April 29, 2021

Harbour Health LLC
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K210944
Trade/Device Name: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ
Dated: March 28, 2021
Received: March 30, 2021

Dear Dave Yungvirt:

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,

Clarence W. Murray III, Ph.D.
Acting 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)*
K210944

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

Indications for Use *(Describe)*
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. Gloves have been 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 Permeation:

No.	Chemotherapy Drug Tested	Concentration	Breakthrough Detection Time (Minutes)
1	Busulfan	6 mg/ml (6,000 ppm)	> 240
2	Carboplatin	10 mg/ml (10,000 ppm)	> 240
3	Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	14.5*
4	Cisplatin	1.0 mg/ml (1,000 ppm)	> 240
5	Cyclophosphamide (Cytoxan)	20.0 mg/ml (20,000 ppm)	> 240
6	Cytarabine	100 mg/ml (100,000 ppm)	> 240
7	Dacarbazine	10.0 mg/ml (10,000 ppm)	> 240
8	Docetaxel	10 mg/ml (10,000 ppm)	> 240
9	Doxorubicin HCI	2.0 mg/ml (2,000 ppm)	> 240
10	Etoposide	20.0 mg/ml (20,000 ppm)	> 240
11	Fluorouracil	50.0 mg/ml (50,000 ppm)	> 240
12	Ifosfamide	50 mg/ml (50,000 ppm)	> 240
13	Mechlorethamine HCI	1 mg/ml (1,000 ppm)	> 240
14	Methotrexate	25 mg/ml (25,000 ppm)	> 240
15	Mitomycin C	0.5 mg/ml (500 ppm)	> 240
16	Mitoxantrone	2 mg/ml (2,000 ppm)	> 240
17	Paclitaxel	6.0 mg/ml (6,000 ppm)	> 240
18	Thiotepa	10.0 mg/ml (10,000 ppm)	47.4*
19	Vincristine Sulfate	1.0 mg/ml (1,000 ppm)	> 240

*WARNING: Not recommended for use with Carmustine and Thiotepa.
The maximum testing time is 240 minutes. Please note that the following drugs have low permeation times:

Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	14.5 minutes
Thiotepa	10.0 mg/ml (10,000 ppm)	47.4 minutes

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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510(k) Summary

510(k) Summary
[As required by 21 CFR 807.92(c)]
K210944

Submitter / 510(k) Sponsor
Harbour Health LLC
4590 MacArthur Boulevard, Suite 500
Newport Beach, CA 92660

Registration Number: 3017153466

Contact Person
Jared Koenig
CEO
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Summary Preparation Date
19 April 2021

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for Use with Chemotherapy Drugs)
Common Name: Non-powdered patient examination glove
Classification Name: Medical Gloves with Chemotherapy Labeling Claims – Test For Use with Chemotherapy Drugs
Product Code: LZA, LZC, OPJ
Review Panel: General Hospital
Regulatory Class: Class 1
Regulation Number: 21 CFR 880.6250

Predicate Device
Device Name: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)
510(k) Number: K182600
510(k) Owner: Better Care Plastic Technology Co., Ltd

Device Description
The Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for Use with Chemotherapy Drugs) is a non-sterile, single use only, disposable examination glove intended for medical purposes to be worn by examiners to prevent contamination between the patient and the examiner. The gloves are nitrile, powder free, and blue in color. They feature an ambidextrous design with textured fingertips,

straight fingers, and a beaded cuff. The gloves are available in sizes small, medium, large, and extra-large, packaged in a chipboard box.

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

Indications for Use
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.

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.

Table 1: Chemotherapy Drug Permeation

Chemotherapy Drug Tested	Concentration	Breakthrough Detection Time (Minutes)
Busulfan	6 mg/ml (6,000 ppm)	> 240
Carboplatin	10 mg/ml (10,000 ppm)	> 240
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	14.5*
Cisplatin	1.0 mg/ml (1,000 ppm)	> 240
Cyclophosphamide (Cytoxan)	20.0 mg/ml (20,000 ppm)	> 240
Cytarabine	100 mg/ml (100,000 ppm)	> 240
Dacarbazine	10.0 mg/ml (10,000 ppm)	> 240
Docetaxel	10 mg/ml (10,000 ppm)	> 240
Doxorubicin HCI	2.0 mg/ml (2,000 ppm)	> 240
Etoposide	20.0 mg/ml (20,000 ppm)	> 240
Fluorouracil	50.0 mg/ml (50,000 ppm)	> 240
Ifosfamide	50 mg/ml (50,000 ppm)	> 240
Mechlorethamine HCI	1 mg/ml (1,000 ppm)	> 240
Methotrexate	25 mg/ml (25,000 ppm)	> 240
Mitomycin C	0.5 mg/ml (500 ppm)	> 240
Mitoxantrone	2 mg/ml (2,000 ppm)	> 240
Paclitaxel	6.0 mg/ml (6,000 ppm)	> 240
Thiotepa	10.0 mg/ml (10,000 ppm)	47.4*
Vincristine Sulfate	1.0 mg/ml (1,000 ppm)	> 240

*WARNING: Not recommended for use with Carmustine and Thiotepa.

The maximum testing time is 240 minutes. Please note that the following drugs have low permeation times:

Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	14.5 minutes
Thiotepa	10.0 mg/ml (10,000 ppm)	47.4 minutes

Summary of Technological Characteristics

Table 2: Comparison of Proposed and Predicate Devices

Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Device Name	Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for Use with Chemotherapy Drugs)	Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)	N/A
510(k) Reference	K210944	K182600	N/A
Product Owner	Harbour Health LLC	Better Care Plastic Technology Co., Ltd.	N/A
Product Code	LZA, LZC, OPJ	LZA, LZC	Similar
Intended Use	The Harbour Health Powder Free Nitrile Examination Glove, Blue (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. The proposed device was tested for use with chemotherapy drugs per ASTM D6978-05(2019), Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs	Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue) 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 using ASTM D6978-05(2013) and will be labeled with a statement of compliance and a summary of the testing results. Chemotherapy Drug Permeation.	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Material	Nitrile	Nitrile	Same
Color	Blue	Blue	Same
Design Features	Ambidextrous Textured fingertips Beaded cuff Straight fingers	Ambidextrous	Similar
Sizes	Small, Medium, Large, Extra Large	Extra Small, Small, Medium, Large, Extra Large	Same
Rx vs OTC	OTC	OTC	Same
Sterile vs Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs Non-Disposable	Disposable	Disposable	Same
Single Use vs Reusable	Single Use	Single Use	Same

Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Dimensions – Width	Complies with ASTM D6319-19 Small: 80 ± 10mm Medium: 95 ± 10mm Large: 110 ± 10mm Extra Large: 120 ± 10mm	Complies with ASTM D6319-19 Extra Small: 70 ± 10mm Small: 80 ± 10mm Medium: 95 ± 10mm Large: 110 ± 10mm Extra Large: 120 ± 10mm	Same
Dimensions – Thickness	Complies with ASTM D6319-19 Palm: 0.05mm min. Finger: 0.05mm min.	Complies with ASTM D6319-19 Palm: 0.05mm min. Finger: 0.05mm min.	Same
Dimensions - Length	Complies with ASTM D6319-19 Small: 220mm min. Medium/Large/Extra Large: 230mm min.	Complies with ASTM D6319-19 230mm min.	Similar
Physical Properties – Tensile Strength	Complies with ASTM D6319-19 Before Aging: ≥14 MPa, min. After Aging: ≥14 MPa, min.	Complies with ASTM D6319-19 Before Aging: ≥14 MPa, min. After Aging: ≥14 MPa, min.	Same
Physical Properties – Elongation	Complies with ASTM D6319-19 Before Aging: 500% min. After Aging: 400% min.	Complies with ASTM D6319-19 Before Aging: 500% min. After Aging: 400% min.	Same
Freedom from Holes	Complies with ASTM D6319-19 and ASTM D5151-19 G-1, AQL 2.5	In accordance with ASTM D 5151-06, following ASTM D6319- 10, G-1, AQL 2.5	Similar
Powder or Powder Free	Powder Free	Powder Free	Same
Residual Powder	Complies with ASTM D6319-19 ≤ 2 mg per glove	In accordance with ASTM D6124-06 (Reapproved 2017), following ASTM D6319-10 ≤ 2 mg per glove	Same

Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Biocompatibility	Complies with ANSI/AAMI/ISO 10993-5 (2009) • Under the conditions of the study, the device is potentially cytotoxic. Complies with ANSI/AAMI/ISO 10993-10 (2010) • Under the conditions of the study, the device is a non-irritant and a non-sensitizer. Complies with ANSI/AAMI/ISO 10993-11 (2017) • Under the conditions of the study, the device does not elicit a systemic toxicity response in the model animal.	Complies with ANSI/AAMI/ISO 10993-10 (2010) • Not a skin irritant • Not a skin sensitizer	Similar
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as tested per ASTM D6978-05 (2019)			
Bleomycin	Not tested	15.0 mg/ml (15,000 ppm) > 240 minutes	Different
Busulfan	6.0 mg/ml (6,000 ppm) > 240 minutes	6.0 mg/ml (6,000 ppm) > 240 minutes	Same
Carboplatin	10.0 mg/ml (10,000 ppm) > 240 minutes	10.0 mg/ml (10,000 ppm) > 240 minutes	Same
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm) 14.5 minutes	3.3 mg/ml (3,300 ppm) 11.0 minutes	Same
Chloroquine	Not tested	50.0 mg/ml (50,000 ppm) > 240 minutes	Different
Cisplatin	1 mg/ml (1,000 ppm) > 240 minutes	1 mg/ml (1,000 ppm) > 240 minutes	Same
Cyclophosphamide (Cytoxan)	20 mg/ml (20,000 ppm) > 240 minutes	20 mg/ml (20,000 ppm) > 240 minutes	Same
Cyclosporin	Not tested	100.0 mg/ml (100,000 ppm) > 240 minutes	Different
Cytarabine	100.0 mg/ml (100,000 ppm) > 240 minutes	100.0 mg/ml (100,000 ppm) > 240 minutes	Same
Dacarbazine	10 mg/ml (10,000 ppm) > 240 minutes	10 mg/ml (10,000 ppm) > 240 minutes	Same
Daunorubicin	Not tested	5.0 mg/ml (5,000 ppm) > 240 minutes	Different
Docetaxel	10.0 mg/ml (10,000 ppm) > 240 minutes	10.0 mg/ml (10,000 ppm) > 240 minutes	Same

Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Doxorubicin HCI	2 mg/ml (2,000 ppm) > 240 minutes	2 mg/ml (2,000 ppm) > 240 minutes	Same
Epirubicin (Ellence)	Not tested	2.0 mg/ml (2,000 ppm) > 240 minutes	Different
Etoposide	20 mg/ml (20,000 ppm) > 240 minutes	20 mg/ml (20,000 ppm) > 240 minutes	Same
Fludarabine	Not tested	25.0 mg/ml (25,000 ppm) > 240 minutes	Different
Fluorouracil	50 mg/ml (50,000 ppm) > 240 minutes	50 mg/ml (50,000 ppm) > 240 minutes	Same
Gemcitabine (Gemzar)	Not tested	38.0 mg/ml (38,000 ppm) > 240 minutes	Different
Idarubicin	Not tested	1.0 mg/ml (1,000 ppm) > 240 minutes	Different
Ifosfamide	50.0 mg/ml (50,000 ppm) > 240 minutes	50.0 mg/ml (50,000 ppm) > 240 minutes	Same
Irinotecan	Not tested	20.0 mg/ml (20,000 ppm) > 240 minutes	Different
Mechlorethamine HCI	1.0 mg/ml (1,000 ppm) > 240 minutes	1.0 mg/ml (1,000 ppm) > 240 minutes	Same
Melphalan	Not tested	5.0 mg/ml (5,000 ppm) > 240 minutes	Different
Methotrexate	25 mg/ml (25,000 ppm) > 240 minutes	25 mg/ml (25,000 ppm) > 240 minutes	Same
Mitomycin C	0.5 mg/ml (500 ppm) > 240 minutes	0.5 mg/ml (500 ppm) > 240 minutes	Same
Mitoxantrone	2.0 mg/ml (2,000 ppm) > 240 minutes	2.0 mg/ml (2,000 ppm) > 240 minutes	Same
Oxaliplatin	Not tested	2.0 mg/ml (2,000 ppm) > 240 minutes	Different
Paclitaxel	6 mg/ml (6,000 ppm) > 240 minutes	6 mg/ml (6,000 ppm) > 240 minutes	Same
Paraplatin	Not tested	10.0 mg/ml (10,000 ppm) > 240 minutes	Different
Retrovir	Not tested	10.0 mg/ml (10,000 ppm) > 240 minutes	Different
Rituximab	Not tested	10.0 mg/ml (10,000 ppm) > 240 minutes	Different
Thiotepa	10 mg/ml (10,000 ppm) 47.4 minutes	10 mg/ml (10,000 ppm) 28.8 minutes	Same
Topotecan HCL	Not tested	1.0 mg/ml (1,000 ppm) > 240 minutes	Different

Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Trisonex	Not tested	1.0 mg/ml (1,000 ppm) > 240 minutes	Different
Velcade (Bortezomib)	Not tested	1.0 mg/ml (1,000 ppm) > 240 minutes	Different
Vincristine Sulfate	1.0 mg/ml (1,000 ppm) > 240 minutes	1.0 mg/ml (1,000 ppm) > 240 minutes	Same

Summary of Non-Clinical Testing
The biocompatibility evaluation for the Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for Use with Chemotherapy Drugs) was conducted in accordance with ANSI/AAMI/ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process, as recognized by the FDA; and ISO 10993-12:2012, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials, with deviations from Clause 11 without negative impact on testing as documented in Section 018_Performance Testing – Bench.

The following tests were performed to evaluate the biocompatibility of the Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for Use with Chemotherapy Drugs) to show substantial equivalence to the predicate device:

- ISO 10993-5:2009 Cytotoxicity
- ISO 10993-10:2010 Primary Skin Sensitization
- ISO 10993-10:2010 Dermal Sensitization
- ISO 10993-11:2017 Systemic Toxicity

Summary of Performance Testing (Bench)
Physical performance qualities of the proposed device were evaluated 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 range of chemotherapy drugs.

In summary, the performance testing of the subject device was conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06 (2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6978-05 (2019), Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Conclusion
In accordance with 21 CFR Part 807 and based on the non-clinical testing and information provided in this premarket notification, Harbour Health LLC concludes that the Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for Use with Chemotherapy Drugs) is as safe, as effective, and

performs as well as the legally marketed predicate device, Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue) (K182600).

Additionally, both the LZA and LZC/OPJ gloves meet the FDA-recognized consensus standards, all labeling claims, and the pinhole acceptable quality level (AQL).