August 28, 2024

Genabio Diagnostics Inc.
Vincent Cai
Vice President of Research and Development
19 Crosby Dr. Ste. 220
Bedford, Massachusetts 01730

Re: K240545
Trade/Device Name: GenaCheck™ Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (XS/S/M/L/XL)
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: July 16, 2024
Received: July 17, 2024

Dear Vincent Cai:

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
DHT4C: Division of Infection Control Devices

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240545

Device Name
GenaCheck™ Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (XS/S/M/L/XL)

Indications for Use *(Describe)*

The GenaCheck™ Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Carmustine	3.3 mg/ml	22.8 Minutes
Cisplatin	1.0 mg/ml	> 240 Minutes
Cyclophosphamide	20.0 mg/ml	> 240 Minutes
Dacarbazine	10.0 mg/ml	> 240 Minutes
Doxorubicin HCI	2.0 mg/ml	> 240 Minutes
Etoposide	20.0 mg/ml	> 240 Minutes
Fluorouracil	50.0 mg/ml	> 240 Minutes
Methotrexate	25.0 mg/ml	> 240 Minutes
Mitomycin C	0.5 mg/ml	> 240 Minutes
Paclitaxel	6.0 mg/ml	> 240 Minutes
Thiotepa	10.0 mg/ml	37.9 Minutes
Vincristine Sulfate	1.0 mg/ml	> 240 Minutes

Tested Fentanyl Citrate is as follows: Average Breakthrough Detection Time

Fentanyl Citrate Injection	100.0mcg/2ml	> 240 Minutes

Please note that the following drugs have low permeation time:
Carmustine 3.3 mg/ml 22.8 Minutes; Thiotepa 10.0 mg/ml 37.9 Minutes
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.

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510(k) Summary

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

1.0 Submitter's Information

Name: Genabio Diagnostics Inc.
Address: 19 Crosby Dr. Ste 220, Bedford, MA 01730, USA
Contact: Vincent Cai, Vice President of Research & Development
Email: Vincent.cai@genabio.com
Date prepared: 08/06/2024

2.0 Device Information

Trade name: GenaCheck™ Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (XS/S/M/L/XL)
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): XS, S, M, L, XL

3.0 Classification

Product code: LZA, LZC, QDO, OPJ
Regulation number: 21 CFR 880.6250
Classification: Class I
Panel: General Hospital

4.0 Predicate Device Information

Manufacturer: Comfort Rubber Gloves Industries Sdn. Bhd
Address:
Lot 821, Jalan Matang,
34750 Matang,
Perak, Malaysia
Device Name: Blue Colored, Power Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
510(k) Number: K192954

5.0 Device Description

The subject device is single use, disposable gloves intended for medical purposes to be worn on the examiner's hands to prevent contamination between patient and examiner. The gloves are powder-free, ambidextrous with beaded cuff, purple colored, nitrile, and tested for use with chemotherapy drugs and Fentanyl Citrate. The gloves are offered in five sizes: XS, S, M, L, XL.

The subject device is non-sterile.

6.0 Indications for Use

The GenaCheck™ Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Carmustine	3.3 mg/ml	22.8
Cisplatin	1.0 mg/ml	> 240
Cyclophosphamide	20.0 mg/ml	> 240
Dacarbazine	10.0 mg/ml	> 240
Doxorubicin HCl	2.0 mg/ml	> 240
Etoposide	20.0 mg/ml	> 240
Fluorouracil	50.0 mg/ml	> 240
Methotrexate	25.0 mg/ml	> 240
Mitomycin C	0.5 mg/ml	> 240
Paclitaxel	6.0 mg/ml	> 240
Thiotepa	10 mg/ml	37.9
Vincristine Sulfate	1.0 mg/ml	> 240

Tested Fentanyl Citrate is as follows: Average Breakthrough Detection Time

Fentanyl Citrate Injection	100.0 mcg/2ml	> 240

Please note that the following drugs have low permeation times:

Carmustine 3.3 mg/ml 22.8 Minutes;
Thiotepa 10.0 mg/ml 37.9 Minutes;
Warning: Do not use with Carmustine and Thiotepa.

7.0 Technological Characteristic Comparison Table

Table 1 – General Comparison

Item	Subject Device	Predicate Device (K192954)	Remark
Product Code	LZA, LZC, QDO, OPJ	LZA, LZC, QDO	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same

Class	I	I	Same
Sterility	Non-sterile	Non-sterile	Same
Shelf-life	/	/	Same
Materials	Nitrile	Nitrile	Same
Available size	XS, S, M, L, XL	XS, S, M, L, XL	Same
Rx or OTC	OTC	OTC	Same
Indications for Use	The GenaCheck™ Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Warning: Do not use with Carmustine and Thiotepa.	The Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a patient medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Warning: Do not use with Carmustine.	Same
Powdered or Powder free	Powder free	Powder free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile, a statement of standard ASTM D6978-05 compliance and a summary of the testing results.	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile, a statement of standard ASTM D6978-05 compliance and a summary of the testing results.	Same

Dimensions(mm)		Length: XS/S:≥220; M/L/XL: ≥230 Width: XS: 70 ± 10; S: 80 ± 10; M: 95 ± 10; L: 110 ± 10; XL: 120 ± 10.		Length: XS/S/M/L/XL: ≥240; Width: XS:70±10; S: 80±10; M: 95±10; L: 110±10; XL: 120±10		Similar
Thickness(mm)		Finger: ≥0.05; Palm: ≥0.05		Finger: ≥0.05; Palm: ≥0.05		Same
Colorant		Purple		Blue		Different
Physical Properties	Before Aging	Tensile Strength	≥14MPa	Tensile Strength	≥14MPa	Same
		Ultimate Elongation	≥500%	Ultimate Elongation	≥500%	
	After Aging	Tensile Strength	≥14MPa	Tensile Strength	≥14MPa	Same
		Ultimate Elongation	≥400%	Ultimate Elongation	≥400%	
Freedom from Holes		Be free from holes when tested in accordance with ASTM D5151 AQL = 2.5		Be free from holes when tested in accordance with ASTM D5151 AQL = 1.5		Same
Powder Content		0.27~0.41 mg per glove, Meet the requirements of ASTM D6124		Meet the requirements of ASTM D6124, ≤2mg/glove		Similar
Biocompatibility		ISO 10993-10, -23; Under the conditions of the study, not an irritant or a sensitizer.		ISO 10993-10; Under the conditions of the study, not an irritant or a sensitizer.		Same
		ISO 10993-5 Under conditions of the study, device extract is cytotoxic.		ISO 10993-5 Under conditions of the study, device extract is cytotoxic.		Same
		ISO 10993-11; Under the conditions of the study, the test article did not show acute systemic toxicity in vivo.		ISO 10993-11; Under the conditions of the study, the test article showed no adverse biological reaction		
	Carmustine 3.3 mg/ml	22.8 Minutes		18.2 Minutes		Similar

Chemotherapy Drugs and Fentanyl Citrate Tested with Minimum Breakthrough Detection Time as Tested per ASTM D6978	Cisplatin 1.0 mg/ml	> 240 Minutes	> 240 Minutes	Same
	Cyclophosphamide 20.0 mg/ml	> 240 Minutes	> 240 Minutes	Same
	Doxorubicin HCl 2.0 mg/ml	> 240 Minutes	> 240 Minutes	Same
	Dacarbazine 10.0 mg/ml	> 240 Minutes	> 240 Minutes	Same
	Etoposide 20.0 mg/ml	> 240 Minutes	> 240 Minutes	Same
	Fluorouracil 50.0 mg/ml	> 240 Minutes	> 240 Minutes	Same
	Methotrexate 25.0 mg/ml	> 240 Minutes	/	Different
	Mitomycin C 0.5 mg/ml	> 240 Minutes	/	Different
	Paclitaxel 6.0 mg/ml	> 240 Minutes	> 240 Minutes	Same
	Thiotepa 10.0 mg/ml	37.9 minutes	57.3 minutes	Similar
	Vincristine Sulfate 1.0 mg/ml	> 240 Minutes	/	Different
	Fentanyl Citrate injection 100mcg/2ml	> 240 Minutes	> 240 Minutes	Same

Analysis 1:

The physical dimensions of the subject device are similar to that the predicate device, and meet the requirements of ASTM D6319-19.

Analysis 2:

The powder content of the subject device is similar to that of the predicate device, and meets the requirements of ASTM D6124-06.

Analysis 3:

The breakthrough detection times of Carmustine and Thiotepa of subject device are similar with that of the predicate device. The Chemotherapy Labeling Claims has clearly defined on the labeling and therefore does not raise any new safety or performance questions.

8.0 Summary of Non-Clinical Testing Biocompatibility Testing

The biocompatibility evaluation for GENACHECK™ Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate was conducted in accordance with the following standards:

ISO 10993-10: 2021, Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization.

ISO 10993-23: 2021, Biological Evaluation of Medical Devices – Part 23: Tests for Irritation.

ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity.

ISO 10993-11:2017, Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity.

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 and fentanyl citrate. In addition, the proposed device was tested according to ASTM D6978-05, Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs, in which minimum breakthrough times were determined for a wide range of chemotherapy drugs and fentanyl citrate.

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 D6124-06 (2022), *Standard Test Method for Residual Powder on Medical Gloves*.
- ASTM D5151-19(2023), *Standard Test Method for Detection of Holes in Medical Gloves*.
- ASTM D6319-19(2023), *Standard Specification for Nitrile Examination Gloves for Medical Application*.
- ASTM D6978-05 (2023), *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*.
- ASTM D412-16(2021), *Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers - Tension*

Table 2 – Summary of non-clinical performance testing

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319-19 (2023)	Physical Dimensions Test	Length: XS/S: ≥220; M/L/XL: ≥230 Width: XS: 70 ± 10; S: 80 ± 10; M: 95 ± 10; L: 110 ± 10; XL: 120 ± 10.	Length: XS/S: ≥220; M/L/XL: ≥230 Width: XS: 73-78/Pass; S: 84-88/Pass; M: 93-98/Pass; L: 103-108/Pass; XL: 113-118/Pass.
		Finger: ≥0.05; Palm: ≥0.05	Thickness (mm): Finger:0.069-0.109/Pass; Palm:0.052-0.079/Pass
ASTM D5151-19 (2023)	Watertightness Test for Detection of Holes	Met the requirements of ASTM D5151 AQL 2.5	0/125/Pass
ASTM D6124-06 (2022)	Powder Content	Meet the requirements of ASTM D6124 < 2.0mg	0.27~0.41 mg

ASTM D412-16 (2021)	Physical properties	Before Aging	Tensile Strength	≥14MPa	14-27 MPa/Pass
			Ultimate Elongation	≥500%	516-769 %/Pass
		After Aging	Tensile Strength	≥14MPa	14-20 MPa/Pass
			Ultimate Elongation	≥400%	452-662 %/Pass
ISO 10993-5 (2009)	Cytotoxicity	Non-In Vitro Cytotoxicity		Under conditions of the study, device extract is cytotoxic.	
ISO 10993-11 (2017)	Acute Systemic Toxicity	Non-acute systemic toxicity		Under conditions of` the study, device extract did not show acute systemic toxicity in vivo	
ISO 10993-23 (2021)	Irritation	Non-irritating		Under conditions of the study, the device was non-irritating.	
ISO 10993-10 (2021)	Sensitization	Non-sensitizing		Under conditions of the study, the device is non-sensitizing.	

9.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, GenaCheck™ Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is as safe, as effective, and performs as well as or better than the legally marketed predicate device under K192954.