April 2, 2024

Syntex Healthcare Products Co., Ltd.
Zhiqiang Qiao
General Manager
No. 1, Fanjiazhuang Industrial Zone
Xinji, Hebei 052360
China

Re: K240080
Trade/Device Name: Aloe Vera Nitrile Examination Gloves (Green) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: January 10, 2024
Received: January 11, 2024

Dear Zhiqiang Qiao:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K240080

Device Name
Aloe Vera Nitrile Examination Gloves (Green) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
The 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 and Fentanyl Citrate using ASTM D6978-05(2019)
The following chemicals have been tested with these gloves:

| Chemotherapy Drug | Minimum Breakthrough Detection Time in Minutes |
|---|---|
| Carmustine 3.3 mg/ml (3,300 ppm) | 21.2 |
| Cisplatin, 1mg/ml (1000 ppm) | >240 |
| Cyclophosphamide 20mg/ml (20,000 ppm) | >240 |
| Dacarbazine, 10 mg/ml (10,000 ppm) | >240 |
| Doxorubicin HCL, 2 mg/ml (2,000 ppm) | >240 |
| Etoposide, 20 mg/ml (20,000 ppm) | >240 |
| Fluorouracil (5 Flu), 50mg/ml (50,000ppm) | >240 |
| Methotrexate, 25mg/ml (25,000ppm) | >240 |
| Mitomycin C, 0.5mg/ml (500 ppm) | >240 |
| Paclitaxel, 6mg/ml (6,000ppm) | >240 |
| Thiotepa, 10mg/ml (10,000ppm) | 24.9 |
| Vincristine sulfate, 1mg/ml (1000 ppm) | >240 |

| Fentanyl Citrate | Minimum Breakthrough Detection Time in Minutes |
|---|---|
| Fentanyl Citrate Injection, 100mcg/2mg | >240 |

*Please note that the following drugs have extremely low permeation times:
Carmustine: 21.2 minutes, Thio Tepa: 24.9minutes
Warning: Do not use with Carmustine and 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.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510K Summary

The assigned 510(K) numbers: K240080

Date Prepared: March 14, 2024

**1. Owner's Identification:**

Syntex Healthcare Products Co., Ltd
No. 1, Fanjiazhuang Industrial Zone, Xinji City, Hebei Province, 052360, China
Contact: Mr. Qiao Zhiqiang / General Manager
Tel:86-311-66179668
Email: fdareg@hongray.com.cn or janicema@hongrayusa.com

**2. Device Identification:**

Trade / Product Name: Aloe Vera Nitrile Examination Gloves (Green) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Common Name: Exam Gloves
Classification Name: Non-powdered patient examination glove
Classification Regulation: 21 CFR 880.6250
Product Code: LZA, LZC, QDO, OPJ
Classification Panel: General Hospital
Device Class: Class I

**3. Predicate Device Information:**

Ansell Healthcare Products LLC.
Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (K200671)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I,
Product Code: LZA, LZC, QDO

**4. Device Description:**

Aloe Vera Nitrile Examination Gloves (Green) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate are Class I Patient Examination Gloves and Specialty Chemotherapy Gloves. They are ambidextrous and come in different sizes - Extra Small, Small, Medium, Large, Extra Large and XXL. Gloves meet the specification of ASTM D6319-19 and have been tested for resistance to permeation by chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05(2019). The gloves are single use, disposable, and provided non-sterile.

**5. Indications for Use:**

The 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 and Fentanyl Citrate using ASTM D6978-05(2019)
The following chemicals have been tested with these gloves:

| Chemotherapy Drug | Minimum Breakthrough Detection Time in Minutes |
|---|---|
| Carmustine 3.3 mg/ml (3,300 ppm) | 21.2 |
| Cisplatin, 1mg/ml (1000 ppm) | >240 |
| Cyclophosphamide 20mg/ml (20,000 ppm) | >240 |
| Dacarbazine, 10 mg/ml (10,000 ppm) | >240 |
| Doxorubicin HCL, 2 mg/ml (2,000 ppm) | >240 |
| Etoposide, 20 mg/ml (20,000 ppm) | >240 |

| | |
|---|---|
| Fluorouracil (5 Flu), 50mg/ml (50,000ppm) | >240 |
| Methotrexate, 25mg/ml (25,000ppm) | >240 |
| Mitomycin C, 0.5mg/ml (500 ppm) | >240 |
| Paclitaxel, 6mg/ml (6,000ppm) | >240 |
| Thiotepa, 10mg/ml (10,000ppm) | 24.9 |
| Vincristine sulfate, 1mg/ml (1000 ppm) | >240 |

| Fentanyl Citrate | Minimum Breakthrough Detection Time in Minutes |
|---|---|
| Fentanyl Citrate Injection, 100mcg/2mg | >240 |

*Please note that the following drugs have extremely low permeation times:
Carmustine: 21.2 minutes, Thiotepa: 24.9 minutes
Warning: Do not use with Carmustine and Thiotepa.

**6. Comparison of Subject Device and Predicate Device:**

The following tables are summaries of the technological characteristics, biocompatibility and testing for use with chemotherapy drugs & Fentanyl Citrate of the subject and predicate devices.
General Comparison Table:

| Characteristics and Parameters | Subject Device K240080 | Predicate Device K200671 | Comparison Result |
|---|---|---|---|
| Trade Name | Aloe Vera Nitrile Examination Gloves (Green) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate | Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate | Different* |
| Product Code | LZA, LZC, QDO,OPJ | LZA, LZC,QDO | Different** |
| Regulation Number | 21 CFR 880.6250 | 21 CFR 880.6250 | Same |
| Class | I | I | Same |
| Indications for Use | The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.<br>Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05(2019) | The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.<br>The gloves was tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05(2019) | Same |
| Material | Synthetic nitrile rubber | Synthetic nitrile rubber | Same |
| Color | Green | Pink | Different*** |
| Design | • Single Use<br>• Non-sterile<br>• Powder-Free<br>• Ambidextrous<br>• Beaded cuff | • Single Use<br>• Non-sterile<br>• Powder-Free<br>• Ambidextrous<br>• Beaded cuff | Same |
| Chemotherapy Drugs and Fentanyl Citrate Claim | See below comparison table | See below comparison table | / |

# 510K Summary

| | | | |
|---|---|---|---|
| Aloe | Aloe coated on the donning surface | Aloe and Chamomile coated on the donning surface | Same |

** The trade name will be provided on the labeling, so the different does not raise any safety concerns.*
*** QDO and OPJ, both designated for Medical Gloves with Fentanyl Labeling Claims - Test For Use With Fentanyl, the subject device added the product code OPJ as per requirements but does not raise questions of safety and effectiveness.*
**** The finished subject device has been tested with performance and Biocompatibility, all the test results meet the requirements, so the difference of color does not raise questions of safety and effectiveness.*

Technological Characteristic Comparison Table:

| Technological Characteristics | Subject Device K240080 | Predicate Device K200671 | Comparison Result |
|---|---|---|---|
| Length | Minimum<br>XS: ≥ 220 mm<br>S: ≥ 220 mm<br>M: ≥ 230 mm<br>L: ≥ 230 mm<br>XL: ≥ 230 mm<br>XXL: ≥ 230 mm | Minimum<br>XS: ≥ 220 mm<br>S: ≥ 220 mm<br>M: ≥ 230 mm<br>L: ≥ 230 mm<br>XL: ≥ 230 mm | Similar* |
| 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 |
| XXL | 130±10 | / | Different* |
| Thickness (mm) (Minimum) | | | |
| Finger | 0.05 | 0.05 | Same |
| Palm | 0.05 | 0.05 | Same |
| Tensile Strength, Before Aging, min | 14MPa | 16MPa | Similar* |
| Ultimate Elongation, Before Aging, min | 500% | 500% | Same |
| Tensile Strength, After Accelerated Aging, min | 14MPa | 14MPa | Same |
| Ultimate Elongation, After Accelerated Aging, min | 400% | 400% | Same |
| Freedom from holes | G-I, AQL 2.5 | G-I, AQL 2.5 | Meet ASTM D6319 and similar |
| Powder residual | Residual Powder: ≤ 2 mg per glove | Residual Powder: ≤ 2 mg per glove | Same |
| In vitro Cytotoxicity ISO 10993-5 | Under the conditions of this study, the test article showed potential toxicity to L929 cells. | Under the conditions of the study, undiluted, 1:2, 1:4, 1:8, 1:16 dilution was cytotoxic., 1:32 and 1:64 are not cytotoxic | Same |

| | | | |
|---|---|---|---|
| Acute Systemic Toxicity Test ISO 10993-11 | Under the conditions of this study, there was no evidence of acute systemic toxicity from the test article. | Under the conditions of the study, no evidence of acute systemic toxicity | Same |
| Dermal Sensitization ISO 10993-10 | Under the conditions of this study, the test article showed no evidence of causing skin sensitization | Under the conditions of the study, not a sensitizer | Same |
| Primary Skin Irritation ISO 10993-23 | The test result showed that the response of the test article was categorized as negligible under the test condition. | Under the conditions of the study, not an irritant | Same |

**The subject device has Size XXL and the predicate device has not size XXL, but the subject device has been tested according to ASTM D6319-19 for dimensions and the dimensions meet the requirements of ASTM D6319-19. It can demonstrate the effectiveness of the subject device.*

Chemotherapy Permeation and Fentanyl Citrate Comparison Claim:

| Tested Chemotherapy Drug and Concentration | Minimum BDT (Minutes) | | Comparison Result |
|---|---|---|---|
| | Subject Device K240080 | Predicate Device K200671 | |
| Carmustine 3.3 mg/ml (3,300 ppm) | 21.2 | 23.4 | Similar * |
| Cisplatin, 1mg/ml (1000 ppm) | >240 | / | Different* |
| Cyclophosphamide 20mg/ml (20,000 ppm) | >240 | >240 | Same |
| Dacarbazine, 10 mg/ml (10,000 ppm) | >240 | / | Different* |
| Doxorubicin HCL, 2 mg/ml (2,000 ppm) | >240 | >240 | Same |
| Etoposide, 20 mg/ml (20,000 ppm) | >240 | >240 | Same |
| Fluorouracil (5 Flu), 50mg/ml (50,000ppm) | >240 | >240 | Same |
| Methotrexate, 25mg/ml (25,000ppm) | >240 | >240 | Same |
| Mitomycin C, 0.5mg/ml (500 ppm) | >240 | / | Different* |
| Paclitaxel, 6mg/ml (6,000ppm) | >240 | >240 | Same |
| Thiotepa, 10mg/ml (10,000ppm) | 24.9 | 64.9 | Similar* |
| Vincristine sulfate, 1mg/ml (1000 ppm) | >240 | >240 | Same |

| Fentanyl Citrate | Minimum BDT (Minutes) | | Comparison Result |
|---|---|---|---|
| | Subject Device K240080 | Predicate Device K200671 | |
| Fentanyl Citrate Injection (100 mcg/2ml) | >240 | >240 | Same |

** Chemotherapy drugs and the minimum breakthrough time of subject device will be listed on labeling, so this difference and similar does not raise questions of safety and effectiveness of subject device.*

**7. Clinical Performance Data**

Not applicable.

**8. Conclusion:**

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.