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

June 22, 2017

Better Care Plastic Technology Co., Ltd.
% Kathy Liu
Project Manager
Hongray USA Medical Products Inc
2235 E Francis St
Ontario, California 91761

Re: K171047
Trade/Device Name: Sterile Polyisoprene Powder Free Surgical Gloves
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO
Dated: May 17, 2017
Received: May 17, 2017

Dear Kathy 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); 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,

Mark S. Fellman -S

for

Lori A. Wiggins, MPT, CLT
Acting 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)*
K171047

Device Name
Sterile Polyisoprene Powder Free Surgical Gloves

Indications for Use *(Describe)*
This surgeon's glove is a sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Better Care Plastic Technology Co., Ltd.

Fuqian Xi Road, West district of Shenze Industrial Base,
Shenze County, Hebei Province, CHINA 050000

510(K) SUMMARY

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

The assigned 510(K) numbers: K171047

1. **Owner's Identification:**

Mrs. Zhu Chunyan
Better Care Plastic Technology Co., Ltd.
Fuqian Xi Road, West district of Shenze Industrial Base, Shenze County, Hebei Province, CHINA 050000

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

Contact: Ms. Kathy Liu, Project Manager
Address: 2235 E Francis St, Ontario CA 91761
Tel:909-590-1611
Fax: 909-673-8347

Date Summary Prepared: March 23, 2017

2**. Name of the Device:**

Trade Name: Sterile Polyisoprene Powder Free Surgical Gloves
Common Name: Surgeon's Gloves
Classification Name: Surgeon's Gloves
Classification Regulation:21 CFR 878.4460
Product Code: KGO
Classification Panel: General and Plastic Surgery
Device Class: Class I

3. **Predicate Device Information:**

Ansell Healthcare Products LLC.
111 Wood Avenue South, Suite 210, Iselin, NJ 08830 USA
Gammex PI Hybrid Surgical Glove (also marketed as Encore PI HybridSurgical Glove) (K 151694)

4. **Device Description:**
The subject device is single-use disposable powder-free surgical glove that is supplied

sterile and made of polyisoprene.

5. **Intended for Use:**

This surgeon's glove is a sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.

6. **Technological Characteristics:**

Sterile Polyisoprene Powder Free Surgical Gloves have the following technological characteristics as compared to ASTM or equivalent standards:

Technological Characteristics	Standard/Test/FDA Guidance	Result Summary
Dimensions	ASTM D3577-09(2015)	Meets ASTM D3577 requirements for length, width and thickness
--Length	Minimum 265mm	Average 305mm
--Palm Width (size)	(mm)	Average value in mm
$5^1/_2$	70±6	73
6	76±6	79
$6^1/_2$	83±6	86
7	89±6	91
$7^1/_2$	95±6	97
8	102±6	105
$8^1/_2$	108±6	111
9	114±6	117
--Thickness		Average value in mm
Finger	Minimum 0.10	0.22
Palm	Minimum 0.10	0.20
Cuff	Minimum 0.10	0.18
Physical Properties	ASTM D3577-09(2015)	Meets ASTM D3577-09(2015) requirements for tensile strength and elongation at break before and after accelerated aging
Tensile Strength, Before Aging	17MPa, min	Average 19.4MPa
Ultimate Elongation, Before Aging	650%, min	Average 823%
Stress at 500% Elongation	7.0 MPa, max	Average 2.2MPa
Tensile Strength, After Accelerated Aging	12MPa, min	Average 17.1 MPa
Ultimate Elongation, After Accelerated Aging	490%, min	Average 748 %
Freedom from holes	ASTM D3577-09(2015)	Meets ASTM D3577-09 (2015)

	ASTM D 5151-06(2015)	and ASTMD5151-06(2015) requirements of AQL1.5
Powder-Free	ASTM D3577-09(2015) ASTM D 6124-06(2011)	Meets Applicable requirement for Powder Free; ≤ 2 mg per glove
Sterility	ANSI/AAMI/ISO 11137-1:2006	Meets ANSI/AAMI/ISO 11137-1:2006 requirement of 10^{-6} SAL
Biocompatibility		
ISO Skin Irritation Study	ISO 10993-10:2010	Under the conditions of the study, not an irritant
ISO Maximization Sensitization Study	ISO 10993-10:2010	Under the conditions of the study, not a sensitizer

7. **Substantial Equivalence:**

Substantial Equivalence Comparison Table

	Predicate	Subject Device	Comparison
Device Class	Class I	Class I	Same
510K	K151694	K171047	Same
Product Code	KGO	KGO	Same
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Same
Regulation Name	Surgeon's	Surgeon's	Same
Indications for Use	This glove is intended to be worn by operating room personnel to protect a surgical wound from contamination.	This surgeon's glove is a sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination	Same
Prescription	Over-The-Counter-Use	Over-The-Counter-Use	Same
Materials	Synthetic rubber blend of polyisoprene and neoprene	Synthetic polyisoprene rubber	Different
Design	Single use	Single use	Same
Sterile	Sterile	Sterile	Same
Powder-free	Powder-free	Powder-free	Same
Hand specific	Hand specific	Hand specific	Same
Beaded cuff	Beaded cuff	Beaded cuff	Same
Color	White	Clear	Different
Sterilization Method	Radiation	Radiation	Same
Sterility Assurance Level (SAL)	10^{-6}SAL	10^{-6}SAL	Same
Shelf Life	3 years	3 years	Same
Dimensions and physical properties	Meets ASTM D3577-09(2015)requirements	Meets ASTM D3577-09(2015)requirements	Same

Freedom from holes	Meets ASTM D3577-09(2015)requirements of	Meets ASTM D3577-09(2015)requirements of	Same

	AQL 1.5	AQL 1.5	
Powder-Free	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	
Biocompatibility	"Under the conditions of the study, not an irritant" and "Under the conditions of the study, not a sensitizer"	"Under the conditions of the study, not an irritant" and "Under the conditions of the study, not a sensitizer"	

The subject device is manufactured from Synthetic polyisoprene rubber with polyurethane polymer inner coating to aid donning. The predicate device is manufactured from Synthetic rubber blend of polyisoprene and neoprene with polyurethane polymer inner coating to aid donning. Though the materials of construction differ, the subject device's materials are functionally equivalent to those of the cited predicate.

The subject device meets the applicable requirements for surgeon's gloves with regard to dimensions and sizes, physical properties, freedom from holes, powder residues, and protein content as found in the following standards: ASTM D3577-09(2015), ASTM D5151-06(2015) and ASTM D6124-06(2011). The subject device passes biological reactivity testing for dermal sensitization and irritation, in accord with the ISO 10993 series of standards.

8. **Performance Data**

A clinical study was not conducted on the subject or predicate devices.

9**. Conclusion:**

Based on the performed nonclinical test results, the Sterile Polyisoprene Powder Free Surgical Gloves is as safe, as effective, and performs as well as or better than the legally marketed device identified as Gammex PI Hybrid Surgical Glove, which was previously cleared under K151694, Class I (21 CFR 878.4460, Product code KGO).