DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 18, 2017

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

Re: K171898
Trade/Device Name: Sterile Polyisoprene Powder Free Surgical Gloves, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO, LZC,
Dated: June 22, 2017
Received: June 26, 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,

Tara A. Ryan -S

for
Lori Wiggins

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)*
K171898

Device Name
Sterile Polyisoprene Powder Free Surgical Gloves, Tested for Use With Chemotherapy Drugs

Indications for Use *(Describe)*
This glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978.
The following chemicals have been tested with these gloves.
The tested chemotherapy drugs' breakthrough detection times are listed as follows:

Chemotherapy Drug	Minimum BDT
Carmustine, 3.3 mg/ml	16.0 min.
Cisplatin, 1.0 mg/ml	>240 min.
Cyclophosphamide (Cytoxan) , 20 mg/ml	>240 min.
Doxorubicin Hydrochloride, 2.0 mg/ml	>240 min.
Etoposide (Toposar) , 20.0 mg/ml	>240 min.
Fluorouracil, 50.0 mg/ml	>240 min.
Methotrexate, 25 mg/ml	>240 min.
Paclitaxel (Taxol) , 6.0 mg/ml	>240 min.
Thiotepa, 10.0 mg/ml	16.6 min.
Vincristine Sulfate, 1.0 mg/ml	>240 min

Please note that the following drugs have extremely low permeation time of less than 30 minutes. Carmustine (3.3 mg/ml) has a minimum breakthrough time of 16.0 minutes; and Thiotepa (10.0 mg/ml) has a minimum breakthrough time of 16.6 minutes. WARNING: Do not use with Carmustine and Thio-Tepa.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Paperwork Reduction Act (PRA) Staff
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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) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR§807.92.

The assigned 510(K) numbers: K171898

1. **Owner's Identification:**

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

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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: August 11, 2017

2**. Name of the Device:**

Trade Name: Sterile Polyisoprene Powder Free Surgical Gloves, Tested for Use With Chemotherapy Drugs
Common Name: Surgeon's Gloves
Classification Name: Surgeon's Gloves
Classification Regulation: 21 CFR878.4460
Product Code: KGO L Z C
Classification Panel: General and Plastic Surgery
Device Class: Class I

3. **Predicate Device Information:**

Medline Industries, Inc.
1 Medline Place, Mundelein, IL 60060
SensiCare PI Surgical Glove (K152428)

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

sterile and made of polyisoprene. The gloves have been tested for use with chemotherapy drugs per ASTM D6978.

5. **Intended for Use:**

This glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978.

The following chemicals have been tested with these gloves.

The tested chemotherapy drugs' breakthrough detection times are listed as follows:

Chemotherapy Drug	Minimum BDT
Carmustine, 3.3 mg/ml	16.0 min.
Cisplatin, 1.0 mg/ml	>240 min.
Cyclophosphamide (Cytoxan) , 20 mg/ml	>240 min.
Doxorubicin Hydrochloride, 2.0 mg/ml	>240 min.
Etoposide (Toposar) , 20.0 mg/ml	>240 min.
Fluorouracil, 50.0 mg/ml	>240 min.
Methotrexate, 25 mg/ml	>240 min.
Paclitaxel (Taxol) , 6.0 mg/ml	>240 min.
Thiotepa, 10.0 mg/ml	16.6 min.
Vincristine Sulfate, 1.0 mg/ml	>240 min

Please note that the following drugs have extremely low permeation time of less than 30 minutes. Carmustine (3.3 mg/ml) has a minimum breakthrough time of 16.0 minutes; and Thiotepa (10.0 mg/ml) has a minimum breakthrough time of 16.6 minutes

6. **Technological Characteristics:**

Sterile Polyisoprene Powder Free Surgical Gloves, Tested for Use With Chemotherapy Drugs is substantially equivalent to the predicate, K152428, SensiCare PI Surgical gloves. Both gloves have the same intended use, same material and the same device performance.

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Predicate Device	Subject Device	Comparison Analysis
Device Class	Class I	Class I	similar
510K	K152428	K171898	/
Product Code	KGO LZC	KGO LZC	similar
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	similar
Regulation Name	Surgeon's	Surgeon's	similar
Indications for Use	The SensiCare PI surgeon's glove is a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. In	This glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978.	similar

Size	addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Warning: Do not use with Carmustine and Thiotepa 5 1/2, 6, 6 1/2, 7, 7 1/2, 8, 8 1/2, 9	Please note that the following drugs have extremely low permeation time of less than 30 minutes. Carmustine (3.3 mg/ml) has a minimum breakthrough time of 16.0 minutes; and Thiotepa (10.0 mg/ml) has a minimum breakthrough time of 16.6 min 5 1/2, 6, 6 1/2, 7, 7 1/2, 8, 8 1/2, 9	similar
Materials	Polyisoprene	Polyisoprene	similar
Color	Cream colored	Cream colored	similar
Dimensions-Length	Meets ASTM D3577 270mm min.	Meets ASTM D3577 270mm min.	similar
Dimensions-Width	Meets ASTM D3577 5 1/2-70±6mm 6-76±6mm 6 1/2-83±6mm 7-89±6mm 71/2-95±6mm 8-102±6mm 8 1/2-108±6mm 9-114±6mm	Meets ASTM D3577 5 1/2-70±6mm 6-76±6mm 6 1/2-83±6mm 7-89±6mm 71/2-95±6mm 8-102±6mm 8 1/2-108±6mm 9-114±6mm	similar
Dimensions-Finger Thickness	Meets ASTM D3577 0.10mm min.	Meets ASTM D3577 0.10mm min.	similar
Dimensions-Palm Thickness	Meets ASTM D3577 0.10mm min.	Meets ASTM D3577 0.10mm min.	similar
Dimensions-Cuff Thickness	Meets ASTM D3577 0.10mm min.	Meets ASTM D3577 0.10mm min.	similar
Physical Properties	Meets ASTM D3577 Before Aging Tensile Strength - 17 MPa min Ultimate Elongation – 650% min Stress at 500% Elongation – 7.0 MPa min	Meets ASTM D3577 Before Aging Tensile Strength - 17 MPa min Ultimate Elongation 650% min Stress at 500% Elongation 7.0 MPa min	similar
	Meets ASTM 3577 After Aging Tensile Strength – 12 MPa min Ultimate Elongation – 490% min	Meets ASTM 3577 After Aging Tensile Strength – 12 MPa min Ultimate Elongation 490%min	similar
Freedom from holes	Meets 21 CFR 800.20 and ASTM D3577 when tested in accordance with ASTM D5151 Inspection Level 1, AQL 1.5	Meets 21 CFR 800.20 and ASTM D3577 when tested in accordance with ASTM D5151 Inspection Level 1, AQL 1.5	similar
Powder-Free-Residual Powder	<2mg of residual powder when tested in accordance with ASTM D3577	<2mg of residual powder when tested in accordance with ASTM D3577	similar
Sterilization Method	Radiation	Radiation	similar

Sterility Assurance Level (SAL)	10^{-6}SAL	10^{-6}SAL	similar
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"	similar
Chemotherapy Drugs Tested	Carmustine 10.1 Cisplatin>240 Cyclophosphamide>240 Doxorubicin Hydrochloride> 240 Etoposide>240 Fluorouracil>240 Methotrexate>240 Paclitaxel>240 Thiotepa 11.6 Vincristine Sulfate>240 Cytarabine>240 Dacarbazine >240 Ifosfamide >240 Mitomycin >240 Mitoxantrone >240	Carmustine, 16.0 Cisplatin,>240 Cyclophosphamide>240 Doxorubicin Hydrochloride >240 Etoposide >240 Fluorouracil, >240 Methotrexate, >240 Paclitaxel >240 Thiotepa, 16.6 Vincristine Sulfate>240	similar
Elements contained on product Labeling			
Product Identifier	Yes	Yes	similar
Size	Yes	Yes	similar
Single use only	Yes	Yes	similar
Country of manufacturing	Yes	Yes	similar
List of chemotherapy drugs and breakthrough times	Yes	Yes	similar

8.**Performance Data**

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), ASTM D6124-06(2011) and ASTM D6978. The subject device passes biological reactivity testing for dermal sensitization and irritation, in accord with the ISO 10993 series of standards.

9.**Summary of clinical Testing**

This section does not apply. No clinical testing was performed.

10**. Conclusion:**

The nonclinical testing performed on the Sterile Polyisoprene Powder Free Surgical Gloves, Tested for use with Chemotherapy Drugs demonstrates that this device is as safe, as effective, and performs as well as the predicate device SensiCare PI Surgical Glove, previously cleared under K152428, Class I (21 CFR 878.4460, Product code KGO).