Better Care Plastic Technology Co., Ltd

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

JUL 0 8 2014

Product: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)

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: K140816

1. **Owner's Identification:**

Ms. 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
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Fax: 909-590-1511
Date Summary Prepared: June 18, 2014

2. **Name of the Device:**

Trade Name: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)
Common Name: Exam Gloves
Classification Name: Patient Examination Glove
Classification Regulation: 880.6250
Classification Panel: 880 General Hospital and Personal Use
Product Code: LZA
Device Class: Class I

3. **Predicate Device Information:**

Syntex Healthcare Products Co., Ltd.
Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue) (K102096)

Better Care Plastic Technology Co., Ltd
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Product: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)

4. **Device Description:**

Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue) are Patient Examination Gloves, Disposable, single use only and non-sterile. The gloves are made of nitrile rubber materials and are powder free. The physical and performance characteristics of the devices meet all requirements of ASTM standard D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application.

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

A patient examination glove 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.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Test Chemotherapy Drug and Concentration	Average BDT
Fluorouracil, 50.0mg/ml (50,000ppm)	>240 min.
Etoposide (Toposar), 20.0mg/ml (20,000ppm)	>240 min.
Cyclophosphamide (Cytoxan), 20mg/ml (20,000ppm)	>240 min.
Carmustine (BCNU), 3.3mg/ml (3,300ppm)	2.3 min.
Thiotepa, 10.0mg/ml (10,000ppm)	30.9 min.
Paclitaxel (Taxol), 6.0mg/ml (6,000ppm)	>240 min.
Doxorubicin Hydrochloride, 2.0mg/ml (2,000ppm)	>240 min.
Dacarbazine (DTIC), 10.0mg/ml (10,000ppm)	>240 min.
Cisplatin, 1.0mg/ml (1,000ppm)	>240 min.

Please note that Carmustine and Thiotepa have extremely low permeation times of 30.9 minutes and 2.3 minutes, respectively.

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

Better Care Plastic Technology Co., Ltd's Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue) is substantially equivalent in safety and effectiveness to the Syntex Healthcare Products Co., Ltd's Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue) (K102096). 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	
Product Code	/	LZA	LZA	Substantial equivalence

Better Care Plastic Technology Co., Ltd
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Product: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)

Characteristics	Standard	Device Performance		Result of comparison
		Predicate device	Subject Device	
Intended Use	/	Predicate device 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. The average BDT for tested chemotherapy drugs of Fluorouracil, 50.0mg/ml (50,000ppm), Etoposide (Toposar), 20.0mg/ml (20,000ppm), Cyclophosphamide (Cytoxan), 20mg/ml (20,000ppm), Paclitaxel (Taxol), 6.0mg/ml (6,000ppm), Doxorubicin Hydrochloride, 2.0mg/ml (2,000ppm), Dacarbazine (DTIC), 10.0mg/ml (10,000ppm), Cisplatin, 1.0mg/ml (1,000ppm) is >240min, and Carmustine and Thiotepa have extremely low permeation times of less than 30 minutes.	Subject device 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. The average BDT for tested chemotherapy drugs of Fluorouracil, 50.0mg/ml (50,000ppm), Etoposide (Toposar), 20.0mg/ml (20,000ppm), Cyclophosphamide (Cytoxan), 20mg/ml (20,000ppm), Paclitaxel (Taxol), 6.0mg/ml (6,000ppm), Doxorubicin Hydrochloride, 2.0mg/ml (2,000ppm), Dacarbazine (DTIC), 10.0mg/ml (10,000ppm), Cisplatin, 1.0mg/ml (1,000ppm) is >240min, and Carmustine and Thiotepa have extremely low permeation times of 30.9 mins and 2.3mins, respectively	Substantial equivalence

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Product: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)

Characteristics	Standard	Device Performance		Result of comparison
		Predicate device	Subject Device	
Labeling	/	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	Substantial equivalence
Device Materials	/	Nitrile compound	Nitrile Compound	Substantial equivalence
Color	/	Blue	Blue	Substantial equivalence
Device tolerances and specifications & Performance Data:				
Tensile strength: before and after aging	ASTM D6319-10	Meets	Meets	Substantial equivalence
Ultimate elongation: before and after aging	ASTM D6319-10	Meets	Meets	Substantial equivalence
Freedom from pinholes	ASTM D6319-10	Meets	Meets	Substantial equivalence
Dimensions: Overall length, Width, Palm and Finger thickness	ASTM D6319-10	Meets	Meets	Substantial equivalence
Residual powder	ASTM D6319-10, ASTM D6124	Meets	Meets	Substantial equivalence
Biocompatibility				
Primary skin irritation test	ISO 10993-10	Under conditions of the study, not an irritant	Under conditions of the study, not an irritant	Substantial equivalence
Dermal sensitization assay	ISO 10993-10	Under conditions of the study, not a sensitizer	Under conditions of the study, not a sensitizer	Substantial equivalence
Resistance to Permeation				
Resistance to Permeation	ASTM D6978-05	Carmustine and Thiotepa have extremely low permeation times of less than 30 minutes.	Carmustine and Thiotepa have extremely low permeation times of 30.9 minutes and 2.3 minutes, respectively.	Substantial equivalence

Better Care Plastic Technology Co., Ltd
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Product: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)

Characteristics	Standard	Device Performance		Result of comparison
		Predicate device	Subject Device	
Indication for Use	/	It 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. The average BDT for tested chemotherapy drugs of Fluorouracil, 50.0mg/ml (50,000ppm), Etoposide (Toposar), 20.0mg/ml (20,000ppm), Cyclophosphamide (Cytoxan), 20mg/ml (20,000ppm), Paclitaxel (Taxol), 6.0mg/ml (6,000ppm), Doxorubicin Hydrochloride, 2.0mg/ml (2,000ppm), Dacarbazine (DTIC), 10.0mg/ml (10,000ppm), Cisplatin, 1.0mg/ml (1,000ppm) is >240min, and Carmustine and Thiotepa have extremely low permeation times of less than 30 minutes.	A patient examination glove 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. The average BDT for tested chemotherapy drugs of Fluorouracil, 50.0mg/ml (50,000ppm), Etoposide (Toposar), 20.0mg/ml (20,000ppm), Cyclophosphamide (Cytoxan), 20mg/ml (20,000ppm), Paclitaxel (Taxol), 6.0mg/ml (6,000ppm), Doxorubicin Hydrochloride, 2.0mg/ml (2,000ppm), Dacarbazine (DTIC), 10.0mg/ml (10,000ppm), Cisplatin, 1.0mg/ml (1,000ppm) is >240min, and Carmustine and Thiotepa have extremely low permeation times of 30.9 mins and 2.3mins, respectively	Substantial equivalence

Product: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)

Better Care Plastic Technology Co., Ltd's Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue) shares the same or comparable technology characteristics compared to the predicate device. The subject device performs according to the glove performance standards ASTM D6319-10, 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:**

Characteristics	Applicable FDA- Recognized Standards	Performance Results
Dimensions	ASTM D 6319-10	Meets
Physical Properties	ASTM D 6319-10	Meets
Freedom from holes	ASTM D 6319-10 ASTM D5151-06(2011) 21CFR800.20	Meets
Residual Powder Test	ASTM D 6319-10 ASTM D6124-06 (Reapproved 2011)	Meets
Primary Skin Irritation and Skin Sensitization	ISO 10993 Part 10	Meets
Resistance to Permeation	ASTM D6978-05	See Data in Section 18

8. **Discussion of Clinical Tests Performed:**
Not Applicable – There is no hypoallergenic Claim. There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing.

9. **Labeling:**
Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue) with a chemotherapy claim, which are tested per ASTM D6978, and provide protection against: Fluorouracil, Etoposide (Toposar), Cyclophosphamide (Cytoxan), Paclitaxel (Taxol), Doxorubicin Hydrochloride, Dacarbazine (DTIC), Cisplatin. Do not use with Carmustine and Thiotepa. The tested chemotherapy drugs' breakthrough detection times, refer to item 5 in this summary for details.

We do not claim our gloves as hypoallergenic on our labels.

Product: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)

10. **Conclusions:**

Better Care Plastic Technology Co., Ltd's Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue) conform fully to ASTM D 6319-10 standard as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data discussed above. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

Drawn from the complete list of non-clinical tests, the device herein mentioned is as safe, as effective, and performs as well as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 8, 2014

Better Care Plastic Technology Company, Limited
C/O Ms. Kathy Liu
Official Correspondent
Hongray USA Medical Products, Incorporated
3973 Schaefer Avenue
Chino, CA 91710

Re: K140816
Trade/Device Name: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA, LZC
Dated: June 4, 2014
Received: June 6, 2014

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); 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mary FDA ner -S

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)*
K140816

Device Name
Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)

Indications for Use *(Describe)*
A patient examination glove 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.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

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Dacarbazine (DTIC), 10.0mg/ml (10,000ppm)	>240 min.
Cisplatin, 1.0mg/ml (1,000ppm)	>240 min.

Please note that Carmustine and Thiotepa have extremely low permeation times of 2.3 minutes and 30.9 minutes, respectively.

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)*

Sreekanth Gutala -S

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