DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 29, 2015

Lifestyle Safety Products (Hui Zhou) Co., Ltd.
c/o Ms. Rhonda Alexander, M.S, M.P.A
Senior Regulatory Specialist
Registrar Corp
144 Research Drive
Hampton, VA 23666

Re: K143277
Trade/Device Name: Cream Stretch Vinyl Patient Examination Glove (Non-Sterile), White Vinyl Patient Examination Glove (Non-Sterile)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: June 3, 2015
Received: June 4, 2015

Dear Ms. Alexander:

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 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)*
K143277

Device Name
Cream Stretch Vinyl Patient Examination Glove (Non-Sterile), White Vinyl Patient Examination Glove (Non-Sterile)

Indications for Use *(Describe)*
The Cream Stretch Vinyl Patient Examination Glove (Non-Sterile) and White Vinyl Patient Examination Glove (Non-Sterile) are disposable devices intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner. They are both sold as non-sterile.

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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510(k) Summary (21 CFR 807.92)

I. SUBMITTER

Lifestyle Safety Products (Hui Zhou) Co., Ltd
Daxiaotang Village, Luoyang Town, Boluo County
Hui Zhou City, Guang Dong Province, 516120
China

0086-0752-6863042 (phone)
0086-0752-6863392 (fax)
Name of contact person: Mr. Lee Hong Chong
Date the summary was prepared: September 9, 2014

II. DEVICE

Name of Device:	Cream Stretch Vinyl Patient Examination Glove(Non-Sterile) White Vinyl Patient Examination Glove (Non-Sterile)
Classification Name:	Patient Examination Glove
Regulatory Class:	1
Product Code:	LYZ

III. PREDICATE DEVICE

K100978: Powder-Free Non-Sterile Vinyl Examination Glove
Manufactured by Jiangsu Sunshine Plastic Products, Co., Ltd

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Cream Stretch Vinyl Patient Examination Glove (Non-Sterile) and White Vinyl Patient Examination Glove (Non-Sterile) are patient examination gloves available in S, M, L, XL. They are provided non-sterile and meet the entire requirement of ASTM standard D 5250-06, except for sterility requirements.

V. INDICATIONS FOR USE

The Cream Stretch Vinyl Patient Examination Glove (Non-Sterile) and White Vinyl Patient Examination Glove (Non-Sterile) are disposable devices intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner. They are both sold as non-sterile.

VI. SUMMARY OF COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

At a high level, the subject and predicate devices are based on the following same technological elements:

Description	**White Vinyl Patient Examination Glove (Non-Sterile)**	**Cream Stretch Vinyl Patient Examination Glove (Non-Sterile)**	**Predicate Device K100978**
Intended Use	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	The 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.
Material	Poly Vinyl Chloride	Poly Vinyl Chloride	Poly Vinyl Chloride
Sizes	S, M, L, XL	S, M, L, XL	Information Unavailable
Single Use	Yes	Yes	Yes
Sterility	Non-sterile	Non-sterile	Non-sterile

There are no significant technological differences between the subject and predicate devices:

Characteristics	**Cream Vinyl Patient Examination Glove (Non-Sterile)**	**White Vinyl Patient Examination Glove (Non-Sterile)**	**Predicate Device performance**
Dimension	Length 246mm Width: S size = 85mm M size = 95mm L size = 105mm XL size = 115mm Finger thickness = 0.05mm Palm thickness = 0.08mm Meets ASTM D 5250-06	Length: 243mm Width: S size = 85mm M size = 95mm L size = 105mm XL size = 115mm Finger thickness = 0.05mm Palm thickness = 0.08mm Meets ASTM D5250-06	Meets ASTM D 5250-06
Physical Properties	Tensile strength = 16.3MPa Elongation = 391% Meets ASTM D 5250-06	Tensile strength = 15.7MPa Elongation = 385% Meets ASTM D 5250-06	Meets ASTM D 5250-06
Freedom from pinholes	Pinhole = 8/500 AQL 1.5 Meets ASTM D5151-06	Pinhole = 10/500 AQL 1.5 Meets ASTM D5151-06	Meets 21 CFR 800.20
Powder Residual	Powder residue = 1mg Meets ASTM D5250-06 and D6124-06	Powder residue = 1mg Meets ASTM D5250-06 and D6124-06	Meets ASTM D6124-06
Cytotoxicity (ISO10993-5)	Passes	Passes	N/A
Biocompatibility	Primary Dermal Irritation in rabbits – under the	Primary Dermal Irritation in rabbits –	Passes

	conditions of the study, not an irritant. Dermal Sensitization in the guinea pig – under conditions of the study; not a sensitizer.	under the conditions of the study, not an irritant. Dermal Sensitization in the guinea pig – under conditions of the study; not a sensitizer.	Passes

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

- ASTM D5250-06
- ASTM D5151

Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The subject device is considered to be a surface device, contacting intact skin, for a duration of less than 24 hours.

VIII. CONCLUSIONS

Since there are minimal differences between the predicate device and the subject devices, we conclude that the subject devices perform comparably to the predicate device that is currently marketed for the same intended use.