DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 18, 2015

YTY INDUSTRY (MANJUNG) SDN. BHD.
Ms. Punitha Samy
Assistant Manager-DC/RA
Lot 1422-1424, Batu 10 Lekir
32020 Sitiawan, Perak
Malaysia

Re: K143289
Trade/Device Name: Non-Sterile, Power Free Nitrile Examination Gloves - Orange, Green, Blue and Violet Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: July 7, 2015
Received: July 13, 2015

Dear Ms. Samy:

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 Keith, M.S.
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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)*
K143289

Device Name
Non-Sterile Powder Free Nitrile Examintion Gloves
– ORANGE, GREEN, BLUE AND VIOLET COLOR

Indications for Use *(Describe)*
A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand 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.

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K143289

510 (K) SUMMARY SHEETS

1.0 **510 (K) SUMMARY**

2.0 Submitter

YTY INDUSTRY (MANJUNG) SDN. BHD.,
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Tel 605-6908533

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Name of Contact Person 1. MS. PUNITHA SAMY
E-mail:punitha@ytygroup.com.my

Date Summary Prepared August 11, 2015

3.0 Name of Device

Trade Name: Non-Sterile, Powder Free Nitrile Examination Gloves – Orange, Green, Blue and Violet Color.

Common Name: Nitrile Examination Gloves

Classification Name: Patient Examination Gloves, Powder Free

Device Classification: I

Regulation Number: 21 CFR 880.6250

Panel: General Hospital (80)

Product Code: LZA

4.0 Identification of The Legally Marketed Devices

Predicate Device Name: Non-Sterile On Line Powder Free Nitrile Blue & White Color Examination Glove]

Predicate 510(K) number: K052502

Manufacturer's Name: YTY Industry (Manjung) Sdn Bhd
Lot 1422-1424, Batu 10 Lekir, 32020 Sitiawan, Perak Darul Ridzuan

5.0 Description of The Device

Non-Sterile, Powder Free Nitrile Examination Gloves – Orange, Green, Blue and Violet Color Color meets all the current specifications listed under the ASTM Specification D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application. The principle operation and mechanism of this device is to prevent contamination between patient and examiner and this principle is achieved through testing of barrier, physical properties and other testing stated in the performance data. This device is for over-the counter single use.

6.0 The Intended Use of Glove

A patient examination gloves 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. This device is for over-the counter use.

7.0 Summary of the Technological Characteristic of the Device compared to the Predicate Device for substantial equivalent discussion

There is no difference in technology characteristic compared to the predicate device. Gloves are made from nitrile latex compound. Non-Sterile, Powder Free Nitrile Examination Gloves – Orange, Green, Blue and Violet Color have the below technological characteristic compared to ASTM or Equivalent standards.

Characteristic	Standards	Performance of Non-Sterile, Powder Free Nitrile Examination Gloves – Orange, Green, Blue and Violet Color
Dimension	ASTM D6319-10	Meets
Physical Properties	ASTM D6319-10	Meets
Freedom from holes	ASTM D6319-10	Meets
Powder-free	ASTM D6319-10	Meets
Bio-compatibility	Primary skin irritation ISO 10993-10 (2010)	Non-Irritant
	Dermal Sensitization ISO 10993-10 (2010)	Non-sensitizer

Test	**FDA 1000ml Water Leak Test**	YTY Powder Free Nitrile Examination Gloves				Non-Sterile On Line Powder Free Nitrile Blue & White Color Examination Glove
1. Watertight (1000ml) ASTM D5151-06 (2011)	Multiple Normal GII AQL = 2.5	Orange	Green	Blue	Violet	Predicate K052502
Test ASTM D6319-10	ASTM D6319-10	Holes found: 0 (Accept 1, Reject 7)	Holes found: 0 (Accept 1, Reject 7)	Holes found: 0 (Accept 1, Reject 7)	Holes found: 0 (Accept 1, Reject 7)	Holes found: 0 (Accept 1, Reject 7)
2. Length (mm) Size M	Min 230	242-257	240-249	240-250	240-244	240-251
3. Palm width (mm) Size M	95 ± 10	96-100	95-99	95-99	96-98	94-96
4. Thickness (mm) (Single Layer) Finger Palm	 Min 0.05 Min 0.05	 0.11-0.14 0.09-0.11	 0.11-0.14 0.07-0.08	 0.09-0.10 0.05-0.06	 0.09-0.11 0.06-0.07	 015-0.19 0.12-0.16
5. Physical Properties Before Aging Tensile Strength (MPa) Ultimate Elongation (%) After Aging Tensile Strength (MPa) Ultimate Elongation (%)	 Min 14 Min 500 Min 14 Min 400	 21.21-29.63 540-600 29.23-33.56 480-520	 24.15-29.21 580-620 28.72-34.84 520-540	 28.46-33.44 520-580 29.76-34.18 440-520	 23.22-29.11 520-580 27.39-30.82 440-500	 26.00-30.00 750-800 25.00-28.00 670-730
6. Residual Powder ASTM-D6124-10 (Reapproved 2011)	Max 2.0mg/glove	0.16mg/ glove	0.24mg/ glove	0.20mg/ glove	0.14mg/ glove	0.20mg/ glove
7. Biocompatibility Primary Skin Irritation Dermal Sensitization	ISO 10993-10 (2010) Non-irritant Non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer	Non-irritant Non-sensitizer

8.0 Substantial Equivalence Comparison Table with Predicate Device, K052502

Characteristics	Applicant				Predicate K052502	Medical Glove Manual (1661)
	Blue - Grape	**Blue - Apple**	**Blue - Peppermint**	**Blue - Vanilla**		
Company Name	YTY Industry (Manjung) Sdn Bhd				YTY Industry (Manjung) Sdn Bhd	FDA
Product Name	Non-Sterile, Powder Free Scented Blue Nitrile Examination Gloves				Non-Sterile, On Line Powder Free Nitrile Blue & White Color Examination Gloves	Patient Examination Gloves
Product Code	LZA				LZA	LZA – (Polymer – other than Vinyl (includes Nitrile, Polyurethane, etc.)
Indication for Use	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.				This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.	**Powder-Free Examination Gloves** 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.
Device Description	Non-Sterile, Powder Free Scented Blue Nitrile Examination Gloves meets all the current specifications listed under the ASTM Specification D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application. This device is for over-the counter single use.				Class 1 Nitrile Patient Examination Glove 80LZA, powder free that meets all requirements of ASTM Standard D6319-00aε3 and FDA water leak test.	This gloves meet all current specifications listed under ASTM specifications D6319-10
Over the Counter Use	This device is for over-the counter single use.				This device is for over-the counter single use.	Indication for use
Single Use	Single Use				Single Use	Labeling
Non Sterile or Sterile	Non Sterile				Non Sterile	Sterilization
Powder Free	Powder Free				Powder Free	Process & Attribute labeling
Compare materials						
Materials	Carboxylated Butadiene Acrylonitrile				Carboxylated Butadiene Acrylonitrile	LZA – (Polymer – other than Vinyl (includes Nitrile, Polyurethane, etc.)

Characteristics	K143289				Predicate K052502	Medical Glove Manual (1661)
	Orange	Geen	Blue	Violet		
Company Name	YTY Industry (Manjung) Sdn Bhd				YTY Industry (Manjung) Sdn Bhd	
Specifications and Performance	Dimension: Finger & Palm Thickness min: 0.05mm Physical Properties: Min 14MPa Before and After Aging Barrier: AQL 2.5					Current gloves meet ASTM D6319-10 Nitrile gloves ASTM D6124-06 (Reapproved 2011) Residual Powder ASTM D5151-06 (Reapproved 2011) Detection of Holes in Medical Gloves
Tensile Strength before aging (MPa)	21.21-29.63	24.15-29.21	28.46-33.44	23.22-29.11	26.00-30.00	
Tensile Strength after aging (MPa)	29.23-33.56	28.72-34.84	29.76-34.18	27.39-30.82	25.00-28.00	
Ultimate Elongation before aging (%)	540-600	580-620	520-580	520-580	750-800	
Ultimate Elongation after aging (%)	480-520	520-540	440-520	440-500	670-730	
Dimensions Length (mm)	242-257	240-249	240-250	240-244	240-251	
Dimensions Width (mm)	96-100	95-99	95-99	96-98	94-96	
Thickness Finger (mm)	0.11-0.14	0.11-0.14	0.09-0.10	0.09-0.11	0.15-0.19	
Thickness Cuff (mm)	0.07-0.09	0.06-0.07	0.04-0.05	0.05-0.06	0.09-0.10	
Thickness Palm (mm)	0.09-0.11	0.07-0.08	0.05-0.06	0.06-0.07	0.12-0.16	
AQL	AQL 2.5 Result: 0	AQL 2.5 Result: 0	AQL 2.5 Result: 0	AQL 2.5 Result: 0	AQL 2.5 Result: 0	
Residual Powder (mg/glove)	0.16mg/ glove	0.24mg/ glove	0.20mg/ glove	0.14mg/ glove	0.20mg/glove	
Size	M	M	M	M	M	
Bio-compatibility	Under the condition of the study the device is non-irritant and non-sensitizer	Under the condition of the study the device is non-irritant and non-sensitizer	Under the condition of the study the device is non-irritant and non-sensitizer	Under the condition of the study the device is non-irritant and non-sensitizer	Non-irritant Non-sensitizer	ISO 10993-10 Test for Irritation and Skin Sensitization
Labeling for legally marketed predicate	-Powder Free -devices color -Scent -Patient Examination Glove -Non sterile -Single Use Only -Manufactured for -Lot -Intended use				-Powder Free -devices color: Clear (Blue) -Patient Examination Glove -Non sterile -Single Use Only -Manufactured for: -Lot	Chapter 4 - Labeling

9.0 Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the device, Non-Sterile, Powder Free Nitrile Examination Gloves – Orange, Green, Blue and Violet Color and the predicate device is substantially equivalent based on intended uses, physical properties, technological characteristics and non-clinical performance. This device is as safe, effective, and performs as well as the predicate device.