DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 31, 2017

Healthy Glove Co., Ltd
Teoh Shee
Managing Director
119 Kanchanavanich Road, Tambol Patong
Hatyai, Songkhla, Thailand
90230

Re: K162381
Trade/Device Name: HG PRO XP® Nitrile Powder Free Examination Gloves Tested For Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: November 28, 2016
Received: December 5, 2016

Dear Teoh Shee:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
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)*
K162381

Device Name
HG PRO® XP Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with the following chemotherapy drugs at specific concentrations as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The gloves have been tested with the following drugs and the respective breakthrough detection times are listed below.

No.	Chemotherapy Drugs and Concentrations	Breakthrough Detection Time in Minutes
1.	Blenoxane (15 mg/ml)	> 240 minutes
2.	Busulfan (6 mg/ml)	> 240 minutes
3.	Carboplatin (10 mg/ml)	> 240 minutes
4.	Carmustine (BCNU) (3.3 mg/ml)*	30.4 minutes
5.	Cisplatin (1.0 mg/ml)	> 240 minutes
6.	Cyclophosphamide (Cytoxan) (20 mg/ml)	> 240 minutes
7.	Cytarabine (100 mg/ml)	> 240 minutes
8.	Dacarbazine (DTIC) (10.0 mg/ml)	> 240 minutes
9.	Daunorubicin (5 mg/ml)	> 240 minutes
10.	Docetaxel (10.0 mg/ml)	> 240 minutes
11.	Doxorubicin Hydrochloride (2.0 mg/ml)	> 240 minutes
12.	Ellence (2 mg/ml)	> 240 minutes
13.	Etoposide (Toposar) (20.0 mg/ml)	> 240 minutes
14.	Fludarabine (25 mg/ml)	> 240 minutes
15.	Fluorouracil (50.0 mg/ml)	> 240 minutes
16.	Ganciclovir (10 mg/ml)	> 240 minutes
17.	Gemcitabine (Gemzar) (38 mg/ml)	> 240 minutes
18.	Idarubicin (1 mg/ml)	> 240 minutes
19.	Ifosfamide (50.0 mg/ml)	> 240 minutes
20.	Irinotecan (20.0 mg/ml)	> 240 minutes
21.	Mechlorethamine HCl (1.0 mg/ml)	> 240 minutes
22.	Melphalan (5 mg/ml)	> 240 minutes
23.	Methotrexate (25 mg/ml)	> 240 minutes
24.	Mitoxantrone (2.0mg/ml)	> 240 minutes
25.	Mitomycin C (0.5 mg/ml)	> 240 minutes
26.	Oxaliplatin (5 mg/ml)	> 240 minutes
27.	Paclitaxel (Taxol) (6.0 mg/ml)	> 240 minutes
28.	Rituximab (10 mg/ml)	> 240 minutes
29.	Thiotepa (10.0 mg/ml)	> 240 minutes
30.	Trisenox (0.1 mg/ml)	> 240 minutes
31.	Vincristine Sulfate (1.0 mg/ml)	> 240 minutes
32.	Vinorelbine (10 mg/ml)	> 240 minutes

*Please note that the following drug has extremely low permeation time:
Carmustine (BCNU) (3.3 mg/ml) at 30.4 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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HEALTHY GLOVE CO., LTD.
119 Kanchanavanich Road, T. Patong, Hatyai, Songkhla 90230, Thailand
Tel: +66 74 536 815 Fax: +66 74 536 816

SRITONG GROUP

K162381

510(k) SUMMARY
Nitrile Powder Free Examination Gloves
Tested for Use with Chemotherapy Drugs

1.0 Submitter:

Applicant:	Healthy Glove Co., Ltd 119 Kanchanavanich Road, Tambol Patong Hat Yai, Songkhla 90230 Thailand
Phone Number:	+66 74 536 815
Fax Number:	+66 74 536 816
Name of Contact Person:	Choh-Shee Teoh (Mr)
Preparation date:	November 24, 2016

2.0 Name of Subject Device:

Trade/Proprietary Name(s):	HG PRO® XP Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs
Common Name:	Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs
Classification Name:	Patient Examination Gloves (21 CFR 880.6250)
Device Class:	I
Product Code:	LZA, LZC

3.0 Identification of The Legally Marketed Devices that equivalency is claimed

Manufacturer:	Kimberly Clark Corporation
Device Name:	PURPLE NITRILE-XTRA* Powder-Free Exam - 12' Length
510(k):	K113423
Regulatory Class:	I
Classification Name:	Patient Examination Gloves (21 CFR 880.6250)
Product Code:	LZA, LZC

4.0 Description of the Device:

Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs are non-sterile, lavender blue colored, powder-free, ambidextrous patient examination glove that meets the specifications of ASTM D 6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application. In addition these gloves were tested for use with the Chemotherapy drugs listed in the Intended Use(s) section below, as per ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

These gloves meet the 2008 Glove Guidance Manual recommended minimum thickness and length specifications for gloves tested for use with chemotherapy drugs.

5.0 Intended Use of the Device:

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with the following chemotherapy drugs at specific concentrations as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The gloves have been tested with the following drugs and the respective breakthrough detection times are listed below.

No.	Chemotherapy Drugs	Concentration	Breakthrough detection time in Minutes
1.	Blenoxane	15 mg/ml	>240 min
2.	Busulfan	6 mg/ml	>240 min
3.	Carboplatin	10 mg/ml	>240 min
4.	Carmustine (BCNU) *	3.3 mg/ml	30.4 min
5.	Cisplatin	1.0 mg/ml	>240 min
6.	Cyclophosphamide (Cytoxan)	20 mg/ml	>240 min
7.	Cytarabine	100 mg/ml	>240 min
8.	Dacarbazine (DTIC)	10.0 mg/ml	>240 min
9.	Daunorubicin	5 mg/ml	>240 min
10.	Docetaxel	10.0 mg/ml	>240 min
11.	Doxorubicin Hydrochloride	2.0 mg/ml	>240 min
12.	Ellence	2 mg/ml	>240 min
13.	Etoposide (Toposar)	20.0 mg/ml	>240 min
14.	Fludarabine	25 mg/ml	>240 min
15.	Fluorouracil	50.0 mg/ml	>240 min
16.	Ganciclovir	10 mg/ml	>240 min
17.	Gemcitabine (Gemzar)	38 mg/ml	>240 min
18.	Idarubicin	1 mg/ml	>240 min

No.	Chemotherapy Drugs	Concentration	Breakthrough detection time in Minutes
19.	Ifosfamide	50.0 mg/ml	>240 min
20.	Irinotecan	20.0 mg/ml	>240 min
21.	Mechlorethamine HCl	1.0 mg/ml	>240 min
22.	Melphalan	5 mg/ml	>240 min
23.	Methotrexate	25 mg/ml	>240 min
24.	Mitoxantrone	2.0mg/ml	>240 min
25.	Mitomycin C	0.5 mg/ml	>240 min
26.	Oxaliplatin	5 mg/ml	>240 min
27.	Paclitaxel (Taxol)	6.0 mg/ml	>240 min
28.	Rituximab	10 mg/ml	>240 min
29.	Thiotepa	10.0 mg/ml	>240 min
30.	Trisenox	0.1 mg/ml	>240 min
31.	Vincristine Sulfate	1.0 mg/ml	>240 min
32.	Vinorelbine	10 mg/ml	>240 min
*Please note that the following drug has extremely low permeation time: Carmustine (BCNU) (3.3 mg/ml) at 30.4 minutes			

6.0 Summary of Technological Characteristics Compared to the Predicate Device:

There are no different technological characteristics of the Subject Device compared to the Predicate Device.

Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs are summarized with the following technological characteristics compared to ASTM D 6319 or equivalent standards as shown in Table 1.

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HEALTHY GLOVE CO., LTD.

119 Kanchanavanich Road, T. Patong, Hatyai, Songkhla 90230, Thailand
Tel: +66 74 536 815 Fax: +66 74 536 816

Table 1. Side-by-Side Comparison of Predicate Device with Subject Device: Indications for Use, Non-clinical Performance Data and Technological Characteristics

Characteristics	Acceptance Criteria/Standards	**Predicate Device: 510K No: 113423** Non-Sterile, Powder Free Nitrile Examination glove, Tested for use with Chemotherapy drugs per ASTM D6978-05	**Subject Device: (New 510(k) submission)** Non-Sterile, Powder Free Nitrile Examination glove, Tested for use with Chemotherapy drugs per ASTM D6978-05
Manufacturer(s)	-	Kimberly Clark Corporation	Healthy Glove Co., Ltd
Indications for Use	Medical Gloves Guidance Manual	A powder-free patient Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	A powder-free patient Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner
Material	ASTM D6319-10	Nitrile Synthetic Rubber	Nitrile Synthetic Rubber
Color	-	Purple	Lavender Blue
Texture	-	Textured Fingers	Textured Fingers
Size	Medical Glove Guidance Manual-Labeling- Issued on January 22, 2008	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large
Single Use	Medical Gloves Guidance Manual -Issued on January 22, 2008	Single use	Single use

Characteristics	**Acceptance Criteria/Standards**	**Predicate Device:** **510K No: 113423** Non-Sterile, Powder Free Nitrile Examination glove, Tested for use with Chemotherapy drugs per ASTM D6978-05	**Subject Device:** **(New 510(k) submission)** Non-Sterile, Powder Free Nitrile Examination glove, Tested for use with Chemotherapy drugs per ASTM D6978-05
Dimension	ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10 ***Length :*** 270 mm minimum ***Palm Width*** Extra Small = 70 ±10 mm Small = 80 ±10 mm Medium = 95 ±10 mm Large = 110 ±10 mm Extra Large = 120 ±10 mm
Thickness	ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10 Finger: 0.10 mm minimum Palm: 0.10 mm minimum
Physical Properties	ASTM D6319-10	Meet ASTM D6319-10	Meet ASTM D6319-10 *Tensile Strength:* 14 MPa min (before aging) 14 MPa min (after aging) *Ultimate Elongation:* 500% min (before aging) 400% min (after aging)
Watertight test (1000 ml)	ASTM D5151-06	Pass	Pass AQL 1.5
Residual Powder	ASTM D6124-06	Meet ≤ 2.0 mg/glove	Meet ≤ 2.0 mg/glove
Biocompatibility	Primary Skin Irritation - ISO 10993-10: 2010	Pass	Pass Not a primary skin irritant under the conditions of the study
	Dermal Sensitization - ISO 10993-10: 2010	Pass	Pass Not a contact sensitizer under the conditions of the study

Characteristics	**Acceptance Criteria/Standards**	**Predicate Device: 510K No: 113423** Non-Sterile, Powder Free Nitrile Examination glove, Tested for use with Chemotherapy drugs per ASTM D6978-05	**Subject Device: (New 510(k) submission)** Non-Sterile, Powder Free Nitrile Examination glove, Tested for use with Chemotherapy drugs per ASTM D6978-05
Resistance against Chemotherapy Drugs	ASTM D6978-05 (2013)	**Breakthrough Detection Time (min)**	
Blenoxane (15 mg/ml)		Not tested	> 240 min
Busulfan (6 mg/ml)		> 240 min	> 240 min
Carboplatin (10 mg/ml)		> 240 min	> 240 min
Carmustine (BCNU) * (3.3 mg/ml)		30.7 min	30.4 min
Cisplatin (1.0 mg/ml)		> 240 min	> 240 min
Cyclophosphamide (Cytoxan) (20 mg/ml)		> 240 min	> 240 min
Cytarabine 100 mg/ml		> 240 min	> 240 min
Dacarbazine (DTIC) (10.0 mg/ml)		> 240 min	> 240 min
Daunorubicin (5 mg/ml)		> 240 min	> 240 min
Docetaxel (10.0 mg/ml)		> 240 min	> 240 min
Doxorubicin Hydrochloride (2.0 mg/ml)		> 240 min	> 240 min
Ellence (2 mg/ml)		> 240 min	> 240 min
Etoposide (Toposar) (20.0 mg/ml)		> 240 min	> 240 min
Fludarabine (25 mg/ml)		> 240 min	> 240 min
Fluorouracil (50.0 mg/ml)		> 240 min	> 240 min
Ganciclovir (10 mg/ml)		Not tested	> 240 min
Gemcitabine (Gemzar) (38 mg/ml)		> 240 min	> 240 min
Idarubicin (1 mg/ml)		> 240 min	> 240 min
Ifosfamide (50.0 mg/ml)		> 240 min	> 240 min
Irinotecan (20.0 mg/ml)		> 240 min	> 240 min
Mechlorethamine HCl (1.0 mg/ml)		> 240 min	> 240 min

Characteristics	**Acceptance Criteria/Standards**	**Predicate Device: 510K No: 113423** Non-Sterile, Powder Free Nitrile Examination glove, Tested for use with Chemotherapy drugs per ASTM D6978-05	**Subject Device: (New 510(k) submission)** Non-Sterile, Powder Free Nitrile Examination glove, Tested for use with Chemotherapy drugs per ASTM D6978-05
Resistance against Chemotherapy Drugs	ASTM D6978-05 (2013)	**Breakthrough Detection Time (min)**	
Melphalan (5 mg/ml)		> 240 min	> 240 min
Methotrexate (25 mg/ml)		> 240 min	> 240 min
Mitoxantrone (2.0mg/ml)		> 240 min	> 240 min
Mitomycin C (0.5 mg/ml)		> 240 min	> 240 min
Oxaliplatin (5 mg/ml)		Not tested	> 240 min
Paclitaxel (Taxol) (6.0 mg/ml)		> 240 min	> 240 min
Rituximab (10 mg/ml)		> 240 min	> 240 min
Thiotepa (10.0 mg/ml)		> 240 min	> 240 min
Trisonex (0.1 mg/ml)		> 240 min	> 240 min
Vincristine Sulfate (1.0 mg/ml)		> 240 min	> 240 min
Vinorelbine (10 mg/ml)		Not tested	> 240 min
		Please note that the following drug has extremely low permeation times: Carmustine (BCNU) (3.3 mg/ml) 30.7 minutes	*Please note that the following drug has extremely low permeation times: Carmustine (BCNU) (3.3 mg/ml) at 30.4 minutes

7.0 Substantial Equivalent Based on Assessment of Non-clinical Performance Data:

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned in the previous section (ASTM Requirements).

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data:

No clinical testing was required to determine substantial equivalence of this device.

9.0 Conclusion:

Based on the comparison of the intended use, technological characteristics and non-clinical performance test data, the subject device, Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs is substantially equivalent to the Predicate Device K113423.