DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 2, 2016

Kaixing Plastic Products Co., Ltd.
% Daniel Qiu
Project Manager
Lichen Commercial Information Consulting Co., Ltd.
Room 1304, Building 8, Yuntai Rd. 453 Pudong New District,
Shanghai, CN 200126

Re: K160675
Trade/Device Name: Powder free vinyl patient examination glove, colored (yellow)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: June 24, 2016
Received: June 24, 2016

Dear Mr. Qiu:

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

Tina Kiang, Ph.D.
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)*
K160675

Device Name

Powder free vinyl patient examination glove, colored(yellow)

Indications for Use *(Describe)*

Powder free vinyl patient examination glove, colored (yellow) is a non-sterile, disposable device intended for medical purposes that is worn on the examiner's hand 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.

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

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510(k) Summary

I, Submitter's information

Name: KAIXING PLASTIC PRODUCTS CO., LTD.
Address: 1101 Tanggang Road Luannan County Tangshan City, Hebei Province China
Contact person: Danny Xing
Telephone: +86-315-4167693
Fax: +86-315-4168700

II, Date prepared

May 27, 2016

III, Device

Name of the device: Powder free vinyl patient examination glove, colored (yellow)
Classification name: Patient examination glove
Regulation class: 1
Regulation number: 21CFR 880.6250
Panel: General hospital
Product code: LYZ

IV, Predicative device

K143277, White vinyl patient examination glove, Life safety products (Hui Zhou) Co., Ltd.

V, Device description

Powder free vinyl patient examination glove, colored (yellow) are patient examination gloves available in S, M, L, XL. They are provided non-sterile and meet the entire requirement of ASTM standard D5250-06(reapproved), except for sterility requirements.

VI, Indication for use

Powder free vinyl patient examination glove, colored (yellow) is a non-sterile, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

VII, Summary of comparison of technological characteristics with the predicative device

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

Description	Powder free vinyl patient examination glove, colored(yellow) Subject device(K160675)	White vinyl patient examination glove(non-sterile) Predicate device(K143277)	Comments
Intended use	Powder free vinyl patient examination glove, colored (yellow) is disposable device intended for medical purposes that is worn on the examiner's hand 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	Substantially Equivalent
Material	Poly vinyl Chloride	Poly vinyl Chloride	Substantially Equivalent
Sizes	S,M,L, XL	S,M,L,XL	Substantially Equivalent
Single use	Yes	Yes	Substantially Equivalent
Sterility	Non-sterile	Non-sterile	Substantially Equivalent

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

Characteristics	Powder free vinyl patient examination glove, colored(yellow)	White vinyl patient examination glove(non-sterile) Predicate device(K143277)	Comments
Dimension	Length: ≥ 230mm Width: S Size 85±5mm M Size 95±5mm L Size 105±5mm XL Size 115±5mm Finger thickness≥0.05mm Palm thickness≥0.08mm Meets ASTM D5250-06	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	Substantially Equivalent
Physical properties	Tensile strengthen≥11MPa Elongation≥300% Meets ASTM D5250-06	Tensile strengthen=15.7MPa Elongation=385% Meets ASTM D5250-06	Substantially Equivalent
Freedom from pinholes	Pinhole=0/200 AQL 2.5 Meets ASTM D5151-06	Pinhole=10/500 AQL 1.5 Meets ASTM D5151-06	Substantially Equivalent

Powder residual	Powder residual=0.5mg per glove Meets ASTM D5250-06 and D6124-06	Powder residual= 1mg Meets ASTM D5250-06 and D6124-06	Substantially Equivalent
Cytotoxicity	Per ISO10993-5, under the conditions tested, the subject glove is non-cytotoxic.	Per ISO10993-5, under the conditions tested, the subject glove is non-cytotoxic.	Substantially Equivalent
Biocompatibity	Per ISO10993-10, under the conditions tested, the subject glove was non-sensitizing and non-irritating.	Per ISO10993-10, under the conditions tested, the subject glove was non-sensitizing and non-irritating.	Substantially Equivalent

VIII, Performance data

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

- ASTM D5250-06
- ASTM D5151-06
- ASTM D6124-06

Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA draft guidance Use of international standard ISO-10993, "Biological evaluation of medical device part 1: Evaluation and testing," dated April 23, 2013 and international standard ISO10993-1 "Biological evaluation of medical devices-part 1: Evaluation and testing within a risk management process," as recognized by FDA. The group of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

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

IX, Conclusions

The Kaixing Plastic Products Co., LTD powder free vinyl patient examination glove, colored(yellow) is substantially equivalent to the predicate device, Lifestyle Safety Products, Co, LTD White vinyl patient examination glove (non-sterile). Based on the non-clinical tests performed, the subject device is as safe, as effective and performs as well as the legally marketed predicate device, Lifestyle Safety Products, Co, LTD White vinyl patient examination glove (non-sterile) cleared under K143277.