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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510k Summary

510(k): k171737

Submitter:

Ansell Healthcare Products LLC.
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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)

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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*

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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

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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).