/ml) (20.0 mg/ml)	
Cyclophosphamide >240 Doxorubicin HCl >240	
(20.0 mg/ml) (2.0 mg/ml)	1

Doxorubicin HCl (2.0 mg/ml)	>240	Etoposide (20.0 mg/ml)	>240	
Etoposide (20.0 mg/ml)	>240	Fentanyl Citrate Injection (100	>240	
Fentanyl Citrate	>240	mcg/2 ml)		
Injection (100 mcg/2 ml)		Fluorouracil (50.0 mg/ml)	>240	
Fluorouracil (50.0 mg/ml)	>240	Methotrexate (25.0 mg/ml)	>240	
Methotrexate (25.0 mg/ml)	>240	Paclitaxel (6.0 mg/ml)	>240	
Paclitaxel (6.0 mg/ml)	>240	Thiotepa (10.0 mg/ml)	>240	
Thiotepa (10.0 mg/ml)	64.9	Vincristine Sulfate (1.0 mg/ml)	>240	
Vincristine Sulfate (1.0 mg/ml)	>240			

The subject devices meet the applicable requirements for patient examination gloves regarding dimensions and sizes, physical properties, freedom from holes, and powder residues as found in the following standards: ASTM D6319, ASTM D5151 and ASTM D6124. The subject devices pass biological reactivity testing for dermal sensitization, irritation and acute systemic toxicity, in accordance with the ISO 10993 series of standards.

A clinical study was not required for the subject or predicate devices.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject devices are as safe, as effective, and performs as well as the legally marketed device.