August 8, 2024

Comfort Rubber Gloves Industries Sdn. Bhd.
% Terrell Cunningham
Regulatory Consultant
T. Cunningham Consulting & Associates, LLC
12812 Meadowbrook LN
Waldorf, Maryland 20601

Re: K241528
Trade/Device Name: Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA

Dear Terrell Cunningham:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 6, 2024. Specifically, FDA is updating this SE Letter to correct a typo in the Regulatory Class as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Bifeng Qian, M.D., Ph.D., OHT4: Office of Surgical and Infection Control Devices, at Bifeng.Qian@fda.hhs.gov.

Sincerely,

Bifeng Qian -S

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

August 6, 2024

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Re: K241528
Trade/Device Name: Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class II
Product Code: LZA
Dated: April 2, 2024
Received: May 30, 2024

Dear Terrell Cunningham:

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

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.

Submission Number *(if known)*

K241528

Device Name

Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential

Indications for Use *(Describe)*

The Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential is a medical glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between examiner and patient.

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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PRAStaff@fda.hhs.gov

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510(k) SUMMARY- K241528

Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential

1.0 Submitter:

Name	:	Comfort Rubber Gloves Industries Sdn. Bhd.
Address	:	Lot 821, Jalan Matang, 34750 Matang, Perak, Malaysia. Malaysia.
Phone No.	:	605-847 2777
Fax No.	:	605-847 9108
Contact Person:		Sumathi d/o Sararavan Sami (Miss.)

Date of Preparation: 1st August 2024

2.0 Name of the Device

Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential

Common Name: Patient Examination Gloves

Classification Name: Patient Examination Gloves (21 CFR 880.6250)

Class: I

Product Code: LZA

3.0 Predicate Device

Device Name: Nitrile Powder Free Examination Glove with Low Dermatitis Potential Claim (Blue)

Company: Hartalega SDN. BHD

510(k) No.: K162646

Common Name: Patient Examination Gloves

Classification Name: Patient Examination Gloves (21 CFR 880.6250)

Class: I

Product Code: LZA

4.0 Description of the Device:

Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential meet ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.

5.0 Indication for Use of the Device

The Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential is a medical glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between examiner and patient.

6.0 Summary of the Technological Characteristics of the Device:

Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential and predicate, K162646 are summarized with the following technological characteristics. Both gloves are made with nitrile and meets ASTM D6319-19 - Standard Specification for Nitrile Examination Gloves for Medical Application or equivalent standards.

CHARACTERISTIC	PREDICATE DEVICE K162646	SUBJECT DEVICE K241528	COMPARISON
Manufacturer(s)	Hartalega SDN. BHD	Comfort Rubber Gloves Industries Sdn. Bhd	Different
Device Name	Nitrile Powder Free Examination Glove, Non-Sterile Low Dermatitis Potential (Blue)	Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential	Similar
Indications for Use	The Nitrile Powder Free Examination Glove, Non-Sterile Low Dermatitis (Blue) Potential is a medical glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between examiner and patient.	The Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential is a medical glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between examiner and patient.	Similar
Material	Nitrile	Nitrile	Same
Color	Blue	Blue	Same

CHARACTERISTIC	PREDICATE DEVICE K162646	SUBJECT DEVICE K241528	COMPARISON
Size	XS, S, M, L, XL	XS, S, M, L, XL	Same
Dimensions	Meets ASTM D6319-10 Thickness at Finger – min. 0.05mm Thickness at Palm – min. 0.05mm Length – Min. 230 mm Width – M – 95±10mm	Meets ASTM D6319-19 Thickness at Finger – min. 0.05mm Thickness at Palm – min. 0.05mm Length – Size XS, S, M, L, XL – Min. 230 Width - XS – 70±10mm S – 80±10mm M – 95±10mm L –	Similar
Physical Properties	Meets ASTM D6319-10. Tensile Strength: Before Aging: Min. 14 MPa After Aging: Min. 14 MPa Ultimate Elongation: Before Aging: min. 500% After Aging: min. 400%	Meets ASTM D6319-19. Tensile Before Aging: Min. 14 MPa After Aging: Min. 14 MPa Ultimate Elongation Before Aging: min. 500% After Aging: min. 400%	Same
Powder Content	Meets ASTM 6124-06 (2011) (≤ 2 mg/glove)	Meets ASTM 6124-06 (2022) (≤ 2 mg/glove)	Same
Freedom from Holes	Meets ASTM D5151-06.	Meets ASTM D5151-19.	Same

CHARACTERISTIC	PREDICATE DEVICE K162646	SUBJECT DEVICE K241528	COMPARISON
Low Dermatitis Potential	Meets Modified Draize ASTM 6355-07 Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves.	Meets Modified Draize ASTM 6355-07 Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves.	Same
Biocompatibility: Irritation Tests	Under the conditions of the study, the subject device is non-irritating.	Under the conditions of the study, the subject device is non-irritating.	Same
Biocompatibility: Skin Sensitization Tests	Under the conditions of the study, the subject device is not sensitizing.	Under the conditions of the study, the subject device is not sensitizing.	Same
Biocompatibility: Cytotoxicity	No test report was submitted for the predicate.	Under the conditions of the study, the subject device extract exhibits mild cytotoxicity reactivity result (2) with the neat extract (100%).	Different
Biocompatibility: Acute systemic Toxicity	No test report was submitted for the predicate.	Did not induce any acute systemic toxicity in swiss albino mice under the conditions of the study.	Different

8.0 Summary of Non-Clinical Performance Data

Non-clinical tests were conducted to demonstrate that the proposed device met all design specifications. The test results demonstrated that the proposed device met the performance criteria with the following standards:

Test	Standard	Acceptance Criteria	Results
Physical Dimensions Thickness	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	ISO 2859-1/S2/AQL 4.0 Length – Size XS, S, M, L, XL – Min. 230 Width - XS – 70±10mm S – 80±10mm M – 95±10mm L – 110±10mm XL - 120±10mm Thickness at Finger – min. 0.05mm Thickness at Palm – min. 0.05mm	Pass
Physical Properties	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application ASTM D412-16(2021) Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension	Before aging: Tensile Strength: ≥14 MPa Ultimate elongation: ≥500% After aging: Tensile Strength: ≥14 MPa Ultimate elongation: ≥400%	Pass
Powder Residue	ASTM D6124-06(2022) Standard Test Method for Residual Powder on Medical Gloves	≤ 2 mg/glove	Pass
Freedom from Holes	ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	AQL 1.5	Pass

Irritation	ISO 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for irritation	Under the conditions of the study, the device is not an irritant.	Under the conditions of the study, the device was not an irritant.
Sensitization	ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization	Under the conditions of the study, the device is not a sensitizer.	Under the conditions of the study, the device was not a sensitizer.
Cytotoxicity	ISO 10993-5 Biological evaluation of medical devices-Part 5 Tests for in vitro cytotoxicity	Under the conditions of the study, the subject device extract does not exhibit cytotoxicity reactivity.	Under the conditions of the study, the subject device extract exhibits cytotoxicity from 100.0 % extract concentrations to 50.0 % extract concentrations and no cytotoxicity reactivity from 25.0 % extract concentrations to 3.125 % extract concentrations.
Acute systemic toxicity	ISO 10993-11 Biological evaluation on medical device Part 11 – Test for systemic toxicity	Under the conditions of this study, the test article does not induce acute systemic toxicity.	Under the conditions of this study, the test article did not induce acute systemic toxicity.
Low Dermatitis Potential	Modified Draize ASTM 6355-07 Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves.	No clinical evidence that the glove may induce Type IV allergy in the unsensitized general user population.	There was no clinical evidence that the glove may induce Type IV allergy in the unsensitized general user population.

9.0 Clinical Performance Data

Clinical data is not needed.

10.0 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 predicate device.