October 11, 2023

Better Care Plastic Technology Co., Ltd
Ms. Zhu Chunyan
General Manager
Fuqian Xi Road, West district of Shenze Industrial Base
Shenze County, Hebei, China 050000

Re: K232070
Trade/Device Name: Biodegradable Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Black, Green)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: September 14, 2023
Received: September 14, 2023

Dear Ms. Zhu Chunyan :

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232070

Device Name
Biodegradable Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Black, Green)

Indications for Use *(Describe)*
The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05(2019).

Black Glove:

Chemotherapy Drug	Minimum Breakthrough Detection Time in Minutes
Carmustine 3.3 mg/ml {3,300 ppm)	23.0
Cisplatin 1mg/ml {1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Paclitaxel, 6mg/ml {6,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	45.9

Fentanyl Citrate	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection, 100mcg/2mg	>240

*Please note that the following drugs have extremely low permeation times: Carmustine: 23.0 minutes, Thie Tepa: 45.9 minutes
Warning: Do not use with Carmustine and Thiotepa.

Green Glove:

Chemotherapy Drug	Minimum Breakthrough Detection Time in Minutes
Carmustine 3.3 mg/ml {3,300 ppm)	15.4
Cisplatin 1mg/ml {1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Paclitaxel, 6mg/ml {6,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	34.4

Fentanyl Citrate	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection, 100mcg/2mg	>240

*Please note that the following drugs have extremely low permeation times: Carmustine: 15.4 minutes, Thio Tepa: 34.4 minutes
Warning: Do not use with Carmustine and Thiotepa.

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.

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Better Care Plastic Technology Co., Ltd

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

510(k) Summary

The assigned 510(K) numbers: K232070

Date Prepared: October 10, 2023

1. Owner's Identification:

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

Contact: Ms. Zhu Chunyan / General Manager
Tel: 909-590-1611
Email: janicema@hongrayusa.com or fdareg@hongray.com.cn

2. Device Identification:

Trade / Product Name: Biodegradable Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Black, Green)
Common Name: Non-Powdered Patient Examination Glove
Classification Name: Patient Examination Glove Specialty
Classification Regulation: 21 CFR 880.6250
Product Code: LZA, LZC, QDO, OPJ
Classification Panel: General Hospital
Device Class: Class I

3. Predicate Device Information:

Hartalega NGC SDN. BHD.
Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Fusion Colour) (K223437)

4. Device Description:

Biodegradable Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Black, Green) are Class I Patient Examination Gloves and Specialty Chemotherapy Gloves. They are ambidextrous and come in different sizes - Extra Small, Small, Medium, Large, Extra Large and XXL. Gloves meet the specification of ASTM D6319-19 and have been tested for resistance to permeation by chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05(2019). The gloves are single use, disposable, and provided non-sterile. The glove has biodegradation property within landfills tested per ASTM D5511.

5. Indications for Use:

The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978- 05(2019).

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

510(k) Summary

Black glove:

Chemotherapy Drug	Minimum Breakthrough Detection Time in Minutes
Carmustine 3.3 mg/ml (3,300 ppm)	23.0
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Paclitaxel, 6mg/ml (6,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	45.9

Fentanyl Citrate	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection, 100mcg/2mg	>240

*Please note that the following drugs have extremely low permeation times:
Carmustine: 23.0 minutes, Thio Tepa: 45.9 minutes
Warning: Do not use with Carmustine and Thiotepa.

Green glove:

Chemotherapy Drug	Minimum Breakthrough Detection Time in Minutes
Carmustine 3.3 mg/ml (3,300 ppm)	15.4
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Paclitaxel, 6mg/ml (6,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	34.4

Fentanyl Citrate	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection, 100mcg/2mg	>240

510(k) Summary

*Please note that the following drugs have extremely low permeation times:
Carmustine: 15.4 minutes, Thio Tepa: 34.4 minutes
Warning: Do not use with Carmustine and Thiotepa.

6. Comparison of Subject Device and Predicate Device:

The following tables are summaries of the technological characteristics, biocompatibility and testing for use with chemotherapy drugs & Fentanyl Citrate of the subject and predicate devices.

General Comparison Table:

Characteristics and Parameters	Subject Device	Predicate Device K223437	Discussion
Trade Name	Biodegradable Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Black, Green)	Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Fusion Colour)	Similar
Product Code	LZA, LZC, QDO, OPJ	LZA, LZC, QDO, OPJ	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indications for Use	The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05(2019)	A non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate. The gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	Same
Material	Nitrile	Nitrile	Same
Color	Black, Green	Fusion Colour	Different
Design	• Single Use • Non-sterile • Powder-Free • Ambidextrous	• Single Use • Non-sterile • Powder-Free • Ambidextrous	Same
Chemotherapy Drugs and Fentanyl Citrate Claim	See below comparison table	See below comparison table	/

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Sterility	Non-sterile	Non-sterile	Same

*** The finished subject device has been tested with performance and Biocompatibility, all the test results meet the requirements, so the difference of color does not raise questions of safety and effectiveness.*

Technological Characteristic Comparison Table:

Technological Characteristics	Subject Device		Predicate Device K223437	Comparison
	Black	Green		
Length	XS: ≥ 220 mm S: ≥ 220 mm M: ≥ 230 mm L: ≥ 230 mm XL: ≥ 230 mm XXL: ≥ 230 mm	XS: ≥ 220 mm S: ≥ 220 mm M: ≥ 230 mm L: ≥ 230 mm XL: ≥ 230 mm XXL: ≥ 230 mm	XS: ≥ 220 mm S: ≥ 220 mm M: ≥ 230 mm L: ≥ 230 mm XL: ≥ 230 mm XXL: ≥ 230 mm	Same
Palm Width (size) (mm)				
XS	70±10	70±10	70±10	Same
S	80±10	80±10	80±10	Same
M	95±10	95±10	95±10	Same
L	110±10	110±10	110±10	Same
XL	120±10	120±10	120±10	Same
XXL	130±10	130±10	130±10	Same
Thickness(mm)				
Finger	Minimum 0.05	Minimum 0.05	Minimum 0.05	Same
Palm	Minimum 0.05	Minimum 0.05	Minimum 0.05	Same
Tensile Strength, Before Aging	14MPa, min	14MPa, min	14MPa, min	Same
Ultimate Elongation, Before Aging	500%, min	500%, min	500%, min	Same
Tensile Strength, After Accelerated Aging	14MPa, min	14MPa, min	14MPa, min	Same
Ultimate Elongation, After Accelerated Aging	400%, min	400%, min	400%, min	Same
Freedom from holes	Meets ASTM D5151-19: AQL 2.5	Meets ASTM D5151-19: AQL 2.5	Meets ASTM D5151-19: AQL 1.5	Meet ASTM D6319 and similar
Powder residue	Meets ASTM D6124-06 (2017): Residual Powder: ≤ 2 mg per glove	Meets ASTM D6124-06 (2017): Residual Powder: ≤ 2 mg per glove	Meets ASTM D6124-06 (2017): Residual Powder: ≤ 2 mg per glove	Same

510(k) Summary

In vitro Cytotoxicity ISO 10993-5	Under the conditions of this study, the test article showed potential toxicity to L929 cells.	Under the conditions of this study, the test article showed potential toxicity to L929 cells.	The neat extract was found to be cytotoxic	Same
Acute Systemic Toxicity Test ISO 10993-11	Under the conditions of this study, there was no evidence of acute systemic toxicity from the test article.	Under the conditions of this study, there was no evidence of acute systemic toxicity from the test article.	Under the conditions of this study, the device showed no evidence of acute systemic toxicity	Same
Dermal Sensitization ISO 10993-10	Under the conditions of this study, the test article showed no significant evidence of causing skin sensitization	Under the conditions of this study, the test article showed no significant evidence of causing skin sensitization	Under the conditions of the study, the device is not a sensitizer	Same
Primary Skin Irritation ISO 10993-23	The test result showed that the response of the test article was categorized as negligible under the test condition.	The test result showed that the response of the test article was categorized as negligible under the test condition.	Under the conditions of the study, the device is not an irritant	Same
Shelf-Life Expiry ASTM D7160-16	3 years	3 years	3 years	Same

Chemotherapy Permeation and Fentanyl Citrate Comparison Claim:

Tested Chemotherapy Drug and Concentration	Minimum BDT (Minutes)			Comparison
	Subject Device		Predicate Device K223437	
	Black	Green		
Carmustine 3.3 mg/ml (3,300 ppm)	23.0	15.4	12.1	Similar
Cisplatin 1mg/ml (1,000 ppm)	>240	>240	>240	Same
Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	>240	Same
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240	>240	Same
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240	Same
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240	>240	Same
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	>240	Same
Methotrexate, 25mg/ml (25,000ppm)	>240	>240	>240	Same
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240	>240	Same
Thiotepa, 10mg/ml (10,000ppm)	45.9	34.4	37.8	Similar
5-Azacytidine (25.0 mg/ml)	/	/	>240	Different
Carboplatin (10.0 mg/ml)	/	/	>240	Different
Doxetacel (10.0 mg/ml)	/	/	>240	Different
Epirubicin (2.0 mg/ml)	/	/	>240	Different

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Gemcitabine (38.0 mg/ml)	/	/	>240	Different
Ifosfamide (50.0 mg/ml)	/	/	>240	Different
Irinotecan (20.0 mg/ml)	/	/	>240	Different
Mitomycin C (0.5 mg/ml)	/	/	>240	Different
Mitoxantrone (2.0 mg/ml)	/	/	>240	Different
Oxalipatin (5.0 mg/ml)	/	/	>240	Different
Vincristine Sulfate (1.0 mg/ml)	/	/	>240	Different
Oncovin (1.0 mg/ml)	/	/	>240	Different
Vinorelbine (10.0mg/ml)	/	/	>240	Different

Tested Opiod Drug and Concentration	Minimum BDT (Minutes)			Comparison
	Subject Device		Predicate Device K223437	
	Black	Green		
Fentanyl Citrate Injection, 100mcg/2mg	>240	>240	>240	Same

** Chemotherapy drugs and the minimum breakthrough time of subject device will be listed on labeling, so this difference does not raise questions of safety and effectiveness of subject device.*

7. Summary of Non-Clinical Performance Data

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device met the performance criteria with the following standards:

Methodology	Test Performed	Acceptance Criteria	Results
ASTM D6319- 19	Physical Dimensions Length	Minimum 220mm for size XS-S Minimum 230mm for size M-XXL	Pass
ASTM D6319- 19	Physical Dimensions Palm Width	XS: 70±10mm S: 80±10mm M: 95±10mm L:110±10mm XL:120±10mm XXL:130±10mm	Pass
ASTM D6319- 19	Physical Dimensions Thickness	Finger: 0.05mm (min) Palm: 0.05mm (min)	Pass
ASTM D6319- 19 ASTM D412-16(2021)	Physical Properties	Tensile Strength (Min14 Mpa) Elongation (Before Aging 500% and after aging 400%) Min	Pass
ASTM D6319- 19 ASTM D5151-19	Freedom from holes	AQL 2.5 (ISO 2859-1)	Pass
ASTM D6319- 19 ASTM D6124-06 (2017)	Powder Residue	≤ 2 mg per glove	Pass
ASTM D6978-05 (2019)	Permeation by Chemotherapy Drugs and Fentanyl Citrate	Refer the above table	Pass
ISO 10993-10 &23:2021	Irritation and Skin Sensitization	Skin sensitization and Skin irritation	Is non-sensitization and Non-irritation

510(k) Summary

ISO 10993-5:2009	Cytotoxicity	Cytotoxicity reactivity	showed potential toxicity to L929 cells.
ISO 10993-11:2017	Acute systemic toxicity study	Subject showed no adverse biological reaction	no evidence of acute systemic toxicity.
ISO 11737-1:2018	Open box bioburden study	No significant increase in bioburden	Pass

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D412-16（2021）Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ASTM D6978-05 (Reapproved 2019), Assessment of Reissuance of Medical Gloves to Permeation by Chemotherapy Drugs.
- ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests For Skin Sensitization.
- ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 23: Tests For Skin Irritation.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
- Biodegradability is not a medical claim and therefore was not reviewed by FDA.

8. Clinical Performance Data

Not applicable.

9. Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K223437).