FEB 19 2013

FDA 510(k), Premarket Notification: 510(k) Summary of Safety and Effectiveness Information

K123469

1.0 Submitter:

Wear Safe (Malaysia) Sdn Bhd - Facility II
LOT 63616, PT 54924, NO 3, Jalan Korporat 7C/KU9,
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2.0 Contact Person:

Contact: Mr Alex Yoong
Telephone No.: +603-3393 6088
Fax No.: +603-3393 3688

3.0 Preparation Date: 15 February 2013

4.0 Name of Device:

Trade Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non-Colored). Non-Sterile, Polymer Coated
Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non-Colored). Non-Sterile, Without Polymer (Chlorinated)
Common Name: Powder-Free Nitrile Patient Examination Glove
Classification Name: Patient Examination Glove (21 CFR Part 880.6250, Product Code LZA)

5.0 Identification of the Legally Marketed Device:

Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non Colored), Non-Sterile; Class I Patient Examination Gloves, Nitrile-80LZA, meets all of the requirements of ASTM D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application.

Predicate Device 1: K093500, Powder Free Nitrile Examination Glove, White (Non-Colored) and Blue (Colored), Non-Sterile (Chemotherapy Drug Protection Labeling Claim).

Predicate Device 2: K111772, Powder Free Nitrile Patient Examination Glove, Blue Colored and White (Non-Colored), Non-Sterile.

There are no different technological characteristics compared to the Predicate Devices. They are all Powder Free Non-Sterile Nitrile Examination Gloves, one predicate polymer coating (K111772), and the other on-line chlorination (K093500).

6.0 Description of Device:

Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non Colored), Non-Sterile meets all of the requirements of ASTM D 6319-10.
The gloves are ambidextrous single-use disposable devices that come in five sizes (XS, S, M, L, XL) in blue or white color.

7.0 Intended Use of the Device:

A 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.

8.0 Summary of the Technological Characteristics of the Device:

Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non Colored). Non-Sterile possesses the following technological characteristic (as compared to ASTM or equivalent standards):

Characteristic	Standards	Device Performance
Dimensions	ASTM D 6319-10	Meets
Physical Properties	ASTM D 6319-10	Meets
Freedom from pin-holes	ASTM D 5151-06 ASTM D 6319-10	Meets Meets
Powder Free Residue	ASTM D 6124-06 ASTM D 6319-10	Meets Meets
Biocompatibility	Dermal Sensitization (as per ISO 10993-10:2010)	Not a contact skin sensitizer
	Primary Skin Irritation Test (as per 16 CFR Part 1500)	Not a primary skin irritant

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

The performance test data that support a determination of substantial equivalence are described above.

10.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

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

11.0 Conclusion

Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non Colored), Non-Sterile performs according to the glove performance standards referenced in Section 8.0 above. This device is substantially equivalent to current marketed devices per Section 12.0.

12.0 Substantial Equivalence Comparison and Analysis

The gloves are identical to Predicate Device cleared under 510(k) K093500 with Proposed Device not tested for use with chemotherapy drugs. The difference with Chemotherapy Protection Labeling Claim in Predicate Device, does not affect the safety and effectiveness of the Proposed Device that is not tested for Chemotherapy Drugs used.

The gloves are also identical to Predicate Device cleared under 510 (k) K111772, both devices are not tested for use with chemotherapy drugs. Predicate Device is with Polymer Coated Labeling Claim, while Proposed Device is with Polymer Coated optional labeling claim.

There is difference in Blue colorant used in Proposed Device, compared with Predicate Devices. The difference Does Not affect the safety and effectiveness of the Proposed Device, as the Proposed Device Pass biocompatibility test, similar with Predicate Devices.

There is no difference between the Proposed Device and the Predicates with respect to indications for use and technological characteristics.

As such, this device is substantially equivalent to currently marketed devices. The Substantial Equivalence Comparison is summarized per Table below:-

Substantial Equivalence Comparison Table

Characteristics	Predicate Device 1 **K093500, Powder Free Nitrile Examination Glove, White (Non-Colored) and Blue (Colored), Non-Sterile (Chemotherapy Drug Protection Labeling Claim) of Wear Safe (Malaysia) Sdn Bhd**	Proposed Device **Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non Colored), Non-Sterile**	Predicate Device 2 **K111772, Powder Free Nitrile Patient Examination Glove, Blue Colored and White (Non-Colored), Non-Sterile of Kossan Latex Industries (M) Sdn Bhd.**	Proposed Device **Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non Colored), Non-Sterile**
Product Code	80 LZC	80 LZA	80 LZA	Identical
Intended Use	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Identical	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Identical
Design	Powder Free, Non Sterile, Ambidextrous, Beaded Cuff	Identical	Powder Free, Non Sterile, Ambidextrous, Beaded Cuff	Identical
Indications for Use	A powder free nitrile examination glove is a disposable device made of synthetic material intended to be worn on the hand for medical purposes to provide barrier against potentially infectious materials and other contaminants. **In addition, this product is tested for use with chemotherapy drugs.**	A 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.	A 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.	Identical

Characteristics	Predicate Device 1 **K093500, Powder Free Nitrile Examination Glove, White (Non-Colored) and Blue (Colored), Non-Sterile (Chemotherapy Drug Protection Labeling Claim) of Wear Safe (Malaysia) Sdn Bhd**	Proposed Device **Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non Colored), Non-Sterile**	Predicate Device 2 **K111772, Powder Free Nitrile Patient Examination Glove, Blue Colored and White (Non-Colored), Non-Sterile of Kossan Latex Industries (M) Sdn Bhd.**	Proposed Device **Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non Colored), Non-Sterile**
Construction	Ambidextrous, Chlorinated, Powder Free Nitrile.	Ambidextrous, Chlorinated *or Polymer Coated*, Powder Free.	Ambidextrous, Polymer Coated, Powder Free Nitrile.	Ambidextrous, Polymer Coated *or Chlorinated*, Powder Free.
Color Description	Blue and White	Identical	Blue and White	Identical
Materials	Nitrile	Identical	Nitrile	Identical
Performance I. Sterility II. Freedom from holes III. Dimension IV. Physical Properties V. Powder Free Residue	 Non-Sterile Meets ASTM D6319 Meets ASTM D6319 Meets ASTM D6319 Meets ASTM D6319	 Identical Identical Identical Identical Identical	 Non-Sterile Meets ASTM D6319 Meets ASTM D6319 Meets ASTM D6319 Meets ASTM D6319	 Identical Identical Identical Identical Identical
Single Use	Yes	Identical	Yes	Identical
Biocompatibility Test	Passes i. Primary Skin Irritation Test ii. Dermal Sensitization Test	 Identical Identical	Passes i. Primary Skin Irritation Test ii. Dermal Sensitization Test	 Identical Identical

Characteristics	**Predicate Device 1** K093500, Powder Free Nitrile Examination Glove, White (Non-Colored) and Blue (Colored), Non-Sterile (Chemotherapy Drug Protection Labeling Claim) of Wear Safe (Malaysia) Sdn Bhd	Proposed Device Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non Colored), Non-Sterile	**Predicate Device 2** K111772, Powder Free Nitrile Patient Examination Glove, Blue Colored and White (Non-Colored), Non-Sterile of Kossan Latex Industries (M) Sdn Bhd.	Proposed Device Powder Free Nitrile Patient Examination Glove, Blue Colored, and White (Non Colored), Non-Sterile
Packaging	Packed in Dispenser Boxes	Identical	Packed in Dispenser Boxes	Identical
Labeling Claim	Tested For Use with Chemotherapy Drugs Labeling Claim	*Not Tested* For Use with Chemotherapy Drugs	i. NO Chemotherapy Drugs Labeling Claim ii. Polymer Coated Labeling Claim	Identical *Optional* Polymer Coated Labeling Claim

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 19, 2013

Mr. Alex Yoong
Quality Assurance Manager
Wear Safe (Malaysia) Sdn Bhd – Facility II
Lot 63616, PT 54924, NO 3, Jalan Korporat 7C/KU9
Taman Perindustrian Meru
Mukim Kapar, Klang
Selangor, Malaysia 42200

Re: K123469
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, 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)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: January 2, 2013
Received: January 10, 2013

Dear Mr. Yoong:

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.

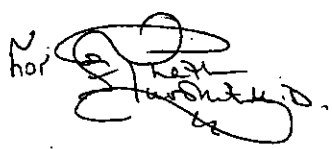
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

510(k) Number (if known): K123469

Device Name: Powder Free Nitrile Patient Examination Gloves,
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)

Indications for Use:

A 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.

Prescription Use		AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)			(21 CFR 801 Subpart C)	X

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

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.02.15 22:09:47 -05'00'

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

510(k) Number: K123469