December 10, 2018

Syntex Healthcare Products Co., Ltd
% Kathy Liu
Project Manager
Hongray USA Medical Products Inc
3973 Schaefer Avenue, Chino, CA 91810, USA

Re: K182156
Trade/Device Name: Powder-Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: September 15, 2018
Received: October 10, 2018

Dear Kathy 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 III -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182156

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

Indications for Use *(Describe)*
Powder-Free Nitrile Examination Gloves (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.
Gloves have been tested for use with chemotherapy drugs using ASTM D6978 and will be labeled with a statement of compliance and a summary of the testing results.
Chemotherapy Drug Permeation
The following chemicals have been tested with these gloves:

Chemotherapy Drug	Minimum Breakthrough Detection Time (Minutes)
Carmustine(BCNU) (3.3 mg/ml)	11.4
Cisplatin (1mg/ml)	>240
Cyclophosphamide (20mg/ml)	>240
Dacarbazine (DTIC) (10mg/ml)	>240
Doxorubicin Hydrochloride (2mg/ml)	>240
Etoposide (Toposar) (20mg/ml)	>240
Fluorouracil (5-Flu) (50mg/ml)	>240
Methotrexate (25mg/ml)	>240
Paclitaxel (Taxol) (6mg/ml)	>240
Thiotepa (THT) (10mg/ml)	13.6

* Please note that the following drugs have extremely low permeation times:
Carmustine: 11.4 minutes and Thiotepa: 13.6 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Syntex Healthcare Products Co., Ltd.

No.1 Fanjiazhuang Industrial Zone, Xinji City, Hebei, China 052360

510(K) SUMMARY: K182156

The 510(K) number: K182156
Date Prepared: December 3, 2018

1. **Owner's Identification:**

Mr. Qiao Zhiqiang
Syntex Healthcare Products Co., Ltd.
No.1 Fanjiazhuang Industrial Zone, Xinji City, Hebei, China 052360
Tel: 86-311-66179653
Fax: 86-311-66179653

Contact: Ms. Kathy Liu, Project Manager
Address: 3973 Schaefer Avenue, Chino, CA 91810, USA
Tel: 909-590-1611
Fax: 909-673-8347

2**. Name of the Device:**
Trade / Product Name: Powder-Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs
Common Name: Exam Gloves
Classification Name: Non-powdered Patient Examination Glove
Classification Regulation: 21 CFR 880.6250
Product Code: LZA, LZC
Classification Panel: General Hospital
Device Class: Class I

3. **Predicate Device Information:**
Central Medicare Sdn. Bhd
Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs (K172525)

4. **Device Description:**
Powder-Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs are Class I Patient Examination Gloves and Specialty Chemotherapy Gloves. They are ambidextrous and come in different sizes—Extra Small, Small, Medium, Large and Extra Large. Gloves meet the specification of ASTM D6319-10(2015) and have been tested for resistance to permeation by chemotherapy drugs as per ASTM D6978-05(2013).

5. Indications for Use:

Syntex Healthcare Products Co., Ltd.

No.1 Fanjiazhuang Industrial Zone, Xinji City, Hebei, China 052360

510(K) SUMMARY: K182156

Powder-Free Nitrile Examination Gloves (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.

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

The following chemicals have been tested with these gloves:

Chemotherapy Drug	Minimum Breakthrough Detection Time (Minutes)
Carmustine(BCNU) (3.3 mg/ml)	11.4
Cisplatin (1mg/ml)	>240
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Dacarbazine (DTIC) (10mg/ml)	>240
Doxorubicin Hydrochloride (2mg/ml)	>240
Etoposide (Toposar) (20mg/ml)	>240
Fluorouracil (5-Flu) (50mg/ml)	>240
Methotrexate (25mg/ml)	>240
Paclitaxel (Taxol) (6mg/ml)	>240
Thiotepa (THT) (10mg/ml)	13.6

* Please note that the following drugs have extremely low permeation times:
Carmustine: 11.4 minutes and Thiotepa: 13.6 minutes

6. Technological Characteristic Comparison Table

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

General Comparison Table:

	Proposed Device K182156	Predicate Device K172525	Comparison
Trade Name	Powder-Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs	Blue Non Sterile Powder Free Nitrile 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

510(K) SUMMARY: K182156

Class	I	I	Same
Indications for Use	Powder-Free Nitrile Examination Gloves (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.	Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Powder or Powder Free	Powder Free	Powder Free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Color	Blue	Blue	Similar
Labeling Information	Single-use indication, powder free, device name, glove size, quantity, Nitrile Examination Gloves, Non Sterile	Single-use indication, powder free, device name, glove size, quantity, Nitrile Examination Gloves, Non Sterile	Same
Chemotherapy Drug Permeation Claim	See below comparison table	See below comparison table	

Dimensions and Performance Comparison Table:

Technological Characteristics	Proposed Device K182156	Predicate Device K172525	Remark
Length	Minimum 230mm	Minimum 230mm	Same
Palm Width (size) (mm)			
XS	70±10	70±10	Same
S	80±10	80±10	Same
M	95±10	95±10	Same
L	110±10	110±10	Same
XL	120±10	120±10	Same
Thickness(mm)			
Finger	Minimum 0.05	0.10±0.03	Similar
Palm	Minimum 0.05	0.08±0.03	Similar

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Tensile Strength, Before Aging	14MPa, min	14MPa, min	Same
Ultimate Elongation, Before Aging	500%, min	500%, min	Same
Tensile Strength, After Accelerated Aging	14MPa, min	14MPa, min	Same
Ultimate Elongation, After Accelerated Aging	400%, min	400%, min	Same
Freedom from holes	In accordance with ASTM D 5151-06, following ASTM D6319-10, G-1, AQL 2.5	In accordance with ASTM D 5151-06, following ASTM D6319-10, G-1, AQL 2.5	Same
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	Similar
10993-10:2010 Skin Irritation Study	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
10993-10:2010 Maximization Sensitization Study	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
10993-5:2009 Cytotoxicity Test	Under the conditions of this study, not cytotoxic		

Chemotherapy Permeation Comparison Claim:

Tested Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Minutes)		Remark
	Proposed Device	Predicate Device	
Carmustine(BCNU) (3.3 mg/ml)	11.4	12.4	Similar
Cisplatin (1mg/ml)	>240	>240	Same
Cyclophosphamide (20mg/ml)	>240	>240	Same
Dacarbazine (DTIC) (10mg/ml)	>240	>240	Same
Doxorubicin Hydrochloride (2mg/ml)	>240	>240	Same
Etoposide (Toposar) (20mg/ml)	>240	>240	Same
Fluorouracil (5-Flu) (50mg/ml)	>240	>240	Same
Methotrexate (25mg/ml)	>240	Not Tested	/

Paclitaxel (Taxol) (6mg/ml)	>240	>240	Same
Thiotepa (THT) (10mg/ml)	13.6	24.4	Similar
Ifosfamide (50.0 mg/ml)	Not Tested	>240	Will not be claimed
Mitoxantrone (2.0 mg/ml)	Not Tested	>240	Will not be claimed
Vincristine Sulfate (1.0mg/ml)	Not Tested	>240	Will not be claimed

7. 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 complies with the following standards:

- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-06 (Reapproved 2015), Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6319-10(Reapproved 2015), Standard Specification for Nitrile Examination Gloves For Medical Application.
- ASTM D6978-05 (Reapproved 2013), Assessment of Reissuance of Medical Gloves to Permeation by Chemotherapy Drugs.

8. Clinical Performance Data

N/A

9. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.