DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 21, 2015

Supermax Plastic Products Co., Ltd
% Ms. Kathy Liu
Project Manager
Hongray USA Medical Products Inc.
3973 Schaefer Ave.
Chino, California 91710

Re: K152692
Trade/Device Name: Powder Free Vinyl Patient Examination Gloves (Green)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: November 24, 2015
Received: November 27, 2015

Dear Ms. Liu:

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 and Part 809); 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.

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 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)*
K152692

Device Name
Powder Free Vinyl Patient Examination Gloves (Green)

Indications for Use *(Describe)*
The Powder Free Vinyl Patient Examination Gloves (Green) is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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Supermax Plastic Products Co., Ltd.

314 Dragon River East Road, Luquan, Hebei Province, CHINA 050000

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR §807.92.

The assigned 510(K) number is: K152692

1. **Owner's Identification :**

Mr. Wu Zhigang
Supermax Plastic Products Co., Ltd.
314 Dragon River East Road, Luquan, Hebei Province, CHINA 050000

Tel: 86-311-83601854
Fax: 86-311-83616934

Contact: Ms. Kathy Liu, Project Manager
Address: 3973 Schaefer Ave., Chino, CA 91710
Tel: 909-590-1611
Fax: 909-590-1511
Date Summary Prepared: December 15, 2015

2**. Name of the Device:**

Trade Name: Powder Free Vinyl Patient Examination Gloves (Green)
Common Name: Patient Examination Gloves
Classification Name: Patient Examination Glove
Classification Regulation: 21 CFR 880.6250
Classification Panel: 80 General Hospitals
Product Code: LYZ
Device Class: Class I

3. **Predicate Device Information:**

Tangshan Hongyun Plastic Products Company Limited
Powder-Free Yellow Vinyl Patient Examination Gloves (K141878)

4. **Device Description:**

Powder Free Vinyl Patient Examination Gloves (Green) are Patient Examination Gloves, Disposable, single use only and non-sterile. The gloves are made of vinyl materials and are powder free. The physical and performance characteristics of the devices meet all requirements of ASTM D5250-06 (Reapproved 2011)--Standard Specification For Poly (Vinyl Chloride) Gloves For Medical Application.

5. **Intended Use of the Device:**

The Powder Free Vinyl Patient Examination Gloves (Green) is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6. **Technological Characteristics and Substantial Equivalence:**

Supermax Plastic Products Co., Ltd.'s Powder Free Vinyl Patient Examination Gloves (Green) is substantially equivalent in safety and effectiveness to the Tangshan Hongyun Plastic Products Company Limited's Powder-Free Yellow Vinyl Patient Examination Gloves (K141878). The subject device and predicate device use a similar plastic flexible barrier film to achieve a device for the intended use.

And the properties between the subject device and the predicate device are compared in the following table:

Characteristics	Standard	Device Performance		Result of comparison
		Predicate device	Subject Device	
510K number	/	K141878	K152692	--
Product name	/	Powder-Free Yellow Vinyl Patient Examination Gloves	Powder Free Vinyl Patient Examination Gloves (Green)	Similar
Product Code	/	LYZ	LYZ	Same
Intended Use	/	Powder-Free Yellow Vinyl Patient Examination Gloves is a non sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	The Powder Free Vinyl Patient Examination Gloves (Green) is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Same
Size	/	S/M/L/XL	S/M/L/XL	Same
Compare all materials used to fabricate the devices	/	PVC	PVC	Same
Dusting or Donning powder	/	PU	PU	Same
Compare performance data supporting substantial equivalence	/	Meets ASTM D5151-06(2011) ASTM D 5250-06 (2011) ASTM D6124-06(2011)	Meets ASTM D5151-06(2011) ASTM D 5250-06 (2011) ASTM D6124-06(2011)	Same
Color	/	Yellow	Green	Similar

Characteristics	Standard	Device Performance		Result of comparison
		Predicate device	Subject Device	
Single patient use	/	Single patient use	Single patient use	Similar
Dimensions: Length	ASTM D 5250-06 (2011)	Meets 230 mm min for all sizes	Meets 230 mm min for all sizes	Similar
Dimensions: Width	ASTM D 5250-06 (2011)	Meets S: 83-86 mm M: 94-97 mm L: 104-107 mm XL: 113-115 mm	Meets S: 85±5 mm M: 95±5 mm L: 105±5 mm XL: 115±5 mm	Similar
Dimensions: Thickness	ASTM D 5250-06 (2011)	Meets Palm: 0.08 mm min Finger: 0.05 mm min	Meets Palm: 0.08 mm min Finger: 0.05 mm min	Similar
Tensile strength: before and after aging	ASTM D 5250-06 (2011)	Meets Tensile Strength≥11MPa	Meets Tensile Strength≥11MPa	Similar
Elongation before and after aging	ASTM D 5250-06 (2011)	Meets Elongation≥300%	Meets Elongation≥300%	Similar
Freedom from pinholes	ASTM D 5250-06 (2011) ASTM D5151-06 (Reapproved 2011)	Meets G-I, AQL2.5	Meets G-I, AQL2.5	Similar
Residual powder	ASTM D 5250-06 (2011) ASTM D6124-06(Reaffirmation 2011)	Meets Results below 2mg of residual powder	Meets Not more than 2mg per glove	Similar
Biocompatibility	Skin irritation ISO 10993-10	Under conditions of the study, not an irritant	Under conditions of the study, not an irritant	Same
	Sensitization ISO 10993-10	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
Labeling	/	Powder Free Devices color: Yellow Patient examination Glove Non Sterile Single use only Manufactured for: Lot	Powder Free Devices color: Green Patient examination Glove Non Sterile Single use only Manufactured for: Lot	Similar

Powder Free Vinyl Patient Examination Gloves (Green) shares the same or comparable technology characteristics compared to the predicate device. The subject device performs according to the glove performance standards ASTM D5250-06(2011), biocompatibility requirement and FDA requirements and the labeling claims for the product. It performs as well as the legally marketed predicate device.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as Follows:**

Powder Free Vinyl Patient Examination Gloves (Green) meet requirements per ASTM D 5250-06(2011), per ASTM D6124-06 (2011), ASTM D5151-06(2011), 21CFR 800.20 and ISO 10993-10 third edition 2010-08-01

8. **Discussion of Clinical Tests Performed:**
Clinical data was not included in the submission. Substantial equivalence of the subject device was supported by non-clinical testing.

9. Conclusions:
Powder Free Vinyl Patient Examination Gloves (Green) conform fully to ASTM D 5250-06（2011） standard as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data discussed above.

Drawn from the complete list of non-clinical tests, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device. The subject device is substantially equivalent to the predicate device.