K130667

PREVENTIVE CARE, INC.

510 (k) SUMMARY

DATE: June 10th, 2013

JUL 24 2013

1. Submitter

Preventive Care, Inc.
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2. Contact Person

Contact: Anil Segat
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3. Name of device

Trade name: Exam Perfect Powderfree Latex Examination Gloves Coated with Allogel®
Common Name: Exam Gloves
Classification Name: Patient Examination Glove
Classification Number: Class 1
Regulation Number: 21 CFR 880.6250
Product code: LYY

4. Legally Marketed Device to which equivalency is claimed: K110102

Powderfree Nitrile Examination Gloves Coated with Allogel®, LZA, Class 1, that meets or exceeds all the applicable requirements of ASTM standards and FDA water leak test.

5. Device Description

The device is a glove with five fingers made from natural rubber that covers the hand on both sides up to the wrist, using a dip technology manufacturing process. The gloves are ambidextrous and therefore can be donned on either hand. The gloves are non sterile and for single use only, to be discarded after each examination is complete. The glove acts as a barrier between the examiner and the subject being examined in order to prevent contamination between the examiner and the subject. The physical properties of the glove are identified in paragraph 9 below, as compared to those required by ASTM D 3578 version 2010.

6. Intended use of the Device

An Examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger, to prevent contamination between the patient and examiner.

7. Summary of the technological characteristics of the Device

The device meets all the applicable technical requirements of :

ASTM D3578 *Version 2010*	Standard specifications for rubber examination gloves. Data of an actual representative shipment is detailed in Section 14 (original submission).
ASTM D5712 *Version 2010*	Standard test method for analysis of aqueous extractable protein in natural rubber and its products using the modified lowry method. Data of an actual representative shipment is detailed in Section 14 (original submission).
ASTM D6124 *Version 2006*	Standard test method for residual powder on medical gloves. Data of an actual representative shipment is detailed in Section 14 (original submission).
ASTM D412 *Version 06ae2*	Test method for vulcanized rubber and thermoplastic rubbers and thermoplastic elastomers-tension. Data of an actual representative shipment is detailed in Section 14 (original submission).
ASTM D5151 *Version 2006*	Standard test method for detection of holes in medical gloves. Data of an actual representative shipment is detailed in Section 14 (original submission).
ISO 10993 *Version 2010*	Biological evaluation of medical devices Part 10, tests for skin irritation and sensitization. The test reports are detailed in section 8 & 9 (original submission). The gloves have passed the biocompatibility test criteria for not being sensitizers or irritants.

The above are the principal technical standards that the device needs to comply with. The device has substantially enhanced physical properties as compared to those required by ASTM and other relevant standards.

8. Substantial Equivalence

The substantial equivalence to the predicate device is based on non clinical assessment data. A comparison was made of the physical properties and characteristics of both devices for the following attributes, which were found to be substantially similar:

a. A glove made from natural or synthetic rubber

b. Use and description

c. Physical properties such as, length, width, thickness, tensile strength, freedom from holes, and residual powder. Although the predicate device made from synthetic rubber has no residual natural rubber proteins, the applicant device made of natural rubber complies with the requirements of ASTM D3578 for the maximum allowable residual proteins. The tensile strength and elongation of the applicant device was found to be superior. The thickness of the applicant device was marginally more than the predicate device, but this is normal for latex examination gloves used for medical purposes and it is within the tolerance levels for such devices.

d. Inner coating made from Allogel®

9. Physical Performance data

TEST	ASTM D3578 -2010 STANDARD REQUIREMENT	POWDER FREE LATEX EXAM GLOVES COATED WITH ALLOGEL® RESULTS
1. Watertight (1000ml) In accordance with ASTM D5151	Multiple Normal In accordance with ISO 2859 Version 10-2006 GI AQL2.5	Pass G1 AQL 2.5
2. Length (mm) Size XS S M L XL	 Min 220 Min 220 Min 230 Min 230 Min 230	240 mm minimum for all sizes
3. Palm Width (mm) Size XS S M L XL	 70 ± 10 80 ± 10 95 ± 10 110 ± 10 120 ± 10	 75 – 80 83 – 84 94 - 96 107-109 113-114
4. Thickness (mm) (Single Layer) Finger Palm Cuff	 Min 0.05 Min 0.05 Min 0.05	 Min 0.12 Min 0.10 Min 0.08
5. Physical Properties In accordance with ASTM D 412 **Before Aging** Tensile Strength(MPa) Ultimate Elongation (%) **After Aging** Tensile Strength(MPa) Ultimate Elongation (%)	 Min 14 Min 500 Min 14 Min 400	 18 – 31 530 – 600 18-29 500-550
6. Powder Content In accordance with ASTM D6124	Max 2.0mg/glove	Below 2.0mg/glove
7. Residual Latex Proteins	Max 200 micro grams/dm^2	Max 200 micro grams/dm^2

10. Substantial equivalence comparison table

	APPLICANT	PREDICATE (K110102)
INICATIONS OF USE	PATIENT EXAMINATION GLOVE	PATIENT EXAMINATION GLOVE
AMBIDEXTROUS	YES	YES
OVER THE COUNTER USE	YES	YES
SINGLE USE	YES	YES
NON STERILE	YES	YES
POWDERFREE	YES	YES
POSITIVE BIOCOMPATABILITY TEST RESULTS	NON IRRITANT	NON IRRITANT
	NON SENSITIZER	NON SENSITIZER
PRIMARY RAW MATERIAL	NATURAL RUBBER	SYNTHETIC NITRILE RUBBER
COATED WITH ALLOGEL®	YES	YES
ALLOGEL® FORMULATION AND PROCESS, CONTROLLED BY PREVENTIVE CARE, INC.	YES	YES
PRIMARY LABEL	ALLOGEL®POWDERFREE LATEX EXAMINATION GLOVES	ALLOGEL®POWDERFREE NITRILE EXAMINATION GLOVES
SPECIFICATIONS AND PERFORMANCE		
TENSILE STRENGTH BEFORE AGING MINIMUM APPLICANT PERFORMANCE (see VOL_014_001)	18 MPA 18 MPA	14 MPA
AFTER AGING AT 70 DEG C 7 DAYS. MINIMUM APPLICANT PERFORMANCE (see VOL_014_001)	14 MPA 17 MPA	14 MPA
ULTIMATE ELONGATION BEFORE AGING MIN. APPLICANT PERFORMANCE (see VOL_014_001)	650% 797%	500%
AFTER AGING AT 70 DEG C 7 DAYS. MINIMUM APPLICANT PERFORMANCE (see VOL_014_001)	500% 753%	400%
WIDTH AT PALM (MEDIUM) +/- 5 MM APPLICANT PERFORMANCE (see VOL_014_001)	95 MM 98 MM	95 MM
LENGTH (MEDIUM) +/- 5 MM APPLICANT PERFORMANCE (see VOL_014_001)	245 241 MM	245 MM
THICKNESS AT PALM MINIMUM APPLICANT PERFORMANCE (see VOL_014_001)	0.08 MM 0.11 MM	0.07 MM
THICKNESS AT FINGER MINIMUM APPLICANT PERFORMANCE (see VOL_014_001)	0.08 MM 0.13 MM	0.07 MM
THICKNESS AT CUFF MINIMUM APPLICANT PERFORMANCE (see VOL_014_001)	0.08 MM 0.08 MM	0.07 MM
DETECTION OF PIN HOLES (ASTM D5151) APPLICANT PERFORMANCE (see VOL_014_001)	AQL 2.5 MAX AQL 1.5	AQL 2.5 MAX
RESIDUAL POWDER APPLICANT PERFORMANCE (see VOL_014_001)	2 MG/GLOVE 0.58 MG/GLOVE (MEDIUM)	2 MG/GLOVE
MINIMUM SHELF LIFE	3 YEARS	3 YEARS

MANUFACTURING PROCESS		
CONTINUOUS LINKED CHAIN DIP TECHNOLOGY	YES	YES
ALLOGEL® DIP PROCESS	YES	YES
PRINCIPAL MATERIALS USED IN THE DIP PROCESS FOR CLEANING, COAGULATING, HEATING AND DRYING ARE THE SAME	YES	YES

11. Substantial equivalence summary discussion & conclusion

The gloves covered by this application are deemed to be substantially equivalent to the predicate, K110102, Powderfree Nitrile Examination gloves coated with Allogel®. Comparisons between the applicant and this predicate device indicate substantial equivalence, in that both:

1. Have the same indication of use
2. Are Powderfree Patient Examination Gloves
3. Do not show any adverse results in bio compatibility tests
4. Are non sterile and are sold over the counter
5. Are coated with Allogel® on the inside
6. Have similar performance specifications and physical properties
7. Meet pin hole AQL requirements as per ASTM D5151 version 2006
8. Are ambidextrous
9. Are manufactured using a continuous linked chain dip technology with the usage of similar chemicals
10. Use a primary raw material that has properties of Rubber (natural/synthetic)
11. Have similar shelf life

The data and explanations provided above, both for the applicant and predicate device, illustrates that there are no substantial differences in the use, physical properties and characteristics of the devices. We can therefore conclude that the two devices are substantially equivalent. The applicant devise is therefore as safe, as effective and performs as well as, or better than the predicate device.

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

July 24, 2013

Preventive Care, Incorporated
Mr. Anil Segat
President
15215 Boulder Trail
ROSEMOUNT MN 55068

Re: K130667
Trade/Device Name: Powder- Free Latex Examination Glove Coated with AlloGel®
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: April 24, 2013
Received: April 25, 2013

Dear Mr. Segat:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K130667

Device Name: : Powder-Free Latex Examination Gloves Coated with AlloGel®

Indications for Use:

An Examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger, to prevent contamination between the patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use __X_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sreekanth Gutala -S
2013.07.22 14:24:51 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130667