K123116

510(k) SUMMARY

FEB 1 1 2013

1.0 Submitter :

Name : Worldmed Manufacturing Sdn. Bhd.
Address : Lot 18873, Jalan Perusahaan 3,
Kamunting Industrial Estate,
34600 Taiping, Perak,
Malaysia.
Phone No. : 605-892 5555
Fax No . : 605-829 5590
Contact Person : Ooi Loon Seng (Madam)

Date of Preparation : September 5, 2012

2.0 Name of the Device

Chlorinated Powder Free Nitrile Examination Gloves (Black Colour)

Common Name : Patient Examination Gloves

Classification Name : Patient Examination Gloves (CLASS I - 21CFR 880.6250)

510(K) Number : _____

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

Primary Predicate:

RS BLACK Black Nitrile Medical Examination Gloves (Powder Free)
Company : Riverstone Resources Sdn. Bhd.
510(K) : K112924

Additional Predicate:

Non-Sterile, Powder-Free, Black Nitrile Examination Glove
Company : YTY Industry (Manjung) Sdn. Bhd.
510(K) : K061553

4.0 Description of the Device:

The Chlorinated Powder Free Nitrile Examination Gloves (Black Colour) 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 Chlorinated Powder Free Nitrile Examination Gloves (Black Colour) is a single use disposable device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between the healthcare personnel and the patient.

6.0 Summary of the Technological Characteristics of the Device:

The Chlorinated Powder Free Nitrile Examination Gloves (Black Colour) are summarized with the following technological characteristics compared to ASTM Specification D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D6319-10	Meets standard requirements
Physical Properties	ASTM D6319-10	Meets standard requirements
Thickness	ASTM D6319-10	Meets standard requirements
Biocompatibility	ISO 10993-10:2002/Amd 1:2006(E) Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity – Amendment 1:2006-07-15	Pass (Not a primary skin irritant)
	ISO 10993-10:2002/Amd 1:2006(E) Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity – Amendment 1:2006-07-15	Pass (Not a contact sensitizer)
Watertight (1000ml)	21 CFR 800.20	Pass

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 mentioned immediately above.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

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

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9.0 Substantial Equivalence Comparison

Characteristic and parameters	Worldmed Manufacturing Sdn. Bhd.	Riverstone Resources Sdn. Bhd. K112924	YTY Industry (Manjung) Sdn. Bhd. K061553	Substantial Equivalence (SE)
Product Code	LZA	LZA	LZA	
Intended use	The Chlorinated Powder Free Nitrile Examination Gloves (Black Colour) is a single use device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between the healthcare personnel and the patient.	RS BLACK Black Nitrile Medical Examination Gloves Powder Free (Non-Sterile) 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. The device is for over-the-counter use.	The Non-Sterile, Powder-Free, Black 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.	SE
Width (Size Large)	Meets ASTM D 6319-10 (mm) XS – 70 ± 10 S – 80 ± 10 M – 95 ± 10 L – 110 ± 10 XL-120 ± 10	Meets ASTM D 6319-10	Palm Width (mm) Size XS: 73-78 S : 83-88 M : 93-98 L : 103-107	SE
Overall length	Length ≥ 240mm	Meets ASTM D 6319-10	240mm minimum for all sizes	SE
Palm thickness	Min 0.05mm	Meets ASTM D 6319-10	Min 0.08	SE
Finger thickness	Min 0.05mm	Meets ASTM D 6319-10	Min 0.08	
Tensile Strength before aging min.	14.0 MPa	Meets ASTM D 6319-10	15-21 MPa	
Tensile Strength after aging min	14.0 MPa	Meets ASTM D 6319-10	14-22 MPa	
Ultimate elongation before aging min	500%	Meets ASTM D 6319-10	550 % - 630 %	
Ultimate elongation after aging	400%	Meets ASTM D 6319-10	520 % - 610 %	

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Meets Biocompatibility	Yes	Yes	Yes	SE
Skin irritation	Passes	Passes	Passes	
Dermal sensitization	Passes	Passes	Passes	
Residual powder test	Passes – Below 2mg/glove	Meets ASTM D 6319-10	Below 2 mg/glove	
Freedom from Holes	Meets Requirements per 21CFR800.20: Gloves Free of Holes at quality level of AQL 1.5 (AQL 2.5 required per standard)	Meets ASTM D 6319-10	Multiple Normal GII AQL=2.5	Yes, SE
Materials	Nitrile Latex	Nitrile Latex compound	-	Yes, Substantial Equivalence

10.0 Conclusion

Chlorinated Powder Free Nitrile Examination Gloves (Black Colour) will perform according to the gloves performance standards referenced in section 6.0 above and meets ASTM standards and FDA requirements for water leak test on pinhole AQL. Consequently, the device is substantially equivalent to currently marketed devices.

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

February 11, 2013

Ms. Ooi Loon Seng
Regulatory Affairs Manager
Worldmed Manufacturing Sdn. Bhd.
Lot 18873, Jalan Perusahaan 3,
Kamunting Industrial Estate
Kamunting
Perak, Malaysia 34600

Re: K123116
Trade/Device Name: Chlorinated Powder Free Nitrile Examination Gloves (Black Colour)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: September 24, 2012
Received: November 13, 2012

Dear Ms. Seng:

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.

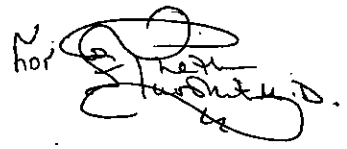
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Anthony D. Watson, B.S., M.S., M.B.A.
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

Applicant : **WORLDMED MANUFACTURING SDN. BHD.**
Lot 18873, Jalan Perusahaan 3,
Kamunting Industrial Estate,
34600 Taiping, Perak,
Malaysia.

510(k) Number (if known) : K123116

Device Name : CHLORINATED POWDER FREE NITRILE EXAMINATION GLOVES (BLACK COLOUR)

Indications For Use :

Chlorinated Powder Free Nitrile Examination Gloves (Black Colour) is a single use device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between the healthcare personnel and the patient.

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter X
Per 21 CFR 801.109

Elizabeth F. Claverie
2013.02.11 13:32:02 -05'00'

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

510(k) Number: K123116