TouchNTuff®
ADVANCED PRODUCT & WORKER PROTECTION

92-665
Disposable Nitrile Glove with Extended Cuff

NBR
Nitrile

Robust, extended cuff protection for food processing and heavy-duty jobs

- Superior chemical splash protection
- Extended cuff for protection of the wrist and forearm
- Soft, durable nitrile material for added comfort
- Textured fingertips provide secure grip
- Compliant with food handling requirements

Industries

- Life Sciences
- Chemical
- Food Processing

Recommended For

- Transferring liquids and solids
- Sample taking and processing
- Handling incoming goods
- Maintenance
- All food processing, applications that have food contact

TouchNTuff®
ADVANCED PRODUCT & WORKER PROTECTION

92-665
Disposable Nitrile Glove with Extended Cuff

TECHNICAL DATA SHEET

PRODUCT INFORMATION

	92-665
Material	Nitrile
Color	Blue
Glove Design	Chlorinated, Powder-Free, Silicone Free, Textured Fingers
Cuff	Beaded
Manufacturing/QMS Audit Standards	ISO 9001:2008
Regulatory/Standards Compliance	ASTM D6319, Category III, EN ISO 374-1:2016, EN 374:2003, EN 420:2003 + A1:2009, EN ISO 374-5:2016, FDA21 CFR 177-2600, ISO 9001
Packaging	100 gloves per dispenser 10 dispensers per case 1000 gloves per case
Storage	Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.
Country of Origin	Thailand
User Needs Segment	High Risk
Available sizes	S (6.5 - 7), M (7.5 - 8), L (8.5 - 9), XL (9.5 - 10)
Anti-static	Yes
Vulcanization Chemical Accelerators	• Zinc Dibutyldithiocarbamate (ZDBC) *Only a very small number of users may be sensitive to this ingredient(s) and hence may develop irritant and/or allergic contact reactions.*

PHYSICAL PROPERTIES

	Typical Values		Testing Method
Length (mm/inches)	300 / 11.8		ASTM D3767,EN 420
Freedom from Holes (Inspection level I)	1.5 AQL		ASTM D5151,EN 455-1
Palm Thickness (mm/mils)	0.11 / 4.3		ASTM D3767,EN 420
Finger Thickness (mm/mils)	0.12 / 4.7		ASTM D3767,EN 420
	BEFORE AGING	**AFTER AGING**	
Ultimate Tensile Strength (MPa)	≥ 14	≥ 14	ASTM D412 & D573
Elongation at Break (%)	≥ 500	≥ 400	ASTM D412
Force at break (N)	≥ 6	≥ 6	EN 455-2

ORDERING INFORMATION

Size	S (6.5 - 7)	M (7.5 - 8)	L (8.5 - 9)	XL (9.5 - 10)
Ansell Product Code	92665070	92665080	92665090	92665100

Performance Standards and Regulatory Compliance

EN ISO 374-1:2016 Type B JKT
EN 374
EN ISO 374-5:2016 VIRUS
ISO 9001

For additional information visit us at www.ansell.com, or call us at

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Ansell

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Date:09-09-2019

Good Manufacturing Practices Declaration for Ansell's materials and articles intended to come in contact with food

Herewith, the undersigned declares that all Ansell gloves that are intended for contact with Food products are manufactured in accordance to the following requirements:

Regulation 1935/2004:

- Gloves are sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or deterioration in its organoleptic properties.
- Gloves are made with only legally acceptable Food-contact ingredients and do not exceed any legal migration levels based on the intended use of the product.
Raw materials used in the production of the gloves are specified safe for food contact and are procured from an approved supplier.

Regulation 2023/2006:

- Gloves are made as per 'Good manufacturing practice (GMP)' meaning they are produced and controlled to ensure conformity with the applicable rules and applicable quality standards. This applies to all activities; from procurement through approved suppliers of materials and all aspects of manufacturing, processing, handling, storage, transport and distribution of the finished article.
- The manufacturing plant has a documented and effective quality assurance system in place with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use.
- The qualifications and training of personnel at manufacturing is documented. As well, the manufacturing facility and equipment is designed, cleaned, and maintained as necessary to ensure that in process materials and finished glove products comply with their specifications. Inherent in these requirements are personnel hygiene, pest

control, contamination control, prevention of material damage from the environment, etc., etc.
- A formal risk analysis according to an established procedure has been conducted and each proposed change for its impact on risk to the user of the finished article is documented.
- The manufacturing plant has an effective quality control system and a documented system of tests, inspections, document reviews and formal dispositions on raw materials, in process materials and finished articles. This system includes clear decision-making criteria on materials and articles not meeting specifications.
- The manufacturing's quality control system monitors compliance with Good Manufacturing Practices and correct any failure to comply with GMP without delay. Ansell shall ensure adherence to the effective implementation of GMP through review of the supplier's internal audit system as described in the ISO 9001 Quality Management System.
- The manufacturing site maintains documentation on specifications, manufacturing formulae, and processing necessary to achieve regulatory compliance and product safety in electronic or paper (hard-copy) format.
- Finished articles are labelled with a unique control number, which relates to specific records held by the manufacturer.

Guido Van Duren
Director – Global Regulatory Affairs
PPE Products
Ansell

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Riverside Business Park, Block J - Boulevard International 55 - B-1070 Brussels, Belgium
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http://www.ansell.eu - E-mail info@ansell.eu

ISO 9002 Certificate Number FM 40130

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 9, 2016

Ansell Healthcare Products, LLC
Vasudev Dobariya
Regulatory Specialist
111 Wood Avenue South, Suite 210
Iselin, New Jersey 08830

Re: K151694
Trade/Device Name: Gammex PI Hybrid Surgical Glove
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: February 3, 2016
Received: February 8, 2016

Dear Vasudev Dobariya:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151694

Device Name
Gammex PI Hybrid Surgical Glove

Indications for Use *(Describe)*
Gammex PI Hybrid Surgical Glove is intended to be worn by operating room personnel to protect a surgical wound from contamination.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The assigned 510(k) number is: **K151694**

Submitter

Ansell Healthcare Products LLC.
111 Wood Avenue South, Suite 210
Iselin, NJ 08830 USA

Contact Person:

Vasudev Dobariya
Regulatory Affairs Specialist
Phone: 732-345-5317
Vasudev.dobariya@ansell.com

Date Prepared

March 7, 2016

Name of Device

Trade Names:	Gammex PI Hybrid Surgical Glove (also marketed as Encore PI Hybrid Surgical Glove)
Common Name:	Surgeon's Gloves
Classification Name:	Surgeon's Gloves
Classification Regulation:	21 CFR 878.4460
Device Class:	I
Product Code:	KGO
Classification Panel:	General and Plastic Surgery

Legally Marketed Predicate Device

K071746 – Derma Prene PI or Isotouch Green sterile Powder-Free Synthetic Polyisoprene Surgical Gloves

Device Description

The subject device is single-use disposable powder-free surgical glove that is supplied sterile and made of synthetic rubber blend of polyisoprene and neoprene.

Indications for Use

Gammex PI Hybrid Surgical Glove is intended to be worn by operating room personnel to protect a surgical wound from contamination.

Technological Characteristics

Gammex PI Hybrid Surgical Glove have the following technological characteristics as compared to ASTM or equivalent standards:

Technological Characteristics	**Standard/Test/FDA Guidance**	**Result Summary**
Dimensions	ASTM D3577-09	Meets ASTM D3577-09 requirements for length, width and thickness
--Length	Minimum 265mm	Average 305mm
--Palm Width(size)	(mm)	Average value in mm
5.5	70±6	73
6.0	76±6	80
6.5	83±6	86
7.0	89±6	91
7.5	95±6	97
8.0	102±6	103
8.5	108±6	110
9.0	114±6	117
--Thickness	(mm)	Average value in mm
Finger	Minimum 0.10	0.22
Palm	Minimum 0.10	0.20
Cuff	Minimum 0.10	0.17
Physical Properties	ASTM D3577-09	Meets ASTM D3577-09 requirements for tensile strength and elongation at break before and after accelerated aging
Freedom from holes	ASTM D3577-09 ASTM D5151-06	Meets ASTM D3577-09 and ASTM D5151-06 requirements of AQL 1.5
Powder-Free	ASTM D3577-09 ASTM D6124-06	Meets Applicable requirement for Powder Free; ≤ 2 mg per glove
Sterility	ANSI/AAMI/ISO 11137-1:2006	Meets ANSI/AAMI/ISO 11137-1:2006 requirement of 10^{-6} SAL
Biocompatibility:		
ISO Skin Irritation Study	ISO 10993-10:2010	Under the conditions of the study, not an irritant
ISO Maximization Sensitization Study	ISO 10993-10:2010	Under the conditions of the study, not a sensitizer

Substantial Equivalence

Substantial Equivalence Comparison Table

	Predicate Device	**Subject Device**	**Substantial Equivalence**
Trade Name	Derma Prene PI or Isotouch Green Sterile Powder-Free Polyisoprene Surgical Gloves	Gammex PI Hybrid Surgical Glove	Not applicable
510(k) Number	K071746	K151694	Not applicable
Submitter	Ansell Healthcare Products LLC	Ansell Healthcare Products LLC	Yes

	Predicate Device	**Subject Device**	**Substantial Equivalence**
Product Code	KGO	KGO	Yes
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Yes
Regulation Name	Surgeon's glove	Surgeon's glove	Yes
Indications for Use	These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination.	This glove is intended to be worn by operating room personnel to protect a surgical wound from contamination.	Yes
Prescription or Over-The Counter-Use	Over-The-Counter-Use	Over-The-Counter-Use	Yes
Materials	Synthetic polyisoprene rubber	Synthetic rubber blend of polyisoprene and neoprene	Yes with difference
Coating	Polyurethane polymer inner coating to aid donning	Polyurethane polymer inner coating to aid donning	Yes
Design	Single use	Single use	Yes
	Sterile	Sterile	Yes
	Powder-free	Powder-free	Yes
	Hand specific	Hand specific	Yes
	Beaded cuff	Beaded cuff	Yes
Color	Green	White	Yes with difference
Sterilization method	Radiation	Radiation	Yes
Sterility Assurance Level (SAL)	10^{-6} SAL	10^{-6} SAL	Yes
Shelf Life	3 years	3 years	Yes
Dimensions and physical properties	Meets ASTM D3577-09 requirements	Meets ASTM D3577-09 requirements	Yes
Freedom from holes	Meets ASTM D3577-09 requirements of AQL 1.5	Meets ASTM D3577-09 requirements of AQL 1.5	Yes
Powder-Free	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Yes
Biocompatibility	"Under the conditions of the study, not an irritant" and "Under the conditions of the study, not a sensitizer"	"Under the conditions of the study, not an irritant" and "Under the conditions of the study, not a sensitizer"	Yes

The subject device is manufactured from synthetic rubber blend of polyisoprene and neoprene with polyurethane polymer inner coating to aid donning. The predicate device is manufactured from synthetic

polyisoprene rubber with polyurethane polymer inner coating to aid donning. Though the materials of construction differ, the subject device's materials are functionally equivalent to those of the cited predicate.

The subject device meets the applicable requirements for surgeon's gloves with regard to dimensions and sizes, physical properties, freedom from holes, powder residues, and protein content as found in the following standards: ASTM D3577-09, ASTM D5151-06 and ASTM D6124-06. The subject device passes biological reactivity testing for dermal sensitization and irritation, in accord with the ISO 10993 series of standards.

Performance Data
A clinical study was not conducted on the subject or predicate devices.

Substantial Equivalence Statement
The Gammex PI Hybrid Surgical Glove is substantially equivalent to the predicate device with respect to design, technological characteristics, intended use and conformance to standard requirements.

Conclusion:
The Gammex PI Hybrid Surgical Glove is substantially equivalent to the Derma Prene PI or Isotouch Green sterile Powder-Free Synthetic Polyisoprene Surgical Gloves. Based on the performed nonclinical tests, the subject device performs as safely and as effectively as the legally marketed predicate device, Derma Prene PI or Isotouch Green sterile Powder-Free Synthetic Polyisoprene Surgical Gloves, previously cleared under K071746, Class I (21 CFR 878.4460, Product code KGO).

December 29, 2017

Ansell Healthcare Products LLC
Robert Mahler
Director, Regulatory Affairs for the Americas
111 Wood Avenue South, Suite 210
Iselin, New Jersey 08830

Re: K171737
Trade/Device Name: Micro Touch Denta Glove Nitrile Hydrasoft Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: December 8, 2017
Received: December 11, 2017

Dear Robert Mahler:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang
-S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171737

Device Name
Micro Touch Denta Glove Nitrile Hydrasoft Patient Examination Glove

Indications for Use *(Describe)*
Micro Touch Denta Glove Nitrile Hydrasoft Patient Examination Gloves are intended for medical purposes that are worn on the examiners hands to prevent contamination between patient and examiner.

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Ansell Healthcare Products LLC.
111 Wood Avenue South, Suite 210
Iselin, NJ 08830 USA

510k Summary

510(k): k171737

Submitter:

Ansell Healthcare Products LLC.
111 Wood Avenue South, Suite 210
Iselin, NJ 08830 USA

Contact Person:

Robert Mahler
Director, Regulatory Affairs for the Americas
Phone: (732) 345-2174
Email: rob.mahler@ansell.com

Date Prepared: **12/8/2017**

Name of the Device:

Trade Names:	**Micro Touch Denta Glove Nitrile Hydrasoft Patient Examination Gloves**
Common Name:	Patient Examination Glove
Classification Name:	Patient Examination Glove
Classification Regulation:	21 CFR 880.6250
Device Class:	1
Product Code:	LZA
Classification Panel:	General and Plastic Surgery

Legally Marketed Predicate Device:

Company:	Wear Safe (Malaysia) Sdn Bhd
Trade Name:	Powder Free Nitrile Patient Examination Glove, Blue Colored and White (Non-colored), Non-sterile, Polymer Coated Powder Free Nitrile Patient Examination Gloves, Blue Colored and white (Non-colored), Non-sterile, without Polymer (Chlorinated)
510(k) Number:	K123469
Device Class:	Class I
Product Code:	LZA (Nitrile)
Device Name:	Patient Examination Glove (21 CFR 880.6250)

Reference Device:

Company:	Ansell Healthcare LLC
Trade Name:	Encore Sterile Powder-Free Polymer Coated Latex Surgical Glove with Hydrasoft™ Coating (containing glycerine) and Protein Labeling Claim (50mg or less)
510(k) Number:	K051793
Device Class:	Class I
Product Code:	KGO
Device Name:	Surgeon's Glove (21 CFR 878.4460)

Ansell Healthcare Products LLC.
111 Wood Avenue South, Suite 210
Iselin, NJ 08830 USA

Device Description:

The MICRO-TOUCH® DENTA-GLOVE® Nitrile HydraSoft™ are non-sterile, single use only, disposable, powder free examination gloves. The glove is made of nitrile butadiene rubber. A polyacrylic polymer is applied to the inner surface of the glove to make donning easy. Hydrasoft coating (containing glycerine) is applied on top of the polymer coating on the glove inner surface..

Characteristic:

- Ambidextrous with beaded cuff and straight fingers
- Finger-textured,
- White colored
- Featuring inner coating of polyacrylic polymer coating and HydraSoft™ coating.
- Five (5) sizes – extra-small, small, medium, large, and extra-large.

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

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

Indications for Use Statement:

A powder-free patient 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.

Technological Characteristics:

Micro Touch Denta Glove with Hydrasoft Coating Nitrile Patient Examination Gloves have the following technological characteristics as compared to ASTM or equivalent standards:

Characteristics	**Standard/Test/ FDA Guidance**	**Result Summary**
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 – XS	*70 ± 10*	*75 ± 5*
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-wall		
Finger	*minimum 0.05*	*Finger – 0.11 ± 0.03*
Palm	*minimum 0.05*	*Palm – 0.07 ± 0.02*
Cuff	-	*Cuff – 0.06 ± 0.02*

Ansell Healthcare Products LLC.
111 Wood Avenue South, Suite 210
Iselin, NJ 08830 USA

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 17 MPa*
After Aging	*minimum 14 MPa*	*minimum 17 MPa*
Ultimate Elongation		
Before Aging	*minimum 500%*	*minimum 500%*
After Aging	*minimum 400%*	*minimum 400%*
Freedom from holes	ASTM D6319-10 ASTM D5151-06	Meets ASTM D6319-10 and ASTM D5151-06 requirements of AQL 2.5
Powder Residual	ASTM D6319-10 ASTM D6124-06	Meets applicable requirement for powder free; ≤ 2 mg per glove
Biocompatibility:		
ISO In Vitro Cytotoxicity	ISO 10993-5:2009	Under the conditions of the study, undiluted and 1:2 dilution was cytotoxic. 1:4, 1:8, 1:16, 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 Sensitization Study	ISO 10993-10:2010	Under the conditions of the study, not a sensitizer
ISO acute systemic toxicity	ISO 10993-11: 2006	Under the conditions of the study, no evidence of systemic toxicity

Substantial Equivalence:

	Predicate Device	**Reference Device**	**Proposed Subject Device**	**Substantial Equivalence to Predicate**
Trade name	Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non-colored). Non-sterile, Polymer Coated	Encore Sterile Powder-Free Polymer Coated Latex Surgical Glove with Hydrasoft Coating (containing glycerine) and Protein Labeling Claim (50mg or less)	MICRO-TOUCH® DENTA-GLOVE® Nitrile HydraSoft™ Non-Sterile Powder-Free Examination Glove	Not applicable
510k Number	K123469	K051793	Pending	Not Applicable
Product Owner	Wear Safe Malaysia	Ansell Healthcare	Ansell Healthcare	Ansell Healthcare
Product Code	LZA	KGO	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 878.4460	21 CFR 880.6250	Same
Regulatory Class	1	1	1	Same
Regulation Name	Patient Examination Glove	Surgeon's Glove	Patient Examination Glove	Same

Ansell Healthcare Products LLC.
111 Wood Avenue South, Suite 210
Iselin, NJ 08830 USA

Intended Uses	The 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 surgical glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. The latex glove contain 50 micrograms or less of water extractable per gram	The 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	Same
Material Composition	Synthetic nitrile rubber	Natural rubber latex	Synthetic nitrile rubber	Same
Coating	Polyacrylic polymer inner coating to aid donning	Polyurethane polymer inner coating to aid donning	Polyacrylic polymer inner coating to aid donning	Same
HydraSoft Coating	N/A	HydraSoft™ Coating coated on the donning surface	HydraSoft™ Coating coated on the donning surface	Different from predicate
Design	Non-sterile	Sterile	Non-sterile	Same
	Single use	Single use	Single use	Same
	Powder-free	Powder-free	Powder-free	Same
	Ambidextrous	Hand specific	Ambidextrous	Same
	Beaded cuff	Beaded cuff	Beaded cuff	Same
Color	White	White	White	Same
Shelf Life	3 years	3 years	3 years	Same
Performance a. **Dimensions**	Meets ASTM D6319-10 requirements	Meets ASTM 3577 requirements	Meets ASTM D6319-10 requirements	Same
b. **Physical Properties**	Meets ASTM D6319-10 requirements	Meets ASTM 3577 requirements	Meets ASTM D6319-10 requirements	Same
c. **Freedom from holes**	Meets ASTM D6319-10 requirements of GI, AQL 2.5	Meets ASTM 3577 requirements of GI, AQL 1.5	Meets ASTM D6319-10 requirements of GI, AQL 2.5	Same
d. **Powder Residual**	Meets ASTM D6319-10 requirements; Not more than 2.0mg/glove	Meets ASTM 3577 requirements; Not more than 2.0mg/glove	Meets ASTM D6319-10 requirements; Not more than 2.0mg/glove	Same
e. **Sterility**	Non-sterile	Sterile	Non-sterile	Same
Biocompatibility	Passes Primary Skin Irritation Test and Dermal Sensitization Test	Passes Primary Skin Irritation Test and Dermal Sensitization Test	"Under the conditions of the study, not an irritant" and "Under the conditions of the study, not a sensitizer"	Same

The MICRO-TOUCH® DENTA-GLOVE® Nitrile HydraSoft™ are non-sterile, single use only, disposable, powder free patient examination gloves. The glove is made of nitrile butadiene rubber. A polyacrylic polymer is applied to the inner surface of the glove to make donning easy. Hydrasoft coating (containing glycerine) is applied on top of the polymer coating on the glove inner surface.

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The subject device meets 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 device passes biological reactivity testing for dermal sensitization and irritation, in accord with the ISO 10993 series of standards.

Performance Data:
A clinical study was not conducted on the subject or predicate devices.

Substantial Equivalence Statement

The Micro-Touch Denta-Glove with HydraSoft Coating Nitrile Patient Examination Glove is as safe and effective as the predicate device with respect to design, technological characteristics, intended use and conformance to standard requirements.

Conclusion

The conclusions drawn from the non clinical tests demonstrate that theMicro-Touch Denta-Glove with HydraSoft Coating Nitrile Patient Examination Glove is as safe and effective as the legally marketed predicate device previously cleared under K123469, Class I (21 CFR 880.6250, Product Code: LZA).

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FOCUS PRODUCT GUIDE
SINGLE USE SOLUTIONS

GLOVES		KEY BENEFITS	APPLICATIONS	VWR Cat. No.	SIZE
MICROFLEX® ULTRAFORM® UF-524		• Designed with ERGOFORM™ Ergonomic Design Technology to support musculoskeletal health • Thin design for superior tactile sensitivity • Soft nitrile formulation forms to hands for comfort during extended wear	*Life Sciences, Healthcare*	89235-576 89235-578 89235-580 89235-582 89235-584	XS S M L XL
MICROFLEX® XCEED® XC-310		• Excellent choice for trimming, packaging and racking applications • Environmentally friendly, smart packaging with 250 gloves per box • Medical examination grade	*Life Sciences, Healthcare*	89174-538 89174-540 89174-542 89174-544 89174-546	XS S M L XL
MICROFLEX® FreeForm® SE FFS-700		• Textured fingertips for enhanced grip • Non-stick properties resists tape and adhesives • Available in half sizes for a unique, tailored fit	*Life Sciences, Healthcare*	32916-680 32916-682 32916-684 32916-686 32916-688	XS S M L XL
MICROFLEX® Supreno® SE SU-690		• Durable nitrile formulation for demanding jobs • More than 240 minutes of resistance to fentanyl and gastric acid (vomit) • Textured fingertips provide secure grip	*Life Sciences, Healthcare*	32916-668 SU-690 32916-660 SU-690 32916-662 SU-690 32916-664 SU-690 32916-666 SU-690	XS S M L XL
MICROFLEX® Supreno® EC SEC-375		• Certified by the National Fire Protection Association • More than 240 minutes of resistance to fentanyl and gastric acid • Approved for use with chemotherapy and cytotoxic drugs	*Life Sciences, Healthcare*	76311-656 SEC-375 32916-670 SEC-375 32916-672 SEC-375 32916-674 SEC-375 32916-676 SEC-375 32916-678 SEC-375 89135-222 SEC-375	XS S M L XL 2XL 3XL
MICROFLEX® MidKnight™ MK-296 & XTRA 93-862		• Black color shows hazardous powders and hides stains • Fully textured for a reliable, consistent grip • More than 240 minutes of resistance to fentanyl and gastric acid (vomit)	*Chemical, Healthcare, Life Sciences,*	Standard / Extended 94001-364 / - 94001-366 / 76312-344 94001-368 / 76312-346 94001-370 / 76312-348 94001-372 / 76312-350 94001-374 / 76312-352	XS S M L XL 2XL
MICROFLEX® LIFESTAR EC® LSE-104		• Tested against both fentanyl and gastric acid (vomit) to simulate hazardous, real world overdose situations • Dual layer, dual color design for two layers of protection • Advanced barrier protection (AQL 0.65) • Non-stick and non-foaming properties for reduced interference when working	*Healthcare*	76201-712 76201-714 76201-702 76201-704 76201-706 76201-708	S M L XL 2XL 3XL
TouchNTuff® 92-600		• Robust proprietary formulation improves durability • FDA-compliant soft nitrile provides high levels of comfort • Silicone-free design eases paint and finish processes	*Life Sciences, Chemical*	76238-380 76238-378 76238-376 76238-382	S M L XL
MICROFLEX® 93-260		• Nitrile & neoprene offer broad resistance against harsh chemicals • Extended cuff, 12" length; 7.8 mil palm thickness • Silicone-free	*Life Sciences, Chemical*	75832-934 75832-936 75832-938 75832-940 75832-942 75832-944	XS S M L XL 2XL

CLEAN AND STERILE SOLUTIONS

GLOVES	KEY BENEFITS	APPLICATIONS	VWR Cat. No.		SIZE
			Non-Sterile	Sterile	
BIOCLEAN™ FUSION BFAP & S-BFAP 	• Low particulate count • Powder-free and latex-free • Excellent ESD properties • Easy double-donning • Chemical resistant	*Life Sciences, Chemical, Pharma Compounding*	75972-620 75972-652 75972-650 75972-612 75972-654 75972-622	75982-304 75982-306 75982-308 75982-310 75982-312 75982-296	XS S M L XL 2XL
MICROFLEX® 93-360 	• Three layer nitrile and neoprene design for broad chemical resistance against harsh chemicals including acids, solvents and bases* • Compatible for cleanroom / controlled environments • Silicone free and anti-static	*Life Sciences*	76289-850 76289-852 76289-854 76289-856 76289-858 76289-860		XS S M L XL 2XL
BIOCLEAN™ N-PLUS BNPS 	• 400mm/16" length for extra protection • Hand specific sterile nitrile • Approved for use with chemotherapy drugs (ASTM D 6978)*	*Life Sciences, Chemical, Healthcare, Pharma Compounding*	75834-048 75834-050 75834-052 75834-054 75834-056 75834-058 75834-060 75834-118		6 6.5 7 7.5 8 8.5 9 10
TouchNTuff® 83-500 	• Powder-free, smooth grip, extended beaded cuff • Suitable for Class 100 (ISO 5) / Grade A Clean Room environments • Prevents Type I allergies	*Life Sciences, Chemical*	89402-724 89402-726 89402-728 89402-730 89402-732 89402-734 89402-736 89402-738		5.5 6 6.5 7 7.5 8 8.5 9
BioClean™ Nitrile Clean RABS/Isolator Gloves CGL & GGL 	• Consistent 10-week lead time; excellent alternative to CSM/ Hypalon & EPDM • Available ISO 4 cleanroom laundered, both validated sterile and non-sterile • FDA approved, VHP and IPA resistant, multiple autoclave cycles	*Life Sciences, Pharma Compounding*	Non-Sterile 76316-252 - 76316-254 76316-256	Sterile 76311-658 76316-262 76316-258 76316-260	6 - 8" 8 - 10" 10 - 12" 12 - 14"

CLOTHING / ACCESSORIES	KEY BENEFITS	APPLICATIONS	VWR Cat. No.	SIZE
BioClean™-D Drop-down Sterile Garment with Hood S-BDSH 	• Innovative quick and easy donning design • Lightweight for increased user comfort/ wearability • Sterile and Class 10 (ISO 4) compatible • Low-linting antistatic CleanTough material	*Life Sciences, Pharma Compounding*	75845-800 75845-796 75845-794 75845-792 75845-798 75845-802 75845-804 75845-806 76271-424 76271-426 76271-428 76271-366	XS S M L XL 2XL 3XL 4XL 5XL 6XL 7XL 8XL
BioClean™ Clearview Autoclavable Panoramic Goggles BCAP 	• With extra depth and width for increased field of vision • Upper vents, indirect ventilation system • Latex-free, non-linting head band • Optically correct polycarbonate lens with anti- scratch coating • PPE Cat 2 certification • Suitable for Class 10 (ISO 4) cleanroom environments	*Life Sciences, Pharma Compounding*	75845-813 75834-001 75834-003	BCAP BCAP-SL BCAP-SS
BioClean™ Cut Resistant Liner S-BCRL 	• ANSI A2 Cut protection • Specifically constructed for optimal dexterity, comfort and fit • Offer cut protection when handling sharp objects or cleaning apparatus which pose a cut risk • Compatible with ISO Class 4 cleanroom or higher: <450 LPC	*Life Sciences, Chemical, Healthcare*	76326-064 76326-066 76326-068 76326-070 76326-144	XS S M L XL

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