October 25, 2024

Comfort Rubber Gloves Industries Sdn. Bhd.
Sumanthi D/O Saravana Sami
RA Manager
Lot 821
Matang, Perak 34750
Malaysia

Re: K240269
Trade/Device Name: Nitrile Powder Free Examination Gloves Biodegradable (Green)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: April 2, 2024
Received: September 30, 2024

Dear Sumanthi D/O Saravana Sami:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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

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)*

K240269

Device Name

Nitrile Powder Free Examination Gloves Biodegradable (Green)

Indications for Use *(Describe)*

The Nitrile Powder Free Examination Gloves Biodegradable (Green) 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.

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510(k) SUMMARY (K240269)
Nitrile Powder Free Examination Gloves Biodegradable (Green)

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: January 8, 2024

2.0 Name of the Device

Nitrile Powder Free Examination Gloves Biodegradable (Green)

Common Name: Patient Examination Gloves

Classification Name: Non-powdered Patient Examination Gloves (21 CFR 880.6250 product code LZA)

3.0 Predicate Device

Device Name: Biodegradable Nitrile Examination Powder Free Glove, Green
Company: Top Glove SDN BHD

510(K) No.: K192111

4.0 Description of the Device:

Nitrile Powder Free Examination Gloves Biodegradable (Green) meet all the requirements of ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application. The gloves are single use, disposable, and non-sterile. The gloves are offered in five sizes: S, M, L, XL, XXL.

5.0 Indication for Use of the Device

The Nitrile Powder Free Examination Gloves Biodegradable (Green) 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 Photo and/or figure of Nitrile Powder Free Examination Gloves Biodegradable (Green)

7.0 Technological Characteristics Comparison Table:

CHARACTERISTICS	STANDARDS	PREDICATE DEVICE K192111	SUBJECT DEVICE K240269	COMPARISON	EXPLANATION
Product Code		LZA	LZA	Same	

Device Name		Biodegradable Nitrile Examination Powder Free Glove, Green	Nitrile Powder Free Examination Gloves Biodegradable (Green)	Similar	Device names are different, but both serve the same intended use as examination gloves.
Manufacturer(s)		Top Gloves Sdn. Bhd.	Comfort Rubber Gloves Industries Sdn. Bhd	Different	Difference in manufacturers. Manufacturers adhere to industry standards and regulations, ensuring that their products are equally safe and effective
Indication for Use		The Biodegradable Nitrile Examination Powder Free Glove, Green is a non-sterile disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.	The Nitrile Powder Free Examination Gloves Biodegradable (Green) 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	The indications are comparable, indicating that both products serve the same function and intended use within clinical settings. This similarity reinforces the claim of substantial equivalence, as both products are designed to meet the same clinical needs and safety standards
Material	ASTM D6319-19	Nitrile	Nitrile	Same	-
Color		Green	Green	Same	-
Size	Medical Glove Guidance Manual Labeling	Small Medium Large Extra Large Double Extra Large	Small Medium Large Extra Large Double Extra Large	Same	-
Single Use	Medical Glove Guidance Manual	Single Use	Single Use	Same	-
Shelf life	Medical Glove Guidance Manual	-	Accelerated 3 Years	Different	Does not impact substantial equivalence because the shelf life is determined by specific stability testing conducted under relevant conditions
Sterile	Medical Glove Guidance Manual	Non-Sterile	Non-Sterile	Same	-
Dimension	ASTM D6319- 19	Length-Min 230mm Thickness palm and finger- Min 0.05mm	Length-Min 230mm Thickness palm and finger-Min 0.05mm Width - S – 80±10mm M – 95±10mm L – 105 ± 5mm XL – 115 ± 5mm XXL – > 120 mm	Similar	Slight variation in length (240 mm vs. 230 mm) does not impact usability or safety, as both dimensions fall within acceptable ranges for examination gloves
Physical Properties	ASTM D6319- 19	Before Aging		Similar	

		Tensile Strength ≥14MPa Ultimate Elongation≥500%	Tensile Strength ≥14MPa Ultimate Elongation≥500%		The test result reading might have variance but meets the ASTM D6319 requirement.
		After Aging			
		Tensile Strength ≥14MPa Ultimate Elongation≥400%	Tensile Strength ≥14MPa Ultimate Elongation≥400%		
Thickness – Finger – Palm	ASTM D6319-19	Min 0.05 Min 0.05	0.16 mm - 0.20 mm 0.12 mm - 0.14 mm	Similar	The test result reading might have variance but meets the ASTM D6319 requirement.
Residual Powder	ASTM 6124-06 -2022	Max - 2 mg/glove	Max - 2 mg/glove 0.36 mg/glove	Same	-
Biodegradable	ASTM D5511	Tested	Tested	Similar	The test result reading might have variance but meets the ASTM D5511 requirement.
Biocompatibility	ISO 10993-23:2021 Biological evaluation of medical devices Part 23:Tests for irritation	Under the conditions of the study, the subject device extracts are not irritating to the animal model.	Under the conditions of the study, the subject device is non-irritating extracts are not irritating to the animal model.	Same	--
	ISO 10993- 10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization	Under the conditions of the study, the subject device extracts are not sensitizing to the animal model.	Under the conditions of the study, the subject device extracts are not sensitizing to the animal model.	Same	-
	Cytotoxicity ISO 10993-5:2009 - Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, the subject device extract exhibits mild cytotoxicity reactivity result (2) with the neat extract (100%).	Under the conditions of the study, the subject device extract exhibits mild cytotoxicity reactivity result (2) with the neat extract (100%).	Same	-
	ISO 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity	No test report was submitted for the predicate.	Under the conditions of the study, did not demonstrate any acute toxic reaction.	Different	The Acute systemic toxicity is additional test tested to evaluate the potential for systemic health effects resulting from exposure to the materials used in the gloves.
Watertight (1000ml)	21 CFR 800.20 ASTM D5151	Passes	Passes	Same	-

8.0 Summary of Non-Clinical Performance Data

Test Methodology	Purpose	Acceptance Criteria	Results		
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 230 for all sizes	Average: S – 246 M – 246 L – 246 XL – 250 XXL – 254		
	To determine the width of the gloves	S – 80±10mm M – 95±10mm L – 105 ± 5mm XL - 115 ± 5mm XXL - > 120 mm	Average: S – 86 M – 99 L – 106 XL – 115 XXL – 125		
	To determine the thickness of the gloves	Thickness palm and finger- Min 0.05mm	Average:		
			Size	Palm	Finger
			S	0.13	0.19
			M	0.13	0.19
			L	0.13	0.18
			XL	0.13	0.17
			XXL	0.12	0.19

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the Physical properties – Tensile Strength	Before Aging – Min 14 MPa After Aging – Min 14 MPa	Size | Before Aging | After Aging M | 29.95 | 29.66
	To determine the Physical properties – Ultimate Elongation	Before Aging – Min.500 After Aging – Min. 400	Size | Before Aging | After Aging M | 561 | 496
ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 1.5	S – Pass AQL 1.5 M – Pass AQL 1.5 L – Pass AQL 1.5 XL – Pass AQL 1.5 XXL – Pass AQL 1.5
ASTM D6124-06(2022) Standard Test Method for Residual Powder on Medical Gloves	To determine the amount of residual powder on the gloves	Max - 2 mg/glove	0.36mg
ASTM D5511-18 Standard Test Method for Determining Anaerobic Biodegradation of Plastic Materials Under High-Solids Anaerobic-Digestion Condition	Determination of the degree and rate of anaerobic biodegradation of plastic materials in high-solids anaerobic conditions	Tested	Adjusted Percent Biodegraded (%) – 7.2
ISO 10993-5 Biological evaluation of medical devices- Part 5 Tests for in vitro cytotoxicity	To determine the biological response of mammalian cells in vitro using appropriate biological parameters	-	Under the conditions of the study, the subject device extract exhibits mild cytotoxicity reactivity result (2) with the neat extract (100%).
ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization	Assessment of medical devices and their constituent materials with regard to their potential to induce skin sensitization	-	Under the conditions of the study, the subject device extracts are not sensitizing to the animal model.
ISO 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for irritation	Assessment of medical devices and their constituent materials with regard to their potential to produce irritation	-	Under the conditions of the study, the subject device is non-irritating extracts are not irritating to the animal model.
ISO 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity	Evaluation of the potential for medical device materials to cause adverse systemic reactions	-	Under the conditions of the study, did not demonstrate any acute toxic reaction.

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:

- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D5511-18 Standard Test Method for Determining Anaerobic Biodegradation of Plastic Materials Under High-Solids Anaerobic-Digestion Condition
- ASTM D6124-06(2022) Standard Test Method for Residual Powder on Medical Gloves
- ISO 2859 Sampling Procedures and Tables for Inspection by Attributes
- ISO 10993-5 Biological evaluation of medical devices-Part 5 Tests for in vitro cytotoxicity
- 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 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity

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.