November 11, 2021

CRDLight Optoelectronic Technology Co., Ltd
Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K212532
Trade/Device Name: Disposable Powder Free Nitrile Exam Gloves (Tested For Use With Chemotherapy Drugs)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: August 11, 2021
Received: August 11, 2021

Dear Ivy Wang:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For Clarence W. Murray III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K212532

Device Name
Disposable Powder Free Nitrile Exam Gloves (Tested For Use With Chemotherapy Drugs)

Indications for Use *(Describe)*
Disposable Powder Free Nitrile Exam Glove (Tested For Use With Chemotherapy Drugs) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Summarized in Table below, the proposed device was tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug	Concentration (mg/mL)	Breakthrough time (minutes)
Carmustine (BCNU)	3.3 mg/mL	6.2min
Cisplatin	1.0 mg/mL	>240min
Cyclophosphamide (Cytoxan)	20.0 mg/mL	>240min
Dacarbazine (DTIC)	10.0 mg/mL	>240min
Doxorubicin HCL (Adriamycin)	2.0 mg/mL	>240min
Etoposide (Toposar)	20.0 mg/mL	>240min
Fluorouracil (Adrucil)	50.0 mg/mL	>240min
Paclitaxel (Taxol)	6.0 mg/mL	>240min
ThioTEPA	10.0 mg/mL	8.4min
Methotrexate	25.0 mg/mL	>240min
Vincristine sulfate	1.0 mg/mL	>240min

Do not use with Carmustine or 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.

510(K) Summary

K212532

(As requirement by 21 CFR 807.92)

Date prepared: 2021-11-10

A. Applicant:

Name: CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO., LTD
Address: Floor 1-5 BULIDING NO.7 & FLOOR 1-4 BUILDING NO.5 NO.18 XINYI ROAD, JIANGHAI DISTRICT, JIANGMEN GUANGDONG, CHINA
Contact: Fishy liang
Title: General Manager
Tel: +86-13924689685
Email: fishy@gdyanyang.com

Submission Correspondent:
Primary contact: Ms. Ivy Wang
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-58817802
Email: haiyu.wang@sungoglobal.com
Secondary contact: Mr. Raymond Luo
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: fda.sungo@gmail.com

B. Device:

Trade Name: Disposable Powder Free Nitrile Exam Gloves (Tested For Use With Chemotherapy Drugs)
Common Name: Non-powdered patient examination glove

Regulatory Information
Classification Name: Medical Gloves with Chemotherapy Labeling Claims – Test For Use with Chemotherapy Drugs
Classification: Class I
Product code: LZA, LZC
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

C. Predicate device:

K200960
Medline Nitrile Powder-Free Dark Blue Examination Gloves (Tested for use with Chemotherapy Drugs)
Medline Industries, Inc.

D. Indications for use of the device:

Disposable Powder Free Nitrile Exam Glove (Tested For Use With Chemotherapy Drugs) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Summarized in Table 1 below, the proposed device was tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug	**Concentration (mg/mL)**	**Breakthrough time (minutes)**
Carmustine (BCNU)	3.3 mg/mL	6.2min
Cisplatin	1.0 mg/mL	>240min
Cyclophosphamide (Cytoxan)	20.0 mg/mL	>240min
Dacarbazine (DTIC)	10.0 mg/mL	>240min
Doxorubicin HCL (Adriamycin)	2.0 mg/mL	>240min
Etoposide (Toposar)	20.0 mg/mL	>240min
Fluorouracil (Adrucil)	50.0 mg/mL	>240min
Paclitaxel (Taxol)	6.0 mg/mL	>240min
ThioTEPA	10.0 mg/mL	8.4min
Methotrexate	25.0 mg/mL	>240min
Vincristine sulfate	1.0 mg/mL	>240min

Do not use with Carmustine or ThioTEPA.

E. Device Description:

The Disposable Powder Free Nitrile Exam Gloves (Tested For Use With Chemotherapy Drugs) are non-sterile, single use only, disposable examination gloves intended for medical purposes to be worn by examiners to prevent contamination between the patient and the examiner. The gloves are blue color, powder free, nitrile ambidextrous gloves. The gloves are offered in sizes small, medium, large, extra large packed in a paper box.

The gloves are designed and manufactured in accordance with the ASTM D6319-19 standard and are tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019).

F. Summary of Technological Characteristics

Table 2 Comparison of Proposed and Predicate Devices

Device	**Proposed Device**	**Predicate Device**	**Result**
510K #	K212532	K200960	**-**
Manufacturer	CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO., LTD	Medline Industries, Inc.	-

Product Name	Disposable Powder Free Nitrile Exam Gloves (Tested For Use With Chemotherapy Drugs)	Medline Nitrile Powder-Free Dark Blue Examination Gloves (Tested for use with Chemotherapy Drugs)	Similar
Product Code	LZA, LZC	LZA, LZC	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Indications for use	Disposable Powder Free Nitrile Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs.	Same
Design configurations	Blue	Dard blue	Similar
Material	Nitrile	Nitrile	Same
Size	S, M, L, XL	S, M, L, XL, XXL	Similar
Contact duration	Limited≤ 24 hours	Limited≤ 24 hours	Same
OTC use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Use	Singe use	Single use	Same
Dimensions	Complies with: ASTM D6319-19	Complies with: ASTM D6319-10	Similar
Dimensions (thickness)	Complies with: ASTM D6319-19 Palm – 0.05mm min. Finger – 0.05mm min.	Complies with: ASTM D6319-10 Palm – 0.05mm min. Finger – 0.05mm min.	Similar
Physical properties	Complies with: ASTM D6319-19 Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min. Elongation: Before Aging 500%, min. After Aging 400%, min.	Complies with: ASTM D6319-10 Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min. Elongation: Before Aging 500%, min. After Aging 400%, min.	Similar
Freedom from holes	Complies with: ASTM D6319-19 and ASTM D5151-19 G-1, AQL 2.5	Complies with: ASTM D6319-10 and ASTM D5151-06 G-1, AQL 1.5	Different
Powder free	Yes	Yes	Same
Residual Powder	Complies with: ASTM D6319-19 <2mg per glove	Complies with: ASTM D6319-10 <2mg per glove	Similar
Biocompatibility	Complies with ISO 10993-10: Not a skin irritant Not a skin sensitizer	Complies with AAMI/ANSI/ISO 10993-10: Not a skin irritant	Similar

<table>
<tr>
<td></td>
<td>ISO 10993-05: cytotoxicity potential
ISO 10993-11:
Non-Toxic</td>
<td>Not a skin sensitizer
AAMI/ANSI/ISO 10993-05
ISO 10993-11:
Non-Toxic</td>
<td></td>
</tr>
<tr>
<td>Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as tested per ASTM D6978</td>
<td>
<table>
<tr><th>Chemotherapy Drug</th><th>Concentration (mg/mL)</th><th>Breakthrough time (minutes)</th></tr>
<tr><td>Carmustine (BCNU)</td><td>3.3 mg/mL</td><td>6.2min</td></tr>
<tr><td>Cisplatin</td><td>1.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Cyclophosphamide (Cytoxan)</td><td>20.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Dacarbazine (DTIC)</td><td>10.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Doxorubicin HCL (Adriamycin)</td><td>2.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Etoposide (Toposar)</td><td>20.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Fluorouracil (Adrucil)</td><td>50.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Paclitaxel (Taxol)</td><td>6.0 mg/mL</td><td>>240min</td></tr>
<tr><td>ThioTEPA</td><td>10.0 mg/mL</td><td>8.4min</td></tr>
<tr><td>Methotrexate</td><td>25.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Vincristine sulfate</td><td>1.0 mg/mL</td><td>>240min</td></tr>
</table>
Do not use with Carmustine or ThioTEPA.
</td>
<td>
<table>
<tr><th>Chemotherapy Drug</th><th>Concentration</th><th>Breakthrough time</th></tr>
<tr><td>Carmustine (BCNU)</td><td>3.3 mg/ml (3,300 ppm)</td><td>12.4 minutes</td></tr>
<tr><td>Cisplatin</td><td>1.0 mg/ml (1,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Cyclophosphamide (Cytoxan)</td><td>20.0 mg/ml (20,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Dacarbazine (DTIC)</td><td>10.0 mg/ml (10,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Doxorubicin Hydrochloride</td><td>2.0 mg/ml (2,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Etoposide (Toposar)</td><td>20.0 mg/ml (20,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Fluorouracil</td><td>50.0 mg/ml (50,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Methotrexate</td><td>25 mg/ml (25,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Mitomycin C</td><td>0.5 mg/ml (500 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Paclitaxel (Taxol)</td><td>6.0 mg/ml (6,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Thio Tepa</td><td>10.0 mg/ml (10,000 ppm)</td><td>27.4 minutes</td></tr>
<tr><td>Vincristine Sulfate (Oncovin)</td><td>1.0 mg/ml (1,000 ppm)</td><td>>240 minutes</td></tr>
</table>
Do Not Use with Carmustine or Thiotepa
</td>
<td>Similar</td>
</tr>
</table>

G. Summary of Non-Clinical Testing

➢ Biocompatibility

Biocompatibility Testing according to ISO 10993-1:2018, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is A-Limited (≤24h). The following tests for the subject device were conducted to evaluated the biocompatibility of Disposable Powder Free Nitrile Exam Gloves:

- ISO 10993-10: Primary Skin Irritation
- ISO 10993-10: Dermal Sensitization
- ISO 10993-05: Cytotoxicity
- ISO 10993-11: Systemic Toxicity

➢ Performance Testing

Physical performance testing of the proposed device were conducted as per ASTM D6319-19 *Standard Specification for Nitrile Examination Gloves for Medical Application*. Permeation testing was conducted to support the addition of the labeling claim: Tested for use with chemotherapy drugs. In addition, the proposed device was tested according to ASTM D6978-05 (Reapproved 2019) *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*, in which minimum breakthrough times were determined for a wide range of chemotherapy drugs.

To summarize, the performance testing of the subject device were conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves

- ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

<table>
<tr><th>Test Method</th><th>Purpose</th><th>Acceptance Criteria</th><th>Results</th></tr>
<tr><td rowspan="2">Dimensions (width) (thickness)</td><td rowspan="2">The purpose of the test is to evaluate the physical dimension of the glove</td><td>Width 70mm min
Length 220mm min</td><td>Pass
76mm min width
229mm min length</td></tr>
<tr><td>Palm – 0.05mm min.
Finger–0.05mm min.</td><td>Pass
Palm – 0.07mm min.
Finger–0.08mm min</td></tr>
<tr><td>Physical properties</td><td>The purpose of the test is to evaluate the tensile strength and ultimate elongation before and after aging</td><td>Tensile Strength:
Before Aging ⩾ 14 MPa, min.
After Aging ⩾ 14 MPa, min.
Elongation:
Before Aging 500%, min.
After Aging 400%, min.</td><td>Pass
Tensile Strength:
Before Aging 15.08 MPa, min.
After Aging 14.87 MPa, min.
Elongation:
Before Aging 570%, min.
After Aging 529%, min.</td></tr>
<tr><td>Freedom from holes</td><td>The purpose of the test is to detect holes in the gloves</td><td>No leakage at sampling level of G-1, AQL 2.5</td><td>Pass
No leakage, 80 of 80 passed of each size</td></tr>
<tr><td>Residual Powder</td><td>The purpose of the test is to detect the powder residue in the glove</td><td><2mg per glove</td><td>Pass
Max. 0.52 mg per glove</td></tr>
<tr><td>Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as tested per ASTM D6978</td><td>The purpose of the test is to test the resistance of medical gloves to permeation by chemotherapy drugs</td><td>>240min</td><td>Pass
<table>
<tr><th>Chemotherapy Drug</th><th>Concentration (mg/mL)</th><th>Breakthrough time (minutes)</th></tr>
<tr><td>Cisplatin</td><td>1.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Cyclophosphamide (Cytoxan)</td><td>20.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Dacarbazine (DTIC)</td><td>10.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Doxorubicin HCL (Adriamycin)</td><td>2.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Etoposide (Toposar)</td><td>20.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Fluorouracil (Adrucil)</td><td>50.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Paclitaxel (Taxol)</td><td>6.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Methotrexate</td><td>25.0 mg/mL</td><td>>240min</td></tr>
<tr><td>Vincristine sulfate</td><td>1.0 mg/mL</td><td>>240min</td></tr>
</table></td></tr>
</table>

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Disposable Powder Free Nitrile Exam Glove (Tested For Use With Chemotherapy Drugs) is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K200960.