July 22, 2021

Guangdong Kingfa Sci. & Tech. Co., Ltd.
Xiaoge Yu
Manager
No. 28 Delong Ave., Shijiao Town, Qingcheng District
Qingyuan, Guangdong 511545
China

Re: K211220
Trade/Device Name: Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs, Nitrile Patient Examination Gloves Blue Violet 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, OPJ
Dated: April 16, 2021
Received: April 23, 2021

Dear Xiaoge Yu:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211220

Device Name
Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs
Nitrile Patient Examination Gloves Blue Violet 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.

These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (2019)Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
Tested chemotherapy drugs are as follows:
Carmustine (BCNU) 3.3 mg/ml 65.3 minutes
Cisplatin 1.0 mg/ml >240 minutes
Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 minutes
Dacarbazine (DTIC)10.0 mg/ml >240 minutes
Doxorubicin Hydrochloride 2.0 mg/ml >240 minutes
Etoposide (Toposar) 20.0 mg/ml >240 minutes
Fluorouracil 50.0 mg/ml >240 minutes
Paclitaxel (Taxol) 6.0 mg/ml >240 minutes
Thiotepa 10.0 mg/ml 58.3minutes

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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510(k) Summary
K211220

I. Submitter

GUANGDONG KINGFA SCI. & TECH.CO., LTD.
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Preparation date: April. 03, 2021

US Agent

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II. Proposed Device

Device Trade Name	Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs Nitrile Patient Examination Gloves Blue Violet Tested For Use With Chemotherapy Drugs
Common name:	Patient Examination Glove
Regulation Number:	21 CFR 880.6250
Regulatory Class:	Class I
Product code:	LZA, LZC,OPJ
Review Panel	General Hospital

III. Predicate Devices

510(k) Number:	K192315
Trade name:	Medline Green Ambidextrous Power-Free Nitrile Examination Gloves With Colloidal Oatmeal USP (Tested For Use With Chemotherapy Drugs)
Common name:	Patient Examination Glove

Classification: Class I

Product Code: LZA, LZC,OPJ
Manufacturer Medline Industries, Inc.

IV. Device description

Power-Free Nitrile Examination Gloves(Tested for Use with Chemotherapy Drugs) are non-sterile, single use, disposable gloves intended for medical purposes to be worn on the hands of examiners to prevent contamination between a patient and an examiner. The gloves are powder-free, ambidextrous with beaded cuff, Blue/Blue violet colored nitrile gloves featuring an inner coating of colloidal oatmeal USP. The gloves are offered in four sizes, small, medium, large and extra-large.

The gloves are designed and manufactured in accordance with the ASTM D6319-10 standard and are tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019).

V. Indication 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.

These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (2019)*Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.*

Tested chemotherapy drugs are as follows:

Carmustine (BCNU) 3.3 mg/ml 65.3 minutes

Cisplatin 1.0 mg/ml >240 minutes

Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 minutes

Dacarbazine (DTIC)10.0 mg/ml >240 minutes

Doxorubicin Hydrochloride 2.0 mg/ml >240 minutes

Etoposide (Toposar) 20.0 mg/ml >240 minutes

Fluorouracil 50.0 mg/ml >240 minutes

Paclitaxel (Taxol) 6.0 mg/ml >240 minutes

Thiotepa 10.0 mg/ml 58.3minutes

VI. Comparison of technological characteristics with the predicate devices

Table 1 Comparison of Natural Rubber Surgical Gloves

Item	Proposed device (K211220)	Predicate device （K192315）	Discussion
Product name	Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs Nitrile Patient Examination Gloves Blue Violet Tested For Use With Chemotherapy Drugs	Medline Green Ambidextrous Powder-Free Nitrile Examination Gloves with Colloidal Oatmeal USP (Tested for use with Chemotherapy Drugs)	-
Product Code	LZA, LZC,OPJ	LZA, LZC,OPJ	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Classification	Class I	Class I	Same
Powder free	Yes	Yes	Same
Indication 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. These gloves were tested for use with Chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves of Permeation by 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 and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves of Permeation by Chemotherapy Drugs	Similar*
Main Material	Powder-Free Nitrile	Powder-Free Nitrile	Same
Color	Blue, Blue violet	Blue	Similar*
Size	small, medium, large, x-large	x-small, small, medium, large, x-large	Similar*

Dimensions – Length	Complies with ASTM D6319-10 S (220mm min) M (230mm min) L (230mm min) XL (230mm min)	Complies with ASTM D6319-10 220mm min.	Similar*
Dimensions – Width	Complies with ASTM D6319-10 Small (80±10mm) Medium (95±10mm) Large (110±10mm) X large (120±10mm)	Complies with ASTM D6319-10 X-small – 70±10mm Small – 80±10mm Medium – 95±10mm Large – 110±10mm X-large – 120±10mm	Similar*
Dimensions – Thickness	Complies with: ASTM D6319-10 Palm: 0.05mm min Finger: 0.11mm min	Complies with: ASTM D6319-10 Palm – 0.05mm min. Finger – 0.05mm min.	Similar*
Physical Properties	Complies with: ASTM D6319-10 minimum: Tensile Strength: Before Aging ⩾14 MPa, min. After Aging ⩾ 14 MPa, min.	Complies with: ASTM D6319-10 minimum: Tensile Strength: Before Aging ⩾ 14 MPa, min. After Aging ⩾14 MPa, min.	Same
	Elongation: Before Aging 500%, min. After Aging 400%, min.	Elongation: Before Aging 500%, min. After Aging 400%, min.	Same
Freedom from Holes	Complies with ASTM D6319-10 and ASTM D5151-06 G-1, AQL 1.5	Complies with: ASTM D6319-10 and ASTM D5151-06 G-1, AQL 1.5	Same
Powder or Powder-Free	Powder-Free	Powder-Free	Same
Residual Powder	Complies with: ASTM D6319-10 <2mg per glove	Complies with: ASTM D6319-10 <2mg per glove	Same

Contact Durations	Limited <24 hours	Limited <24 hours	Same
Biocompatibility	AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer At the neat extraction, the test article is considered cytotoxic, but the acute systemic toxicity results demonstrate the device will not cause a systemic effect.	AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer At the neat extraction, the test article is considered cytotoxic, but the acute systemic toxicity results demonstrate the device will not cause a systemic effect.	Same
Sterility	Non-sterile	Non-sterile	Same
Rx Only or OTC	Over the Counter	Over the Counter	Same
Tested Chemotherapy Drugs	Carmustine (BCNU) 3.3 mg/ml 65.3 minutes	Carmustine (BCNU) 3.3 mg/ml 65.3 minutes	Similar The Tested Chemotherapy Drugs of Predicate device is more than Proposed device
	Cisplatin 1.0 mg/ml >240 minutes	Cisplatin 1.0 mg/ml >240 minutes	
	Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 minutes	Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 minutes	
	Dacarbazine (DTIC)10.0 mg/ml >240 minutes	Dacarbazine (DTIC)10.0 mg/ml >240 minutes	
	Doxorubicin Hydrochloride 2.0 mg/ml >240 minutes	Doxorubicin Hydrochloride 2.0 mg/ml >240 minutes	
	Etoposide (Toposar) 20.0 mg/ml >240 minutes	Etoposide (Toposar) 20.0 mg/ml >240 minutes	
	Fluorouracil 50.0 mg/ml >240 minutes	Fluorouracil 50.0 mg/ml >240 minutes	
	Paclitaxel (Taxol) 6.0 mg/ml >240 minutes	Paclitaxel (Taxol) 6.0 mg/ml >240 minutes	
	Thiotepa 10.0 mg/ml 58.3minutes	Thiotepa 10.0 mg/ml 58.3minutes	
		Other Drugs	

*As above comparison, the difference in the dimensions and reference standard version of the subject and predicate device does not raise additional questions for safety and effectiveness of the device. The biocompatibility test and performance test of the subject devices have been performed on the final finished device. The test results shows pass the requirements.

VII. Non-Clinical Testing

Non clinical tests were conducted in accordance with following standards to verify that the proposed device met all design specifications.

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D3767-03(2020), Practice for rubber-Measurement of Dimensions
- 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 D573-04(2019), Standard Test Method for Rubber—Deterioration in an Air Oven
- ASTM D412-16, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ASTM D6978-05(2019), Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-11:2017, Biological evaluation of medical devices - Part11:Tests for Systemic Toxicity

Test Method	Purpose	Acceptance Criteria	Results
ASTM D5151	Water Leak Test	The gloves shall be free from hole when tested in accordance with the method given in ASTM D5151.	pass
ASTM D3767	Dimension	The actual measured dimension of the gloves shall be meet the stated tolerance in Table 2 of the ASTM D 6319-19	pass
Before aging ASTM D412, After aging ASTM D573	Physical Properties Tensile Strength, Ultimate Elongation	Before and after accelerated aging, the gloves shall conform to the physical requirements in the	pass

		Table 3 of ASTM 6319-19	
ASTM D6124	Residual Powder Content	The powder residue content shall be not more than 2mg per gloves.	pass
	Powder amount		pass
ASTM D6978-05	Chemotherapy Drugs	Carmustine (BCNU) 3.3 mg/ml 65.3 minutes Cisplatin 1.0 mg/ml >240 minutes Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 minutes Dacarbazine (DTIC)10.0 mg/ml >240 minutes Doxorubicin Hydrochloride 2.0 mg/ml >240 minutes Etoposide (Toposar) 20.0 mg/ml >240 minutes Fluorouracil 50.0 mg/ml >240 minutes Paclitaxel (Taxol) 6.0 mg/ml >240 minutes Thiotepa 10.0 mg/ml 58.3minutes	pass
ISO 10993-10:2010	Skin irritation	non-sensitizing	pass
ISO 10993-10:2010	Skin Sensitization	non-irritating	pass
ISO 10993-11:2017	Acute Systemic Toxicity	No acute system toxicity	pass

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

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