



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

October 9, 2015

Gallant Quality SDN. BHD.
Ms. Sumathi Saravana Sami
Assistant QA Manager
Lot 1874, Jalan Kampung Dew
34700 Taiping, Perak
MALAYSIA

Re: K151528

Trade/Device Name: Powder Free Nitrile (Black) Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name:
Regulatory Class: I
Product Code: LZA
Dated: September 3, 2015
Received: September 9, 2015

Dear Ms. Sumathi Saravana Sami:

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" (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 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.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiologic Health

Enclosure

Indications for Use

510(k) Number (if known)

K151528

Device Name

Powder Free Nitrile (Black) Examination Gloves

Indications for Use (Describe)

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) SUMMARY
K151528**

1.0 Submitter :

Name : Gallant Quality Sdn. Bhd.
Address : Lot 1874, Jalan Kampung Dew,
34700 Taiping, Perak,
Malaysia
Phone No. : 605-847 2777
Fax No . : 605-847 9108

Contact Person : Sumathi Saravana Sami (Ms)
Email : sumathisaravana@comfort-rubber.com.my
Date of Preparation: 28 September 2015

2.0 Name of the Device

Powder Free Nitrile (Black) Examination Gloves

Common Name : Nitrile Exam Gloves
Classification Name : Patient Examination Gloves (21 CFR 880.6250)
Product Code : LZA

3.0 Identification of The Legally Marketed Devices That equivalency is claimed:

Primary Predicate:

Chlorinated Powder Free Nitrile Examination Gloves (Black Colour)
Company: Worldmed Manufacturing Sdn. Bhd.
510(k): K123116
Regulatory Class I
Product Code: LZA

4.0 Description of the Device:

The Powder Free Nitrile (Black) Examination Gloves meets all the requirements of ASTM Specification D6319-10 - Standard Specification for Nitrile Examination Gloves for Medical Application.

5.0 Intended Use of the Device

The Powder Free Nitrile (Black) Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile (Black) Examination Gloves are summarized with the following technological characteristics and is substantially equivalent to the predicate device with regard to physical characteristics, design, product features, and intended use. Both gloves

are made with nitrile and meets ASTM Specification D6319-10 - Standard Specification for Nitrile Examination Gloves for Medical Application or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D6319-10: Length – min. 230mm Width – min. 95 ± 10mm	Meets ASTM D6319-10 Standard requirements Minimal value for Length: 242 mm Minimal value for Width: 94mm
Physical Properties	ASTM D6319-10: Tensile Strength: Before Aging: 14 MPa After Aging: 14 MPa Ultimate Elongation: Before Aging: min. 500% After Aging: min. 400%	Meets ASTM D6319-10 Standard requirements Tensile Strength: Before Aging: Minimal Value: 24.74 MPa After Accelerated Aging: Minimal Value: 31.67 MPa Ultimate Elongation: Before Aging Minimal Value: 528% After Aging Minimal Value: 439%
Thickness	ASTM D6319-10 Min 0.05mm	Meets standard requirements Standard requirements Palm – min. 0.09mm Finger – min. 0.13mm
Biocompatibility	ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Under the condition of the Study – Not an irritant
	ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Under the condition of the Study – Not a sensitizer
Freedom from Pinholes	21 CFR 800.20; ASTM D5151-06 AQL 2.5	Meets 21 CFR 800.20 and ASTM D5151 – 06 Standard Requirements Passes AQL 2.5
Powder Residual	ASTM D6124-06: ≤ 2 mg/ glove	Meets ASTM D6124-06 Standard requirements Minimal Value: 0.32 mg

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of non-clinical tests that support a determination of substantial equivalence is the same as described in section 6.0 above and meets ASTM standards, and FDA requirements for water leak test on pinhole AQL.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Not applicable - Clinical data is not needed for gloves or most devices cleared by the 510(k) process.

9.0 Substantial Equivalence Comparison

The Powder Free Nitrile (Black) Examination Gloves is substantially equivalent to the predicate device with respect to intended use, product features and the technological characteristics. The substantial equivalence comparison is presented in the table below:

Characteristic and parameters	Worldmed Manufacturing Sdn. Bhd. K123116 (Predicate)	Powder Free Nitrile (Black) Examination Gloves (Proposed)	Substantial Equivalence (SE)
Product Code	LZA	LZA	SE
Intended use	Intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.	Intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.	SE
Indications for Use Statement	The nitrile examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	The Powder Free Nitrile (Black) Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.	SE
Device Material	Nitrile Synthetic Latex	Nitrile Synthetic Latex	SE
Color	Black	Black	SE
Additives	No flavor additive	No flavor additive	SE
Instruction for Use on Labeling	Single Use Only	Single Use Only	SE
Construction	Ambidextrous	Ambidextrous	SE
Sterility	Non-sterile	Non-sterile	SE
Acceptance Criteria	ASTM D6319-10	ASTM D6319-10	SE
Device Tolerance & Specifications:			
Dimensions	Meets ASTM D 6319-10	Meets ASTM D 6319-10 Overall Length – min. 230 mm Width(±10mm) Size XS – 70mm Size S – 80mm Size M – 95mm Size L – 110mm	SE

	Thickness at Finger – min. 0.05mm Thickness at Palm – min. 0.05mm	Size XL-120mm Thickness at Finger – min. 0.05mm Thickness at Palm – min. 0.05mm	
Physical Properties	Meets ASTM D6319-10: <u>Before Aging</u> Tensile strength – min. 14.0 MPa Ultimate Elongation – min. 500% <u>After Aging</u> Tensile Strength – min 14.0 MPa Ultimate Elongation – min. 400%	Meets ASTM D6319-10: <u>Before Aging</u> Tensile strength – min. 14.0 MPa Ultimate Elongation – min. 500% <u>After Aging</u> Tensile Strength – min 14.0 MPa Ultimate Elongation – min. 400%	SE
Biocompatibility Test a. Irritation Tests b. Skin Sensitization Tests	Under the conditions of the study, not an irritant and contact non-sensitizer.	Under the conditions of the study, not an irritant and contact non-sensitizer.	SE
Residual Powder Test	Meets ASTM D6124-06: ≤ 2 mg/ glove	Meets ASTM D6124-06: ≤ 2 mg/ glove	SE
Freedom from Holes	Meets ASTM D5151-06	Meets ASTM D5151-06 Passes AQL 2.5	SE

10.0 Conclusion

The Powder Free Nitrile (Black) Examination Gloves meet all of the requirements of FDA-recognized consensus standards; ASTM D6319-10, ASTM D5151-06, ASTM D6124-06 and ISO 10993-10:2010 and meet our labeling claims and pinhole acceptable quality level (AQL) as shown above.

There are no significant differences between the two products and are identical in terms of intended use, materials and performance.

The conclusion drawn from the nonclinical tests demonstrate that the device is as safe and as effective and performs as well as the legally marketed device.

Based on the comparison of intended use, design, device materials, performance and specification, the Powder Free Nitrile (Black) Examination Gloves are substantially equivalent to the predicate device.